ACCESS TO QUALITY MEDICINES AND MEDICAL DEVICES FOR DIABETES CARE IN EUROPE
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Although effective treatment of diabetes has been possible for 90 years, ever since insulin was first discovered, there are, even today, hundreds of thousands of people living with diabetes in Europe who do not have adequate access to the treatment they need.

This publication from the International Diabetes Federation Europe presents the results of a detailed survey of the reality facing people with diabetes as they seek access to medicines and medical devices in the many countries which make up the World Health Organization’s European Region.

Meaningful information on the treatment of this common condition was often not easy to obtain. However, the picture that does emerge is one of real difficulties in many European countries. The causes vary, but include a lack of political commitment to provide adequate funding for health services, failures of organisation of healthcare systems, or the physical constraints imposed by geographic remoteness.

In the worst cases identified, some people faced delays of several months to obtain their prescriptions or to see their healthcare professional. Some of the strategies employed to contain expenditure, such as reducing reserve stock levels throughout the supply chain, while superficially attractive, can cause real difficulties for individuals and their healthcare team who often experience real anxiety and additional expense in obtaining necessary supplies. Imposition of quotas on subsidised or free medicines and devices often meant that people either had to go without or pay for their own supplies. It was alarming that there was an overall lack of continuous education on diabetes, something acknowledged to be cost effective in reducing serious complications.

Some countries are more severely affected by the economic downturn than others and in the most serious, healthcare facilities have had to reduce their staffing or simply to close down. At the same time, people living in these countries have experienced job losses and pay cuts – rendering the additional costs of a chronic health condition unaffordable. However, a few countries have attempted to mitigate the worst effects of shortfalls in funding for healthcare.

A failure to ensure adequate access to medicines and devices for diabetes has obvious adverse consequences for health, and even survival, but is seriously short-sighted as a means of containing expenditure, given the high cost of treating avoidable complications, including blindness, stroke, kidney failure and amputations.

This is an important report that should be read by all those who can influence health policy, whether they are in government, civil society, or academia. It is a valuable resource for advocacy, helping to raise awareness of the real problems in accessing medicines and medical devices for those with diabetes; while offering a regional perspective that may inspire new solutions based on the experiences of other countries. However, this is not just a call for more resources, although in many cases these are needed and justified. Often improvements in the organisation of health care can be achieved without additional cost, through a more inclusive and transparent decision-making process.

Professor Martin McKee CBE MD FRCP
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M. McKee
Access to Quality Medicines and Medical Devices for Diabetes Care in Europe

This publication highlights disparities in access to quality medicines and medical devices for diabetes care in the 47 countries of the IDF Europe Region. This study aims to provide evidence to policy makers and stakeholders on the current challenges faced by people living with diabetes in terms of access to the treatment they need. While the study recognises country-specific circumstances, it has also identified common issues that would benefit from coordinated European action.

Key findings

Restrictions on availability?

Understanding market factors
There is no level playing field for diabetes medicines and devices in Europe. The availability of treatment options is affected by the unequal number of types of products that are on the market in each country.

Defining treatment options
The availability of different treatment options is further impacted upon by the assessment by health institutions of each product’s clinical role – which is also a way to control health spending. A consensus has yet to be reached on these issues among European countries.

Accessibility under threat?

Securing continuous accessibility
Striking disparities in physical access to diabetes care and supplies are significant obstacles in some countries. These are major contributors to inequity in access. However, several European countries have managed to overcome these obstacles.

Supporting self-management
Access to diabetes treatment is undermined by unequal access to appropriate diabetes education for those living with this condition and their relatives. Without good education and information about treatment and self-management, diabetes cannot be controlled properly.

Are treatment options affordable?

Balancing individual protection with the sustainability of health systems
In times of economic hardship, financial safety nets that protect individuals and the viability of health systems are challenged. Consequently, competing needs and priorities complicate decisions on the financial support applied on different diabetes treatments.

Fostering pricing policy
For health systems and people with diabetes, the affordability of a diabetes medicine or device depends on prices. However, publicly available information on prices is scarce. Price regulation policies should be developed further and applied systematically to all products across all countries in Europe.

Protecting equity in financial support for diabetes products
Differentiated schemes and subsidies on diabetes supplies facilitate the provision of additional financial safety nets to vulnerable groups. But such mechanisms remain partially implemented or are overly selective in some European countries. Moreover, some of the current mechanisms may actually create further inequities, or widen existing gaps.
Address these concerns now…

Ensuring access to diabetes treatment is a costly, complex and resource-consuming challenge. It is also only one element in high-quality comprehensive diabetes care. This study does not underestimate the difficult tasks involved for governments and other stakeholders. It aims to identify bottlenecks and inequalities, while offering a regional perspective that might inspire effective novel solutions based on the experiences of different countries. People with diabetes rely on continuous access to medicines and devices to manage their life-long condition. This requires sufficient investment to ensure sustainable and uninterrupted access to diabetes medicines and devices.

**Access to diabetes medicines and devices**
Access depends on the provision of all products required to respond to the population’s health needs, wherever and whenever these are needed. Supplies must be delivered in the appropriate format and following the correct protocols – and at prices that do not cause financial hardship to individuals or place a strain on society.

… Or face the consequences of inaction

The cost of ensuring access to diabetes medicines and devices is a small price to pay compared to the human and financial burden of poorly controlled diabetes and its complications. For most countries, the largest single element of diabetes expenditure is hospital admissions for the treatment of long-term complications, such as heart disease and stroke, kidney failure and foot problems. Many of these are preventable with a timely diagnosis of diabetes, effective patient and professional education, and comprehensive, multidisciplinary long-term care. A rise in diabetes-related complications, as currently projected, will place a severe strain on national health systems throughout Europe. These countries currently spend on average an estimated 10% of their budget on diabetes care. In some of them, this figure is as high as 20%.

The social and indirect costs – such as the loss of productivity due to illness – of diabetes-related complications may be even greater than their direct cost to health systems. It is imperative that access to diabetes care be seen as an investment to promote a healthier and more productive society, and as a contributor to long-term economic growth.

About IDF Europe

IDF Europe is the European Region of the International Diabetes Federation. We are an umbrella organisation uniting 66 diabetes associations in 47 countries. We represent people with diabetes and their families, as well as health professionals working in diabetes.

Through our work, we aim to influence policy, increase public awareness and encourage health improvement, promote the exchange of best practice and high-quality information about diabetes in all countries throughout the Region.

For more information visit www.idf-europe.org or contact us at idfeurope@idf-europe.org
Access to healthcare and specifically to medicines has risen to the top of the international health agenda. In June 2013, further to the Report of the United Nations Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,¹ the UN Human Rights Council adopted a resolution¹ recognising access to medicines as being fundamental to the right to health. The resolution urged Member States and international organisations to work to ensure “access, without discrimination, to medicines (…) that are affordable, safe, efficacious and of quality”². The resolution endorsed the Special Rapporteur’s main recommendations that aim to secure long-term, reliable access to quality medicines that fit the needs of the population; promoting the removal of barriers to access through a participative process that includes all stakeholders and especially affected communities.³ Although medical devices are not directly covered by the resolution, their role in healthcare also makes these recommendations highly relevant to such medical supplies.

At the EU level however, the economic crisis of the last five years has put this matter in competition with two issues that are high on the European agenda: reduced public spending, and more efficient and effective public spending.⁴ Austerity measures have led 17 of the 28 EU countries to cut their spending on healthcare.⁵ The latest European Commission review of Member States expressed concerns over the rising cost of healthcare and the financial sustainability of European health systems; and called for more effective and strategic public spending on health.⁶ However, this has raised concerns that even in strong, comprehensive health systems austerity measures and cuts in public spending may endanger people’s access to healthcare and medicines. Indeed, the economic crisis may be being used as an excuse for drastic rationing and reductions in resources for health. In the same vein, calls for effectiveness may be misinterpreted as a synonym for budget cuts.

On 4 July 2013, the European Parliament adopted a report drafted by Green Party MEP, Jean Lambert on access to care for vulnerable groups, calling on EU Member States and the European Commission to ensure that austerity measures would not jeopardise access to healthcare and other social services for the most vulnerable people. To this end, the report recommends the systematic completion of social impact assessments before policy can be implemented.⁷ Similar requests are being made in the voluntary sector, where NGOs have expressed their concerns.⁸ Indeed, in times of financial hardship, vulnerable groups and people living with chronic disease appear to face a dual burden: on the one hand, individuals are likely to suffer unemployment and have low financial resources, leading to impoverishment and worsening quality of life; on the other, cuts in public spending on health and social care further reduce public support for these populations, shifting the financial burden of healthcare to households. Notably, pharmaceutical spending is among the first areas of public health expenditure to be cut.⁹ People living with diabetes are particularly vulnerable in such situations. Their capacity to live a long and productive, healthy life relies on a healthful lifestyle and regular uninterrupted access to healthcare, including treatment for their disease.

The same debates and concerns over the impact of the economic crisis on health were found at the broader European level. In April 2013, WHO European Region Member States met in Oslo to discuss this issue with experts and formulate a potential policy response.¹⁰ The evidence presented underlined that economic downturns are associated with rising health needs, while unwise cuts in the health sector may exacerbate the situation. In the words of WHO Regional Director for Europe, Zsuzsanna Jakab, speaking at that meeting: “If you have to cut, cut wisely, not broadly, and protect the vulnerable to ensure universal health coverage”. At the same time, WHO Europe recognised the efforts made across the region to absorb budget cuts while protecting access to services via the development of more efficient and effective health systems. It was acknowledged that the current crisis might present an opportunity for Member States to improve their health systems, and achieve and sustain universal coverage.

European leaders are also looking at the sustainability of health systems and their capacity to meet future challenges. Several initiatives have already been undertaken in that respect. At EU level, the European Commission is about to launch the EUR 70 billion health research programme, Horizon 2020.¹¹ This will provide grants supporting research that aims at addressing European health challenges through a multi-sectorial approach – that includes sciences, industry and social policy. The forthcoming multi-annual EU health programme, Health for Growth, will focus on innovation, uptake and sustainability in the reform of health systems.¹² At the WHO European Region level, the 2013 Report, Priority Medicines for Europe and the World highlights pharmaceutical gaps and research needs to address Europe’s disease burden. Diabetes is among the 24 diseases and disease groups, which have been identified as priority fields for research due to their
contribution to Europe’s burden of disease and mortality.\textsuperscript{13}

In this context of growing concerns over access to healthcare and medicines, wide health system reforms, and the challenges of long-term care for chronic diseases like diabetes, the current publication offers a snapshot of access to quality diabetes medicines and medical devices across the 47 European countries where IDF Europe’s Member Associations are present. By identifying main barriers to access and inequalities within and between countries, it intends to provide policy makers and stakeholders with evidence to address a number of the challenges caused by the diabetes epidemic.

\section*{Methods}

All 47 countries in the IDF Europe Region were included in this study. To better contextualise the analysis, these were grouped according to sub-regional organisations and geographical proximity, bearing in mind IDF Europe’s sub-regional working groups. The scope of the survey was defined through a review of the literature as well as interviews with healthcare professionals specialising in diabetes care.

The definition of access and selection of its dimensions to be included in this survey were based on existing definitions and frameworks applied to access to medicines and access to healthcare.\textsuperscript{14,15,16,17,18} Articles and reports on access to healthcare were included in order to partially integrate the notion of access to treatment. This notion encompasses access to the products required to treat a condition, and the factors affecting the capacity of each healthcare system to offer such a treatment: the availability of trained human resources, patient information and education, and healthcare facilities.\textsuperscript{19} This contextualization facilitated cautious comparisons between the 47 countries as it may take into account constraints on the health system. Based on the different aspects of access identified in the literature, three core elements were chosen for study: availability, accessibility and affordability. Additionally two interconnect factors – quality and equity – were integrated into reporting on the three core elements. These dimensions were then detailed in a set of components to assess (see Definitions for further explanation).

To maintain a certain level of comparability given the diversity of the situations studied, diabetes medicines and devices were grouped into categories, rather than studying individual products, devices or brands. The selection of these categories was made using two types of source: IDF guidelines; and interviews with diabetes healthcare professionals. IDF’s guidelines for the treatment of different types of diabetes facilitated the identification of care practices.\textsuperscript{20,21,22} Feedback from healthcare professionals in different parts of the Region ensured a degree of comparability across countries.\textsuperscript{21,24,25} The following criteria were used to build the final list of product groups: their integration into guidelines; their ranking in terms of line of treatment; usage across the Region. Furthermore, in order to take into account access to innovation, the newness of products was also included as a criterion to select certain product groups. As a result, a total of 12 categories were identified.

Given the difficulty of obtaining comparable data on the prices of such a large number of types of products, a narrower list of specific supplies was used for price analyses (see Annex 3).

The method used for data collection was developed by adapting existing methodologies measuring access to medicines\textsuperscript{26,27,28} and previous work by IDF on access to insulin.\textsuperscript{29,30,31,32} This study was carried out in three phases.

To collect information, three questionnaires were developed targeting three different groups: national health institutions; healthcare professionals; and people with diabetes. Using the different sources of information the study attempted to crosscheck the information compiled and identify the level(s) at which barriers occurred. Before being disseminated, the different questionnaires were translated into 20 languages. They were made available through the online survey website, and in Word format, downloadable from IDF Europe’s website. Data collection took place from 2 to 31 May 2013\textsuperscript{a}. The questionnaires reached their targeted audience primarily through IDF Europe’s Member Associations and via IDF Europe’s communication networks.

To clarify some of the information collected and acquire further details, the second phase of this survey included interviews with Member Associations based on a primary analysis of questionnaire results, as well as desk research. This included peer-reviewed articles, grey literature and publicly available national databases, due to translation constraints, the English and Russian versions were available earlier than those in other languages. Additionally, few countries where response rates were particularly low benefited from an extended deadline of one week.
or lists obtained through web searches. Additionally, interviews were held with academics with expertise on the different issues identified, and with different stakeholders (the pharmaceuticals and medical devices industry, wholesalers, pharmacists). This phase took place from 20 May to 23 July. A full list of the interviewees is available in Annex 1.

Data validation was ensured through a review by IDF Europe Member Associations and by the publication’s Review Committee. The Review Committee included a panel of experts in diabetes care and/or access issues. Member Associations were also offered the opportunity to comment on the primary results during the interviews that took place during the second phase of the study. Additionally, review sessions were organised during the EASD meeting in Barcelona in September 2013.

### Definitions

#### What is diabetes?\(^{23}\)

Diabetes is a chronic disease that occurs when the pancreas does not produce enough insulin (the hormone that regulates blood glucose), or when the body cannot effectively use the insulin it produces. Uncontrolled diabetes results in raised blood glucose (hyperglycaemia), which over time causes damage to blood vessels, nerves and other tissues. Combined with disturbances in lipid metabolism (dyslipidaemia), raised blood pressure (hypertension) and smoking, these often lead to serious complications, such as cardiovascular disease and stroke. Additionally, circulatory impairment combined with nerve damage may lead to lower-limb ulceration and amputation, impaired vision (retinopathy) and blindness, and kidney disease (nephropathy).

#### Type 1 diabetes mellitus

Type 1 diabetes is characterised by a complete deficiency of insulin production. Symptoms include excessive urination, constant thirst, weight loss, vision changes and fatigue. The onset of symptoms is usually rapid. Most people with type 1 diabetes are diagnosed at young age. Without a regular and reliable supply of insulin, people with type 1 diabetes will not survive.

#### Type 2 diabetes mellitus

Type 2 diabetes results from the body’s relative lack, or ineffective use of, insulin (insulin resistance – also known as insensitivity to insulin). Type 2 diabetes represents over 90% of all cases of diabetes around the world, and is associated with being overweight, excess abdominal adiposity and physical inactivity. Symptoms may be similar to those of type 1 diabetes, but are far less marked. As a result, type 2 diabetes may be diagnosed several years after onset, and after complications have already developed. Until recently, this type of diabetes was seen only in older adults but it is now also occurring in overweight and obese children and adolescents.

Type 2 diabetes is largely preventable, the complications of which can be prevented or delayed through evidence-based interventions. Depending on the status of the condition, type 2 diabetes can be treated through lifestyle changes and/or oral medications and/or insulin therapy.\(^{36}\)
Gestational diabetes mellitus

Gestational diabetes is high blood glucose that starts or is first diagnosed during pregnancy. This occurs because pregnancy hormones can reduce the action of insulin. Factors that put a woman at risk of developing gestational diabetes include being overweight before pregnancy. Gestational diabetes is primarily treated through lifestyle changes with close monitoring of blood glucose levels, but may also require insulin therapy or oral medications.\textsuperscript{20}

In several European countries, diabetes and its complications have caused the greatest increase of deaths over the past 20 years. Diabetes is ranked among the leading causes of cardiovascular disease, blindness, renal failure and lower limb amputation. About 75\% of people with diabetes die of cardiovascular events – the number one cause of death in Europe. People with type 2 diabetes have a two- to four-fold higher risk of coronary heart disease than the overall population.

Of great concern is that more recently also children and adolescents are developing type 2 diabetes, largely due to increasingly sedentary lifestyle and the growing levels of obesity in these age groups. Estimates suggest that one in five children in Europe are overweight and that each year 400,000 children become overweight.

While diabetes is reported to be the fourth main cause of death, these statistics are likely to be an underestimate given the number of people with diabetes in Europe: diabetes-related deaths are based on death certification, which may only record deaths directly attributable to diabetes, rather than to its long-term complications and other associated co-morbidities, such as cardiovascular disease.

Diabetes is an important public health challenge. Only by substantially increasing public awareness of diabetes and its complications, and through primary prevention measures, early detection and evidence-based management of the disease, will the growing epidemic and its financial costs be contained.\textsuperscript{37}

What is access to medicines and medical devices?

Access to any health technology is determined by ensuring that products required to respond to the population’s health needs, are provided where and when they are needed, in an adequate format and according to proper protocols, at a price that would not cause financial hardship to the community or the individual.\textsuperscript{14,17} Thus, it is part of the broader concept of access to healthcare and so, relies on a functioning health system.\textsuperscript{17} Therefore, a distinction should be made between access to medicines and medical devices vs. access to treatment, which includes the different healthcare system’s factors that affect care and performances.\textsuperscript{16}

Hence, access to medicines and medical devices can be achieved by ensuring the following:

Availability

Availability is defined as the presence in a country of products that meet the population’s health needs.\textsuperscript{18} It refers to the range of products marketed in a country; which of them are selected by the health system; and how and according to which indications and guidelines they should be prescribed and delivered.\textsuperscript{17} Thus, not only is availability influenced by national health policies and the decision-making within the health system, but also by the structure of the market for each type of product – how many products and manufacturers exist, competition between them, and the extent of innovation in each disease area.

Accessibility

Accessibility refers to physical access to the products, or where the products can be delivered to people.\textsuperscript{19} It involves the overall organisation of the health system and especially, its procurement, supply and dispensing systems.\textsuperscript{17,18} In order to embrace the notion of access to treatment,\textsuperscript{19} accessibility in this publication is also understood as encompassing factors such as access to prescribers and proper education and information about the products.

Affordability

Affordability refers to a product’s cost vs. the ability and willingness of people (as well as health systems and third-party payers) to pay for it. Affordability entails a product’s price components (manufacturing, supply, taxes, mark-ups), as well as policies and other factors that affect these components – such as pricing and reimbursement policies, intellectual property and competition laws, regulatory standards and requirements.\textsuperscript{17,18} Affordability also must be considered in terms of the ways in which these products are paid for – health system financing, the role of public vs. private payers, out-of-pocket payment by people with diabetes – and whether these elements are able to ensure the system’s sustainability.\textsuperscript{17}
Use

Use by healthcare professionals and people with diabetes covers the responsiveness and adequacy of products for people’s needs; acceptability by both parties; and rational use. A study of these elements could not be included in this survey and constitute a field for future research.

Availability, accessibility, affordability and proper use should be achieved while ensuring *equity* and *quality* at each level. Quality is defined here as compliance to international, regional and national standards. Equitable access refers to the imperative to ensure access according to needs. The main potential equity issues that were investigated in this study were differences in access between product categories, between people with different types of diabetes, and between people living in rural or urban settings.

**In this publication**

This publication is organised around the five sub-regions of Europe and the three elements of access described above. The first chapters provide a comparative analysis of access to diabetes medicines and medical devices in each of the five sub-regions:

- North-West Europe
- South-West Europe
- Central and Eastern Europe
- South-East Europe
- Eastern Europe

These sections are complemented by a short country profile for each of the 47 countries surveyed. Finally, main findings and future perspectives are summarised in the conclusion.

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b For the purpose of this study, as each country has its own definition of rurality, the latter was defined as remoteness from healthcare services. Respondents reporting living more than 5 km away from a practising doctor or pharmacist were defined as rural respondents.
SUB-REGIONAL ANALYSIS
## Categories of diabetes supplies surveyed

<table>
<thead>
<tr>
<th>Description</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Human insulin</strong></td>
<td>A synthetic medication that is identical to the insulin produced by the body. There are three types of human insulin, according to how fast and long they act in the body. Human insulin can come in vial or cartridge, depending on the injection device used.</td>
</tr>
<tr>
<td><strong>Insulin analogues</strong></td>
<td>Insulin that has been modified to imitate the action of endogenous insulin in the body and offer different timing of action. There are different types of analogues, according to their action in the body. They come in vial or cartridge, depending on the injection device used.</td>
</tr>
<tr>
<td><strong>Hypoglycaemia medication</strong></td>
<td>These medicines bring blood glucose levels up to the normal range, so that the body has enough glucose to function adequately. These types of medicines include simple glucose tablets and injectable medicines, like glucagon. The choice of medication depends on the severity of hypoglycaemia.</td>
</tr>
<tr>
<td><strong>Metformin</strong></td>
<td>This medication reduces the release of glucose from the liver. It is the main first-line medication for type 2 diabetes.</td>
</tr>
<tr>
<td><strong>DPP4 inhibitors</strong></td>
<td>This type of medicines acts on insulin levels and the release of glucose from the liver. They include vildagliptin, sitagliptin, saxagliptin and linagliptin (alogliptin is not authorised in Europe yet). This type of medicines is mainly used as a second- or third-line treatment for type 2 diabetes.</td>
</tr>
<tr>
<td><strong>Other oral or injectable medicines</strong></td>
<td>This category was created to include all the other types of oral or injectable medicines that can be used to treat diabetes.</td>
</tr>
<tr>
<td><strong>Syringes and needles</strong></td>
<td>These medical devices are used to inject insulin. They may be pre-filled or used in association with vials of any type of insulin.</td>
</tr>
<tr>
<td><strong>Insulin pens and supplies</strong></td>
<td>Depending on whether they are pre-filled (disposable) or re-usable, these injection supplies are considered either as medicines or as medical devices (which has regulatory implications). In both cases, the needle is disposable and has to be replaced. Re-usable pens have to be filled with insulin cartridges that match the associated pen: a change in the type or brand of insulin may require changing the pen used to inject it.</td>
</tr>
<tr>
<td><strong>Conventional insulin pumps and supplies</strong></td>
<td>An insulin pump is a computerised medical device designed to infuse insulin continually into the body. The pump itself can last many years, but some components such as tubing and the infusion set, have to be replaced every few days. While pumps may help achieving better self-management for some people on insulin, they are not suitable for all of them – criteria vary from one country to another. Insulin pump therapy requires a good knowledge of diabetes self-management, as well as commitment and capacity to follow the associated treatment and testing requirements.</td>
</tr>
<tr>
<td><strong>Blood glucose test strips</strong></td>
<td>These are disposable diagnostic devices used in blood glucose meters (see below) to measure the glucose in a drop of blood, supporting self-management and, thus, good control of diabetes and the avoidance of hypo- and hyperglycaemia. Self-monitoring also requires good information and education about how to use and understand blood glucose testing and its results. While most studies agree on the effectiveness of multiple daily testing for people with type 1 diabetes and gestational diabetes, the debate continues around their optimal use for people with type 2 diabetes — especially for those who are not treated with insulin.</td>
</tr>
<tr>
<td><strong>Blood glucose meters</strong></td>
<td>These devices measure glucose levels in the blood. Most models work with test strips (see above).</td>
</tr>
<tr>
<td><strong>Ketone test strips</strong></td>
<td>These are disposable diagnostic devices to detect ketones, which typically build up when the body needs to break down fats instead of sugars as primary energy source. The amount of ketones can rise to life-threatening levels in certain people with diabetes — primarily those with type 1 diabetes.</td>
</tr>
</tbody>
</table>

### References

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NORTH-WEST EUROPE
Access to medicines and medical devices in the Western European Union (EU) and European Free Trade Association (EFTA) Member States

As members of the EU or the European Economic Area, 14 of these countries have harmonised much of their legislation on the authorisation and distribution of medicines and medical devices. Mutual recognition agreements covering some of these aspects are in place with Switzerland, the 15th country in the sub-region. However, the implementation of these regulations, as well as health policy, healthcare provision and health financing, remain the responsibility of each individual state. All 15 countries have well-established health systems and health coverage schemes (Table 1), based on either mandatory health insurance or national health services, which ensure the provision and coverage of a set of health services. Nonetheless, the way each country has chosen to address the diabetes epidemic within its health system varies. While this sub-regional group includes countries with the highest number of people with diabetes in the European region (Germany, France, UK), diabetes prevalence and the related disease burden for each health system differ: from less than 4% in Iceland to more than 6% in Austria (see Graph 1). These elements inevitably influence people’s access to diabetes medicines and other medical devices.

* The Faroe Islands are an autonomous territory of the Kingdom of Denmark. However, as their diabetes care and treatment function independently of the Danish system, they will be considered here as a separate entity.
Availability

All the products surveyed were reported as being authorised for sale and present in each of these countries. However, while authorisation occurs almost simultaneously across the countries, there may be differences between countries in terms of a product’s actual presence. As mentioned above, authorisation and associated controls have been harmonised across the sub-region, either through the centralisation of procedures, as is the case for diabetes medicines in the EU plus Iceland and Norway, or through the recognition of certifications and authorisation granted by other countries – principally for medical devices. On the other hand, as diabetes products are to some extent publicly financed throughout the sub-region, authorisation to market a product does not automatically result in it actually being marketed and present in a country – which, as representatives of the industry explain, would happen only once a price and eventual reimbursement level have been set. Depending on these country-specific procedures, the introduction of a new product may take more or less time. Additionally, pricing and reimbursement procedures play a role in the marketing strategies of the companies producing these products. An example on this occurred recently in Germany, where disagreements over the price and reimbursement of a diabetes medicine led to its withdrawal from the German market. Pricing and reimbursement policies have been identified by national diabetes associations as a factor in delaying access to certain diabetes products in a number of countries in this sub-region. However, some of the literature and the information provided by the pharmaceutical industry suggest that in the 15 countries considered here, delays in market launch due to pricing and reimbursement are actually minor compared to other countries in Europe.

“...There is a new law in Germany: the benefit of a new drug must be judged superior to a comparative therapy. No extra benefit means that the new product will be available at the same price as the comparative therapy. That’s why some pharmaceutical companies decide not to introduce their new products on the German market.”

A response from Germany

The fact that diabetes products are partially or fully financed by health systems also impacts on prescription. If control over prescription follows primarily clinical rational, it is also used as a tool to contain health spending. However, the constraints associated with health system’s financing of prescriptions vary across the sub-region and between medicines and medical devices (see also Affordability). In four countries (Austria, Belgium, Luxembourg, Germany), the prescription of certain medicines and/or medical devices requires the previous approval of a person’s health insurance company or fund. In some of these countries and in certain Nordic countries, such as Finland and Sweden, the financing institution (health insurance companies or local authorities) are also directly involved in defining prescription criteria for some diabetes products. The availability of diabetes medicines and devices to individual cases is thus strongly influenced by the overall structure of the health system and, specifically, by the level of autonomy and responsibility conferred to the entities responsible for financing. However, in Germany, Sweden and Finland, the autonomy granted to each financing institution appears to have resulted in the application of different criteria within the same country. This has been reported as the cause of inequalities in access to certain medicines and medical devices.

These systemic constraints are further to those included in clinical guidelines. All 15 countries have adopted such guidelines. These guidelines may confine the prescription of certain diabetes products to specific healthcare professionals or healthcare settings, or certain categories of people with diabetes, or different lines of treatment. More than half of the 15 countries limit the prescription of new oral medications, such as DPP-4 inhibitors, to second- or third-line treatments. About a third of them restrain the prescription of some or all insulin analogues to certain types of diabetes and/or to second-line treatment – after human insulin. In almost all of the countries, criteria relating to a person’s type of diabetes and/or treatment regimen were found regarding prescription of insulin pumps, and in at least six of them for blood glucose-monitoring devices. In at least four countries, the prescription of insulin pumps was reportedly limited to hospitals and mainly to diabetologists and endocrinologists. Apart from the therapeutic elements of these criteria, these limitations (which appear to be applied primarily to newer – and often higher-priced technologies and medicines) also reflect the use of prescription control to contain health expenditure. However, although good practice sharing and recommendations exist at the European level regarding...
aspects of diabetes treatment, the definition and implementation of guidelines remains a national (or even local) competence. This is carried out through different procedures and methods of assessment – leading to differences in evaluations and recommendations across the sub-region. Moreover, the binding power of guidelines on prescribers is uneven. For example, in France, Ireland and Belgium, the prescription of diabetes medicines appears to be left mainly to the assessment a prescriber makes of each patient’s condition. At the opposite end, the prescription of both types of devices mentioned above appears to be subject to tighter control in almost all 15 countries.

Although the level of constraint applied prior to the actual distribution of diabetes products differs from one country of this sub-region to another, in all 15, people's access to diabetes medicines and medical devices is to some extent determined as soon as these products receive authorisation – and often, before they are even launched. This may place de facto constraints on individual treatment options and local accessibility of diabetes products. Additionally, because of the connection with healthcare financing and cost-containment, this is closely related to the affordability of these products.

**Accessibility**

The available information suggests that physical access to diabetes medicines and devices – from the prescriber to the point of dispensing – is not a crucial issue in this sub-region. In all 15 countries, the prescription of diabetes products has been moved into primary care, with GPs/family doctors being the main prescribers for certain categories of people with diabetes, especially those with type 2 diabetes. In Belgium and the Faroe Islands, the provision of diabetes care and treatment at the primary care level is also a response to the low number of specialists in the countries. Physical access to a prescriber appears to be almost universal across the sub-region. Difficulties were reported only in France, Iceland and Ireland, where access to specialised care when needed remains an issue in certain rural or isolated areas, or for a specific group in the population.

As new technologies are further integrated into diabetes care, the training of healthcare professionals in their use is becoming a key factor in access for people with diabetes. For example, the lack of healthcare professionals trained in insulin pump therapy was identified as an obstacle to the uptake of this type of therapy in the UK and Denmark. Continuous healthcare professional training covering all treatment options is also central to access to diabetes education and information about medicines and devices. While other channels of information, including diabetes associations and the industry, may play a role in certain countries, prescribers and diabetes care teams appear to remain the principal point of diabetes information and advice about treatment.

“All people with diabetes only receive very basic information on how to use diabetes products. It also varies a lot across the country due to our municipality structure. In general, people don't receive holistic training on managing their diabetes.”

A response from Finland

If most people with diabetes living in this sub-region appear to have received some information and education about the diabetes medicines and medical devices they use, this has yet to be made systematic. The provision of information and education to the relatives of people with diabetes is also far less frequent in all countries. Additionally, in some countries the type and quality of information and education provided to people with diabetes has been reported as uneven. In this regards, disparities between regions were reported in Denmark, Finland and in some parts of Ireland; while differences between primary and specialised care were underlined in Iceland. On the other hand, in Belgium and Denmark, access to education and diabetes products are being linked via the integration of some categories of people with diabetes into a care pathway, which aims at a holistic approach of diabetes care. The key role of continuous diabetes education for people with diabetes and their relatives in diabetes management should not be underestimated – as it is associated with improved clinical outcomes and quality of life.

While access to prescribers and information may require some improvements, physical access to points of dispensing appears to be universal across the sub-region. However, the accessibility of diabetes products themselves is more complex, mainly because of stock issues. On the one hand, although such issues were reported occasionally in almost half of these countries, their impact on people's treatment was in most cases very limited. Such problems either were solved within a few days or alternatives were found via healthcare professionals and/or diabetes associations. Occasional stock shortages may be a source of frustration and/or stress for people with diabetes – as managing their condition requires uninterrupted treatment. However, any related scarcity does not appear to create disruptions in treatment. On the other hand, it was, in fact, healthcare professionals who often reported these difficulties, so the impact on daily practice
may be different. Reports from various professional organisations highlight how time-consuming such situations can be for healthcare professionals and how they impact quality of care.\textsuperscript{15} This issue has no simple answer. With the increasing regulatory and financial pressure that actors of the pharmaceutical and medical-device supply chain report, ensuring an uninterrupted supply of these products at points of dispensing or point of care is becoming increasingly challenging and any delays or incidents may create stock issues.\textsuperscript{16,17} However, as diabetes is not the only condition affected by these difficulties in supply, some initiatives have been developed by professional associations to address these issues. For example, in the Netherlands, the National Association of Pharmacists is gathering and disseminating information to its members regarding supply issues – when these are expected to be resolved and what alternative treatment can be offered in the meantime. Also, some countries have implemented specific measures to guarantee that sufficient stocks are available to respond to the needs of healthcare facilities and patients. Certain countries, including Germany and Belgium, have created a legal public-service obligation for wholesalers to guarantee adequate supplies of medicines needed locally at all times.\textsuperscript{16} In Finland, legislation obliges designated actors in the supply chain to maintain a minimum level of stock of certain products.

Although shortages barely affect the accessibility of medicines and medical devices, other constraints on the provision and dispensing of diabetes products are applied at the local level in about five of the 15 countries. In most cases, difficulties are due to local budget constraints, which lead to the implementation of additional eligibility criteria for certain products – especially medical devices – and/or to their rationing. For people with diabetes, this may result in being put on a waiting list for a specific device or medicine, or being denied a prescription for it. Moreover, as in some of these countries, the supply of certain medical devices is subject to local tenders, the number and types of brands available to people with diabetes may vary from one area to another. Because these are local factors, they vary within countries and lead to unequal local access to a number of medicines and medical devices.

While no major barriers affect overall accessibility of diabetes supplies across the sub-region, the fact that access to some of its components has yet to be made universal and uninterrupted, adds further constraints to those described above under ‘Availability.’ These hurdles require further efforts from each person with diabetes to obtain and secure a continuous and reliable access to the medicines and medical devices they need to treat their condition. More importantly, as these constraints affect certain people and areas more than others, they may result in inequalities within countries.

**Affordability**

As mentioned above, most diabetes products are financed by health systems. Hence, they are subject to the application of specific requirements and evaluations as a method of cost containment. However, the ways in which these measures are decided and implemented, and the consequent impact in terms of financial barriers for people with diabetes, vary strongly from one health system to another. For example, six countries in the sub-region cover the cost of diabetes products under a special scheme, usually alongside other chronic conditions. Furthermore, although most countries in this sub-region mix therapeutic and economic criteria in their assessments of diabetes products, the methodology they use for this also varies. It appears also that the methods and policies used to set prices and reimbursement levels for medical devices are less developed and clear than those applied to medicines.\textsuperscript{19}
### Table 2: Out-of-pocket expenditure on diabetes medicines and medical devices per year

<table>
<thead>
<tr>
<th></th>
<th>Annual median out-of-pocket spending on diabetes products</th>
<th>Share of Household Net Adjusted Disposable Income spent on diabetes products</th>
<th>Share of Household Net Adjusted Disposable Income for the poorest 20% spent on diabetes products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>USD 623</td>
<td>2%</td>
<td>5%</td>
</tr>
<tr>
<td>Belgium</td>
<td>USD 312</td>
<td>1%</td>
<td>3%</td>
</tr>
<tr>
<td>France</td>
<td>USD 0</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Germany*</td>
<td>USD 179</td>
<td>0.6%</td>
<td>1.4%</td>
</tr>
<tr>
<td>Ireland</td>
<td>USD 0</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Luxembourg*</td>
<td>USD 234</td>
<td>1%</td>
<td>OECD data unavailable</td>
</tr>
<tr>
<td>Netherlands*</td>
<td>USD 78</td>
<td>0.3%</td>
<td>1%</td>
</tr>
<tr>
<td>Sweden</td>
<td>USD 0</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Switzerland</td>
<td>USD 758</td>
<td>2.5%</td>
<td>6%</td>
</tr>
<tr>
<td>UK</td>
<td>USD 0</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

*The samples of respondents in these countries were only constituted of people with type 1 diabetes or people treated with insulin. Thus the annual out-of-pocket expenditure that was reported may not be representative.

†This information could not be obtained in the following countries: Denmark, the Faroe Islands, Finland, Iceland and Norway.

Details of coverage for diabetes products in each country can be found in the country profiles. However, a number of trends have been identified in coverage for diabetes products. Most countries provide full coverage for insulin and oral medications. Four Nordic countries do not but they apply a ceiling on out-of-pocket spending. Austria, Germany and Switzerland apply fees – paid by the person with diabetes – on the prescription or dispensing of some or all diabetes products. Coverage for medical devices is even more diverse. At least ten of the 15 countries leave some of the cost of medical devices to people with diabetes; or fully cover them for certain categories of people only – mainly people with type 1 diabetes or those treated with insulin. Thus, access to medical devices for people who are not on insulin – a large proportion of the people with type 2 diabetes, for example – appears to be highly sensitive to people's ability either to afford to pay for these supplies or manage their diabetes without them.

Thus, in this sub-region, out-of-pocket expenditure (Table 2) may occur for the following reasons. This may result from the scope of the coverage offered by health systems. In this case, out-of-pocket expense would cover the costs of diabetes products that are partially or not covered by the health system, or those of the additional supply people may have to buy to complement that covered by the health system. Out-of-pocket spending may also be related to more specific elements of their countries' pricing and reimbursement policies. In some countries, prescription or dispensing fees paid by people with diabetes make them participate to the remuneration of the health care providers. In countries using internal reference pricing to set reimbursement levels, out-of-pocket payments may occur because of the difference between the reimbursed price and the retail price.

Generally speaking, in countries where co-payments are compulsory, having to pay a share of treatment out-of-pocket appears not to be perceived as a barrier per se by most people living with diabetes. Some people may benefit from additional coverage from voluntary private insurances. Additionally, most countries in the sub-region have policies in place to limit annual out-of-pocket expenditure on healthcare for all people with diabetes and some specific groups, such as people with a low-income, children or elderly people.

**“Theoretically, any person with diabetes treated with any medication is eligible to 100% coverage under the long-term illness scheme. However, only two-thirds of them have requested it and are actually covered by the scheme.”**

A response from France

However, some gaps have yet to be closed. In almost half of the countries in the sub-region, eligibility for subsidies mentioned above or full coverage of certain diabetes products requires specific, in some cases lengthy, procedures to be undertaken by people with diabetes and their healthcare providers. As a result, some people with diabetes may not actually benefit from policies designed to avoid high expenditure. The causes of such implementation gaps are not always clearly identified. However, national diabetes associations have often identified the under-provision of information about these subsidies to people with diabetes and healthcare providers as the main reason for these discrepancies – an issue many of these associations are currently trying to address. Beyond these implementation issues, the design of coverage itself may result in
inequitable access to diabetes products. As mentioned above, coverage of certain supplies, such as self-monitoring devices, depends on a person’s type of diabetes and/or treatment regimen in over half of the countries. Some countries have ensured a degree of flexibility by providing coverage where healthcare providers identify a need for self-monitoring; others have not. Furthermore, in countries where local authorities or individual healthcare facilities have budgetary responsibility for diabetes supplies, people may benefit from a more- or less-generous coverage, depending on where they live (see also Availability).

In order to limit both public and out-of-pocket expenditure on diabetes, all 15 countries regulate the prices of devices and medicines either directly through specific price-setting policies, or indirectly through levels of reimbursement. Despite the removal of many trade barriers within the sub-region and although a majority of these countries are using external reference pricing – where they follow prices applied in neighbouring countries – the information collected during our survey (see Annex 3) suggests that significant price differences remain, for health systems as well as people. These findings coincide with previous research. Pricing and reimbursement remain a national competence. Although a number of the same tools may be used across the sub-region, their details differ: from the methodology used, to the way suppliers are paid, or the types and levels of taxes applied. Individual pricing schemes can be found in each country’s profile.

In the context of increased pressure on public finances, most countries have been reforming their pricing and reimbursement policies. At least five of the countries in the sub-region have implemented a price freeze or price cuts on medicines in the last three years, and some have redesigned their overall methodology for setting the price of medicines. Although most of these countries are also developing regulations promoting the use of low-cost and/or non-branded products, the impact of such policies on diabetes supplies is likely to be limited in the short-term. While differences exist across the sub-region, it appears that the number of brands available for each category of diabetes products, especially insulin and new oral medications, is generally limited. For the most part, only branded products are available and used in these 15 countries. Some national diabetes associations are following closely the development of low-cost alternatives, such as biosimilar insulin in the UK and Norway; others have expressed concerns that, in this push for lower prices and cost-constraints, authorities and financing institutions may be sacrificing quality as a priority factor in the choice of product.

To date, cuts in reimbursement or coverage appear to have impacted only marginally on diabetes. However, with public expenses under review across the sub-region, discussions are under way in at least four countries on the redefinition of coverage for diabetes medicines and devices – starting with new, more expensive products. Given that the cost of diabetes products remains an issue for a number of people living with diabetes, the potential side effects of these measures on vulnerable groups, as well as their long-term public health impact, should also be considered.

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Note: references related to individual countries can be found on the country profiles.
SOUTH-WEST EUROPE
Access to medicines and medical devices in Mediterranean EU Member States

As members of the EU, all countries have harmonised, to a greater or lesser degree, their legislation on the authorisation and distribution of medicines and devices, as well as some quality certification and standards. However, as health and healthcare policies and financing remain a national competence of EU members, how each country addresses the challenge diabetes makes varies. The countries in this sub-region have indeed among the highest diabetes prevalence and/or the highest number of people with diabetes in the European region. Although nearly all countries (with the exception of Cyprus) have health coverage schemes (either National Health Services or mandatory Health Insurance System), the range of services and population covered strongly vary between countries. Strong disparities within this sub-region also exist in terms of the public resources made available for health in general, and diabetes in particular (see Table 1). Additionally, this sub-region has been very heavily impacted upon by the economic crisis. Nonetheless, all countries offer some public support for diabetes care and supplies.

Table 1: Key health expenditure figures (2011)

<table>
<thead>
<tr>
<th>Country</th>
<th>Total health expenditure per capita</th>
<th>Public spending in total health expenditure</th>
<th>Private spending in total health expenditure</th>
<th>Proportion of total government expenditure on health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Croatia</td>
<td>USD 1,137.30</td>
<td>84.7%</td>
<td>15.3%</td>
<td>17.7%</td>
</tr>
<tr>
<td>Cyprus</td>
<td>USD 2,123.20</td>
<td>43.3%</td>
<td>56.7%</td>
<td>6.9%</td>
</tr>
<tr>
<td>Greece</td>
<td>USD 2,864.20</td>
<td>61.2%</td>
<td>38.8%</td>
<td>13.2%</td>
</tr>
<tr>
<td>Italy</td>
<td>USD 3,453.60</td>
<td>77.2%</td>
<td>22.8%</td>
<td>14.7%</td>
</tr>
<tr>
<td>Malta</td>
<td>USD 1,896.95</td>
<td>67.4%</td>
<td>32.6%</td>
<td>13.3%</td>
</tr>
<tr>
<td>Portugal</td>
<td>USD 2,310.62</td>
<td>64.1%</td>
<td>35.9%</td>
<td>13.4%</td>
</tr>
<tr>
<td>Slovenia</td>
<td>USD 2,218.50</td>
<td>72.8%</td>
<td>27.2%</td>
<td>13.0%</td>
</tr>
<tr>
<td>Spain</td>
<td>USD 3,026.65</td>
<td>73.6%</td>
<td>26.4%</td>
<td>15.4%</td>
</tr>
</tbody>
</table>

Graph 1: Diabetes comparative prevalence (2011)

Availabiliy

Following EU regulations, all eight countries have centralised the authorisation procedures for diabetes medicines and harmonised the procedures authorising diabetes devices. All the products surveyed were reported present in seven of the eight countries; in Malta, the presence of some of the newest supplies (DPP4-inhibitors and insulin pumps) could not be confirmed. The reasons for their absence from the Maltese market could not be determined.

Clinical guidelines and the coverage of costs offered by the health system are two important factors affecting the availability of diabetes treatment in each country: as they influence their prescription, they determine the products each person with diabetes is eligible to receive. All eight countries have clinical guidelines for diabetes care. Beside their therapeutic value, prescription guidelines also function as a cost-containment tool for the health system. In Malta and Cyprus, the range of diabetes supplies actually available to people living with diabetes seems to
be determined by the state's procurement choices under the specific schemes for people with chronic diseases. In other countries, prescription criteria and financial coverage are related: prescription criteria are used to control the consumption of diabetes products covered by the system – in terms of the types of products and their quantity. Almost all countries apply specific criteria for prescribing insulin pumps, which either are limited to certain categories of people with diabetes (people with type 1 diabetes, children, women during pregnancy), or (as in Greece) require a specific procedure. Specific criteria are also applied to the prescription of blood glucose monitoring devices in most countries of the sub-region. These appear to be related to a person's type of diabetes (as in Malta or Greece) or to their treatment regimen (as in Croatia, Italy, Slovenia and Spain). As for diabetes medicines, it appears that constraining criteria mainly apply to newer medications: prescribed only to certain categories of people with diabetes; as second- or third-line treatments; or prescribed only by specialists. Additionally, when budget responsibility for some or all of these diabetes products has been decentralised to regional authorities (like in Spain or Italy) or individual facilities (as is the case of insulin pumps in Croatia), these prescription criteria and/or quotas may vary according to the local resources available and/or local health priorities. These differences within each country appear to affect the prescription of medical devices in particular. However, the constraints that these guidelines represent for prescribers differ: around half of the countries in the sub-region reported that some degree of flexibility, especially when selecting diabetes medicines, is left to prescribers.

The difficult economic situation is raising concerns about the availability of diabetes supplies, including new technologies for diabetes care. In half of the countries, diabetes associations have reported that further criteria and/or quotas mainly affecting diabetes medical devices, were under discussion or had already been applied to the different types of products surveyed here, while budget constraints were placing great pressure on the evaluation of new technologies. Due to its links with the financial coverage offered by the health system on diabetes products, the availability of diabetes supplies is interlinked with affordability – availability determining affordability. The growing strain on public finances is placing both of these components of access under further pressure. The economic situation also seems to have a direct impact on the accessibility of diabetes products.

**Accessibility**

The economic situation also has a direct impact on the accessibility of diabetes products. Although this component of access may not be the most problematic in the sub-region, economic difficulties appear to be taking most of these countries further away from the objective of universal accessibility of diabetes supplies in all eight countries. The crisis affects the accessibility of diabetes products in different ways.

Firstly, the economic crisis has led to cuts in staff and resources at healthcare facilities. Access to prescribers is reported as becoming increasingly difficult in at least two countries, Greece and Portugal, where local healthcare centres outside main cities are being closed and staff reduced – leading to longer waiting times and more difficult and costly physical access to care, especially for people living outside urban areas. Difficult access to prescribers is also impacting on people's access to information and education. Although other sources of information have been developed – such as community pharmacists, associations or product manufacturers' support services; prescribers remain the principal point of diabetes information and advice in all the countries of the sub-region. Additionally, the provision of diabetes information and education to the relatives of people with diabetes appears to remain a serious challenge in all countries. Continuous diabetes education for people with diabetes and their relatives is essential to diabetes management. Not only is it associated with improved clinical outcomes but also better quality of life.6,7

Each of the 17 autonomous communities has its own criteria. There are also the criteria by the Spanish Diabetes Society. In some regions, the main impact of the economic crisis has been the restriction in the use of glucose test strips.’

A response from Spain

Due to its links with the financial coverage offered by the health system on diabetes products, the availability of diabetes supplies is interlinked with affordability – availability determining affordability. The growing strain on public finances is placing both of these components of access under further pressure. The economic situation also seems to have a direct impact on the accessibility of diabetes products.

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A response from Spain

“Healthcare centers are having growing difficulties to function as they are understaffed and under-resourced.”

A response from Greece

The difficult economic situation is raising concerns about the availability of diabetes supplies, including new technologies for diabetes care. In half of the countries, diabetes associations have reported that further criteria and/or quotas mainly affecting diabetes medical devices, were under discussion or had already been applied to the different types of products surveyed here, while budget constraints were placing great pressure on the evaluation of new technologies. Due to its links with the financial coverage offered by the health system on diabetes products, the availability of diabetes supplies is interlinked with affordability – availability determining affordability. The growing strain on public finances is placing both of these components of access under further pressure. The economic situation also seems to have a direct impact on the accessibility of diabetes products.
Similar problems are found in about a third of the countries regarding physical access to certain diabetes products and their points of dispensing. In all these countries, most diabetes supplies can be dispensed at community level – mainly through local pharmacies. However, some supplies, especially medical devices, are dispensed at healthcare facilities, alongside visits to the doctor – and thus, are also affected by the difficulties mentioned above. Additionally, quotas and budget constraints are causing delays and inequalities in local access to certain devices, such as insulin pumps. In Portugal, the national quota on pumps translates into an up to two-year waiting list. As they can only be offered and dispensed at city hospitals, this leads to inequalities between urban and rural populations. Similar discrepancies are found in Croatia, where pumps have to be financed on the individual budget of each healthcare facility, and are therefore less available outside the capital city.

Economic constraints also cause difficulties in the supply chain. Diabetes products do not appear to be affected to the same degree as healthcare professionals report for other medicines or devices. Nonetheless, some stock issues affecting diabetes supplies were reported in at least four countries of the sub-region. The causes for these problems varied from one country to another and were not always clearly identified but a number of issues were cited as potential explanations. In a supply chain described by certain stakeholders as being under increasing regulatory and financial pressure, the smaller stocks and delays across the supply chain may lead to temporary shortages at the point of dispensing. In Cyprus, such delays in delivery appear to be also related to the difficulties experienced by healthcare facilities to pay their suppliers. An interesting issue for this sub-region is parallel trade, while Portugal continues apparently to experience shortages because of parallel trade, other countries have already implemented measures to prevent that such a practice affects people's access to the supplies they need. For example, Greece has implemented compulsory reporting on parallel exports and requires certain stakeholders in the supply chain to maintain a set stock level at all times. As communications from the European Commission recalls, although restrictions on exports are generally prohibited by EU treaties, such restrictions may be justified and authorised to protect health and life. Despite the difficulties, it appears that the impact of stock shortages on people's treatment is limited. In the four countries where such supply issues were reported, alternatives could be offered within a few days. However, these difficulties appear to be more of a burden for healthcare professionals than for people with diabetes.

Although the accessibility of diabetes treatment and supplies does not represent the biggest barrier in this sub-region, the growing difficulties that people with diabetes face in this regard are making this issue a concern for the future: the difficulties above place at risk much of what has been achieved in terms of access to treatment. Moreover, while these difficulties might have a small impact individually, they have a cumulative effect when added to the constraints relating to the availability of diabetes products and those due to their costs.

Affordability

All the countries in the sub-region provide some kind of financial coverage for diabetes medicines and medical devices. However, as healthcare and healthcare funding remain national or local competences, the organisation of healthcare coverage and the coverage offered to individuals vary from one country to another. An overview of each country's coverage is available in the country profiles. However a number of trends have been identified. Please note that financial criteria have to be paired or added to those applied to each prescription. Six countries out of the eight offer insulin free of charge. The two that do not, Greece and Spain, cover most of the cost of insulin. Insulin injection devices and consumables – except insulin pumps, which follow specific criteria – are also provided for free in almost all countries of the sub-region. However, the quantity may be limited. The situation is more divided concerning oral medications. Only Italy appears to fully cover all anti-diabetes medication. The other countries may be split in two groups. Four of them have chosen...
to cover certain oral medicines fully, while other drugs have lower or no financial coverage. The other three countries opted for partial coverage of all anti-diabetes medication. The coverage for self-monitoring devices and consumables is limited throughout the sub-region. Each person’s disease status (treatment regimen, type of diabetes) is the determining factor. Although most people with diabetes have limited out-pocket expenditure for their diabetes products (see Table 2 and Annex), the coverage available in the sub-region raises two issues in terms of affordability. In the countries where some co-payments are required, any out-of-pocket expenditure may be an issue for those affected by the economic crisis, while the limited coverage offered to certain categories of people with diabetes (typically, people with type 2 diabetes and/or treated with oral medication) leads to affordability issues in these groups, and inequalities within the countries. Note that income-related waivers or benefits for spending on diabetes supplies are not available in all the countries of the sub-region. Additionally, even the above-mentioned coverage has yet to be extended to all people with diabetes, either because the overall health coverage scheme does not cover the whole population (as in Cyprus and Greece, for example) or because specific procedures need to be undertaken by people with diabetes or their healthcare providers (as in Italy and Malta).

Table 2: Expenditure on diabetes medicines and medical devices per year †

<table>
<thead>
<tr>
<th>Country</th>
<th>Annual median out-of-pocket spending on diabetes products</th>
<th>Share of Household Net Adjusted Disposable Income spent on diabetes products</th>
<th>Share of Household Net Adjusted Disposable Income for the poorest 20% spent on diabetes products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Croatia</td>
<td>USD 0</td>
<td>OECD data unavailable</td>
<td>OECD data unavailable</td>
</tr>
<tr>
<td>Cyprus</td>
<td>USD 0</td>
<td>OECD data unavailable</td>
<td>OECD data unavailable</td>
</tr>
<tr>
<td>Greece*</td>
<td>USD 0</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Italy</td>
<td>USD 0</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Portugal</td>
<td>USD 353</td>
<td>2%</td>
<td>5%</td>
</tr>
<tr>
<td>Slovenia*</td>
<td>USD 0</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Spain*</td>
<td>USD 428</td>
<td>2%</td>
<td>6%</td>
</tr>
</tbody>
</table>

* The samples of respondents in these countries included only people with type 1 diabetes or people treated with insulin. Thus, the reported annual out-of-pocket spending may not be representative.
† This information could not be obtained in Malta.

Most countries in the sub-region appear to have protected the coverage scheme for diabetes since the economic crisis began. But the financial pressure on health systems has led to the introduction of new payments or an increase of fees for some or all people with diabetes – in Italy and Spain for example. Meanwhile across half of the sub-region, national diabetes associations fear that new or further constraints will be applied on diabetes products, starting with device consumables and/or new technologies.

The pressure on public finances is making many countries in the sub-region try to reduce the costs of all medicines and medical devices. As prices of some or all diabetes products appear to be regulated by the authorities, price reductions appear to be one of the main tools used by countries of the sub-region. At least five countries have applied price cuts to some or all reimbursed products. These cuts may also impact other countries in the area as six of the eight use external reference pricing as a price-setting tool. The two countries that do not, Cyprus and Malta, apply public tenders to provide diabetes products to their public sector, which may also give them some room for price reductions. Policies to promote non-branded products over branded ones have been reported only in Italy and Spain. However, since the number of non-branded diabetes supplies available on these markets appears to be very limited, such policies are unlikely to affect strongly diabetes-related spending. Additionally, the choice of brand for some or all diabetes products is constrained by public tenders in at least four countries, while in others, prescribers appear to be the key decision-makers in this matter.

As described above, many national diabetes associations worry that, under the current economic pressure, further cost-containment measures may be applied to diabetes supplies. A number of the associations expressed concerns that the quality of supplies available to people with diabetes may be also impacted by some of these measures. While certain cost-containment measures may not have a direct impact on people’s access to

“A response from Slovenia: “Six months ago, the authorities agreed with manufacturers to lower the price of blood glucose test strips. Agreements were also made with suppliers to lower profits on these throughout the supply chain.”
diabetes products, others (such as decisions on the coverage of new products or changes in co-payments and/or criteria for eligibility) may constrain it. In such cases, the regular exchanges that the health financing institutions of some of these countries have established with representatives of people with diabetes may be a way to ensure that these measures do not build further barriers for people with diabetes.

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Note: references related to individual countries can be found on the country profiles
CENTRAL AND EASTERN EUROPE
Access to medicines and medical devices in Central and Eastern EU States

All the countries in this sub-region have established health systems and health coverage schemes (a mandatory health insurance scheme in most; a national health system in one), which provide a set of services and/or supplies to people with diabetes. Legislation and regulation regarding the authorisation and distribution of medicines and medical devices, as well as quality certification and standards, have been harmonised according to EU regulations. However, the resources that are effectively allocated to health and the share of health resources that can be drawn on by public finances vary (Table 1). Additionally, while the comparative diabetes prevalence of the majority of these countries is close to or above the European one, this ranges from 5.5% in the Czech Republic to over 9% in Poland. ¹ Each of these factors, individually or combined, determines to some extent how each country performs regarding access to diabetes medicines and devices.

<table>
<thead>
<tr>
<th>Country</th>
<th>Total health expenditure per capita</th>
<th>Public spending in total health expenditure</th>
<th>Private spending in total health expenditure</th>
<th>Proportion of total government expenditure on health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>USD 521.50</td>
<td>55.3%</td>
<td>44.7%</td>
<td>11.3%</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>USD 1,506.90</td>
<td>83.5%</td>
<td>16.5%</td>
<td>14.2%</td>
</tr>
<tr>
<td>Estonia</td>
<td>USD 986.90</td>
<td>78.9%</td>
<td>21.1%</td>
<td>12.3%</td>
</tr>
<tr>
<td>Hungary</td>
<td>USD 1,084.80</td>
<td>64.8%</td>
<td>35.2%</td>
<td>10.2%</td>
</tr>
<tr>
<td>Latvia</td>
<td>USD 840.90</td>
<td>58.5%</td>
<td>41.5%</td>
<td>9.3%</td>
</tr>
<tr>
<td>Lithuania</td>
<td>USD 875.38</td>
<td>71.3%</td>
<td>28.7%</td>
<td>12.6%</td>
</tr>
<tr>
<td>Poland</td>
<td>USD 898.98</td>
<td>71.2%</td>
<td>28.8%</td>
<td>11.0%</td>
</tr>
<tr>
<td>Romania</td>
<td>USD 499.70</td>
<td>80.2%</td>
<td>19.8%</td>
<td>11.9%</td>
</tr>
<tr>
<td>Slovakia</td>
<td>USD 1,533.83</td>
<td>63.8%</td>
<td>36.2%</td>
<td>14.5%</td>
</tr>
</tbody>
</table>

Table 1: Key health expenditure figures (2011)²

Graph 1: Diabetes comparative prevalence (2011)¹
Availability

All of the products surveyed were reported as being authorised for sale and present in every country in the sub-region. Under EU laws, diabetes medicines are authorised via a central procedure,\(^3,4\) while harmonised procedures are in place for the authorisation of medical devices.\(^5\) Information from the industry reflects the concerns it has over the lengthy and uncertain pricing and reimbursement procedures in place in most of these countries.\(^4,6\) However, this does not seem to prevent product launches, as has been reported in other sub-regions of the EU. Nevertheless, delays in such procedures impact on people's access to the newest products in other ways (see Affordability).

“The prescription of newer medications, including insulin analogues, is subject to a person giving evidence of necessity, or a person’s adherence to treatment.”

A response from Bulgaria

The decision to have some of the costs of certain diabetes products covered by health systems has an impact on their actual availability to people with diabetes. Indeed, coverage and prescription criteria appear to be closely associated with one another in all these countries. For example, in the Czech Republic, Hungary, Latvia and Lithuania, the institution responsible for healthcare financing is directly involved in the definition of prescription recommendations, which either function as a complement to clinical guidelines or are directly integrated into them. In the other countries in the sub-region, coverage also appears to strongly constrain prescribing. This close association between prescription guidelines and coverage supplies’ costs by health systems demonstrates that across this sub-region, care and treatment guidelines are also designed as a cost-containment tool. The details of each country’s specific criteria can be found in the country profiles. Whichever these differences, the following trends have been identified. Most countries in the sub-region have prescription criteria for medicines, which affect treatment regimens for the different types of diabetes and/or define the different lines of treatment (the order in which medication should be prescribed), principally for new medications. Criteria may also affect prescribing itself, as in Hungary, where most of the newest medications have to be prescribed by specialists; or in Romania, where the prescription of certain products and prescriptions for certain categories of people with diabetes have to be reviewed and approved by a particular institution. Additionally, in Hungary and Bulgaria, the prescription of certain medicines and/or devices, such as insulin pumps, depends on a person’s ability to follow treatment recommendations and their achieving treatment targets. Insulin pumps appear to be subject to specific prescription criteria in at least two-thirds of the countries. These criteria limit primarily the prescription of pumps to specific categories of people with diabetes: people with type 1 diabetes, children, or pregnant women for instance.

The range of types of diabetes products on the market appear to be quite comprehensive in this sub-region. However, the actual availability of supplies to people with diabetes appears to be under tight control, mainly because of budget concerns. As a result, availability is closely related to affordability. And while the availability of diabetes products to people with diabetes appears constrained, their accessibility may even be more problematic.

Accessibility

Reaching an appropriate prescriber, the first step toward obtaining diabetes medicines and devices, is an issue that most countries in the sub-region have resolved. However, this remains an obstacle in some cases – mainly people whose treatment depends on specialists. In Latvia, Hungary and Lithuania, the number of specialists, either locally or at the national level, appears to be insufficient to respond to the needs of the diabetes population. In order to address this, Latvia and Hungary have been transferring diabetes care for some people to GPs; while in Lithuania, where waiting times can be long in the major cities, mechanisms are in place to prevent people from running out of the supplies they need – they may be allowed on an exceptional basis to visit another doctor or clinic than the one they are registered with for example. In Bulgaria and Romania, this difficulty arises from the unequal distribution...
of specialists across the country. Because specialists are apparently located mainly in major cities, it remains difficult for people living in rural areas to access them. To a lesser extent, this rural/urban imbalance also appears to affect access to points of dispensing in these two countries. Access to points of dispensing was not reported as a problem in other countries in the sub-region.

“Training and education about their treatment is not systematic yet for people with diabetes. So far, it is carried out during consultations or at association meetings. But it has no dedicated, publicly funded time.”

A response from Slovakia

have received some information about their treatment, improvements are still required in order to ensure universal access to diabetes education. The provision of diabetes education to relatives of people with diabetes would appear to require much improvement; in most of the countries, relatives are usually much less likely to receive any information than people with diabetes. Continuous diabetes education for people with diabetes and their relatives is an essential component of diabetes management, which is associated with improved clinical outcomes but also better quality of life.7,8

Accessibility of diabetes supplies in the sub-region appears also to be affected by disruptions in supply. Occasional retail out-of-stocks have been reported in most of the countries. However, the products affected by these disruptions, and their cause, appear to be country-specific. For example, in Bulgaria and Hungary, shortages appear to have affected specific brands of insulin, which were apparently supplied in insufficient quantities compared to countries’ needs. Shortages reported in Romania were related to delayed payments from the insurance fund, preventing pharmacies from being able to pay their suppliers on time. Another issue in Romania appears to relate to national quotas on insulin pumps. On the top of somewhat restrictive eligibility criteria, the yearly quota on pumps is insufficient to provide all those eligible with a pump. Poland was the only country of the sub-region where shortages due to parallel exports were reported. These supply issues seem to have had limited impact on people with diabetes, as in most cases they were able to find alternative solutions with the help of their healthcare providers or their local diabetes association. However, their impact on healthcare professionals’ practice may be different.

Overall, most people with diabetes, helped by their healthcare providers and/or their diabetes associations, are apparently able to find alternatives to mitigate the impact of these different issues on their diabetes treatment. However, such ad hoc solutions do not address the cause or causes of these problems, which may require deeper organisational changes in diabetes care and the supply chain. Moreover, while these obstacles are occasional, they represent further hurdles in an already complicated path to diabetes medicines and devices.

Affordability

As the tight control over prescribing suggests, public budgets for diabetes supplies are under close scrutiny. Although all of the countries offer some coverage for the costs of diabetes supplies, the share of the costs covered varies a great deal. In the majority of the countries in this sub-region, people with diabetes have to pay a share of their treatment out-of-pocket. As a result, difficulties in access due to affordability issues were reported in at least five of the countries. An overview of each country’s coverage is available in the country profiles. While disparities exist, a number of trends have been identified. All of the countries except Poland offer human insulin free of charge; insulin analogues are often covered under specific criteria only, or under lower rates. Large differences seem to exist in the coverage of anti-diabetes medications. All countries offer some coverage for at least some of these medications; but only four countries reportedly provide all of them free of charge. The other seem to have different coverage rates for the different types of medicine, with lower or

“Variations in coverage for insulin analogues and insulin pumps exist between age groups, types of diabetes, and according to HbA1c levels. The system is very complicated.”

A response from Hungary

"Usually, there are problems with test strips, often because of delayed settlement by insurance funds. So pharmacies cannot pay their bills on time and suppliers no longer deliver strips!" 

A response from Romania
no coverage being applied to newer, more expensive medicines. Coverage provided by health systems appears to be even more circumscribed for medical devices. Most countries either ration the quantities they cover, or apply different levels of coverage to different groups – with children and young people often enjoying the best coverage. Injection devices like pens and syringes are partially or fully covered in seven countries while in the two remaining countries – Latvia and Lithuania – some supplies are obtainable free of charge via donations from the industry. Neither Bulgaria nor Latvia offers any coverage for insulin pumps and consumables, while other countries cover insulin pump therapy primarily for children. As for self-monitoring devices, all countries in the sub-region offer apparently some coverage for blood glucose-testing devices. However, four of them do not offer any coverage for ketone test strips. Additionally, all countries in the sub-region limit the quantity of consumables covered depending on recipients’ characteristics – age, treatment regimen or pregnancy, for instance. Hungary, Bulgaria and Romania cover blood glucose-monitoring devices only for people on insulin. It should also be born in mind that these different coverage criteria are additional to the prescription criteria mentioned above.

Out-of-pocket payments may arise due to various factors. As mentioned above, the majority of countries in the sub-region require most people with diabetes either to participate to the cost of their treatment through co-payments, or to complement the quantity of consumables and medical devices covered by the system. Additionally, Poland, Romania, Lithuania and Latvia base their coverage rates on a reference pricing, so the need for out-of-pocket payments may result from differences between the reference price and the actual price. Furthermore, Hungary, Latvia and Estonia apply prescription or dispensing fees to some or all diabetes supplies.

However, the majority of these countries also have mechanisms in place for some or all people to avoid high out-of-pocket spending on healthcare. Czech Republic and Estonia have expenditure ceilings. Hungary, Poland, Slovakia and Latvia offer either fee exemptions or subsidies for people under a certain income level. The institutions in charge of setting coverage rates for medicines and devices in Lithuania and Slovakia usually ensure that at least one line of treatment for diabetes is available at no cost to people with this condition.

Despite these measures, affordability issues were identified as a barrier to access to diabetes supplies in least four countries: Bulgaria, Lithuania, Poland and Romania. In Estonia, affordability seems to be a problem for many people with chronic conditions. Additionally, due to the disparities in health systems’ coverage in these countries, significant differences between people were found in terms of the financial burden due to diabetes.

As well as control over prescribing and limited reimbursement, all countries of the sub-region have implemented further measures to reduce the cost of diabetes products to the health system. Most of them appear to have policies in place to encourage the use of non-branded, low-priced products either through differentiated coverage of their prices or via a policy of

### Table 2: Expenditure on diabetes medicines and medical devices per year

<table>
<thead>
<tr>
<th></th>
<th>Annual median out-of-pocket spending on diabetes products</th>
<th>Share of Household Net Adjusted Disposable Income spent on diabetes products</th>
<th>Share of Household Net Adjusted Disposable Income for the poorest 20% spent on diabetes products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bulgaria</td>
<td>USD 1,590</td>
<td>OECD data unavailable</td>
<td>OECD data unavailable</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>USD 0</td>
<td>0.0%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Hungary*</td>
<td>USD 533</td>
<td>3.8%</td>
<td>8.5%</td>
</tr>
<tr>
<td>Latvia</td>
<td>USD 208</td>
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<td>USD 259</td>
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<tr>
<td>Poland</td>
<td>USD 560</td>
<td>3.6%</td>
<td>9.1%</td>
</tr>
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<td>Romania*</td>
<td>USD 538</td>
<td>OECD data unavailable</td>
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</tr>
<tr>
<td>Slovakia*</td>
<td>USD 273</td>
<td>1.6%</td>
<td>3.6%</td>
</tr>
</tbody>
</table>

* The samples of respondents in these countries were mainly people with type 1 diabetes or people living in urban areas. Thus the annual out-of-pocket expenditure that was reported may not be representative.

† This information could not be obtained in Estonia.
substituting more expensive for cheaper products. However, the impact of such policies may be limited. Although a small number of non-branded products appear to be available in all these countries, the evidence suggests that the healthcare provider's advice is the determining factor in people's choice of brand. To be certain as to whether people with diabetes are actually informed of and offered cheaper alternatives will require further research.

All of the countries regulate the prices of diabetes supplies. However, significant price differences were reported at the retail level (see Annex). The cause or causes of such price differences could not be assessed. Given that all the countries appear to use external reference pricing in determining some prices, regulation of the different elements down the supply chain may play a role. This hypothesis would require further research to be confirmed.

As in the rest of Europe, pressure on public finances is forcing many of these countries to review their pricing and reimbursement policies. However, the impact this may have on people with diabetes varies. For example, while the different reforms rolled out in the Czech Republic do not appear to have affected people with diabetes, those implemented in Poland have been raising concerns. Changes in diabetes supplies' coverage by the health system in Poland have even led to shortages locally, as people began stock-piling supplies before the reduced levels of coverage were implemented. Concerns over the impact of reforms solely driven by budgetary interests have been expressed in Hungary, Latvia, Romania and Lithuania. These concerns are even stronger in countries where diabetes-representative associations have not been included in discussions. Associations fear that the impact of new policies on people with diabetes may not be adequately taken into account.

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9 EURADIA, FEND, IDF, & PCDE, 2011

Note: references related to individual countries can be found on the country profiles
SOUTH-EAST EUROPE
Access to medicines and medical devices in South-East Mediterranean States

This sub-region shows great variety. The resources available and invested in health, including those made available for diabetes care, differ greatly from one country to another (see Table 1). Additionally, while all of these countries have chosen to establish a mandatory health insurance scheme to cover health services and treatment, the scope of these schemes and the degree to which they are established vary. The burden represented by diabetes in each country also differs (see Graph 1). With such diversity across this sub-region, careful consideration is needed when assessing each country’s achievements regarding access to diabetes medicines and devices.

Table 1: Key health expenditure figures (2011)²

<table>
<thead>
<tr>
<th></th>
<th>Total health expenditure per capita</th>
<th>Public spending in total health expenditure</th>
<th>Private spending in total health expenditure</th>
<th>Proportion of total government expenditure on health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albania</td>
<td>USD 254.60</td>
<td>44.8%</td>
<td>55.2%</td>
<td>9.8%</td>
</tr>
<tr>
<td>Turkey</td>
<td>USD 696.23</td>
<td>74.9%</td>
<td>25.1%</td>
<td>12.8%</td>
</tr>
<tr>
<td>Israel</td>
<td>USD 2,426.10</td>
<td>61.5%</td>
<td>35.2%</td>
<td>10.7%</td>
</tr>
<tr>
<td>TFYR Macedonia</td>
<td>USD 333.77</td>
<td>61.4%</td>
<td>38.6%</td>
<td>11.7%</td>
</tr>
<tr>
<td>Serbia</td>
<td>USD 622.05</td>
<td>62.2%</td>
<td>37.9%</td>
<td>14.1%</td>
</tr>
<tr>
<td>Albania</td>
<td>USD 233.40</td>
<td>66.3%</td>
<td>33.7%</td>
<td>13.3%</td>
</tr>
</tbody>
</table>

Graph 1: Diabetes comparative prevalence (2011)¹

Availability

A key disparity across the sub-region was found in the presence of diabetes products on each national market. All of these countries have agreements with some neighbouring states, and especially with the EU,³⁴ which facilitate mutual market access to certain products. However, country-specific applications or procedures have to be carried out in each country for a diabetes product to be authorised and marketed there. All the products surveyed have been reported as being authorised for sale and present on the market in Turkey, Serbia and Israel. However, the presence of some of the newer oral medications, including DPP4-inhibitors, was unclear in TFYR Macedonia, and pumps and some medications to treat hypoglycaemia are not on the market in Albania. Consequently, in these two countries the range of available diabetes supplies is more limited than in the rest of the sub-region.

* Israel is geographically located in this sub-region and shares common features with the other countries in this group regarding its interaction and integration with other European sub-regional organisations. However, it is an outlier in this group in terms of the resources available for and invested in health, as well as the degree of implementation of its health system and coverage scheme.
Moreover, the range of products that are actually available to people with diabetes is further conditioned by criteria for prescribing; all the countries have guidelines on diabetes treatment and apply specific prescription criteria to some or all diabetes products. These norms may circumscribe the prescription of a number of diabetes products to specific healthcare professionals, healthcare settings, or certain categories of people with diabetes. Or they may define the different lines of treatment. Significant differences exist between countries as to which products are subject to such criteria. Nevertheless newer medicines such as insulin analogues and/or new oral medications appear to often follow such provisions – a reminder of the cost-containment role played by some of these stipulations. Further requirements from the health insurance system may also influence prescribing. For example, in Serbia, the quantity of insulin prescribed by each physician is closely monitored, and limited, by the health insurance fund. In Turkey, a specific certificate describing the health status and treatment regimen of each person with diabetes is required every two years for prescribers to be permitted to issue prescriptions and for people with diabetes to receive free or partially covered diabetes supplies. However, the impact of these various requirements on prescribing differs. The information collected in Israel, for instance, indicates that while some criteria apply to the prescription of some medical devices, certain flexibility is given to each prescriber regarding medicines; guidelines play a merely advisory role. Meanwhile, in Albania, issues have been reported around the implementation of guidelines, suggesting that the key elements constraining prescription are out-of-pocket spending and health insurance coverage.

The diversity described in the first paragraph is also reflected in the availability of the different diabetes products. While in Israel, the market appears to include a wide range of diabetes products and prescribers are allowed a degree of freedom to personalise treatment regimens, the range of products available to treat diabetes in some other countries of the sub-region, such as Albania, appears to be under much stronger constraints. Financial issues, as well as the interrelations between prescription criteria and coverage provided by the health insurance schemes, also have an impact on the affordability of diabetes supplies (see Affordability). Moreover, while the range of products effectively available differs from one country to another, ensuring uninterrupted universal accessibility remains a challenge in most of the countries.

**Accessibility**

Difficulties relating to accessibility vary widely across the sub-region in terms of their magnitude, frequency, and above all, their impact on people with diabetes.

The first step in the path to obtain medicines and medical devices is to reach an appropriate prescriber and, subsequently, point of dispensing. This does not appear to be an obstacle for the majority of people with diabetes living in this sub-region. However, it remains apparently problematic for some categories of people with diabetes in each of the countries – in most cases, people living in rural settings or remote areas. Improvements in this field have been reported in all countries of the sub-region though. These difficulties may be also occasional - in Albania, for instance, the distance to a prescriber or dispensing point appears to become problematic when people encounter difficulties relating to their treatment – also because of the lack of flexibility in treatment regimen. Ad hoc voluntary-sector support may be available locally to help to overcome these difficulties.

Access to education and information about treatment appears to be a much bigger issue in all countries of the sub-region but Israel. In Albania, TFYR Macedonia and Turkey, diabetes education and information about treatment have yet to be made universal because people living in certain areas or receiving care outside specialised care settings appear not to be offered such services. In Serbia, this issue is set to become a concern in the future: resources for education have been withdrawn. Access to continuous
education may also be affected by the difficulties mentioned above regarding physical access to prescribers, who are reportedly the principal source of diabetes information and advice throughout the sub-region. The key role of continuous diabetes education for people with diabetes and their relatives in diabetes management should not be overlooked: it is associated with improved clinical outcomes as well as better quality of life.5,6

“I do not recall cases of shortages because all institutions hold an adequate reserve. If there is a short-term problem with the supply chain, it never affects the person with diabetes.”

A response from Israel

Continuity in the supply of diabetes supplies has yet to be secured. Occasional or recurring stock issues at dispensing points and healthcare facilities have been reported in almost all of these countries. Delays along the supply chain and at the national level were the most commonly reported reasons for stock issues. While these may affect healthcare professionals’ practice, the impact they have on people with diabetes appears in many cases to be limited: healthcare facilities or people themselves were able to find alternatives – from other suppliers or diabetes associations for instance. Disruptions in treatment have been reported only in Serbia and Albania, particularly among certain categories of people with diabetes. In Albania, difficulties accessing dispensing points have resulted in disruptions, as some people have not been able to replenish stocks as quickly as necessary. In Serbia, occasional shortages of insulin among people with diabetes result from rationing by the health insurers (see Availability).

While these difficulties might not create recurring barriers to treatment for most people with diabetes, they do represent additional obstacles for some in an already constrained environment, and may jeopardise the continuity of treatment – a key element in the management of a chronic disease like diabetes.

Affordability

Affordability was reported as the greatest challenge to access to diabetes supplies throughout the sub-region.

Each of the countries defines the package of diabetes supplies covered by its health insurance scheme or national diabetes programme (see country profiles). However, a number of trends have been identified. Apart from Israel, all the countries offer at least one type of insulin and an injection device free of charge; Israel’s health funds cover most of the cost for both. The situation is slightly different with regard to anti-diabetes medications. In Israel, all types of oral medications appear to be partially covered. In Turkey, these are fully covered but constrained by product-specific prescription criteria and procedures. In Albania, TFYR Macedonia and Serbia, the health insurance scheme or national diabetes programme provide full or partial cover to only a limited list of molecules and the newer, more expensive diabetes medicines are usually excluded from it. Most of the countries provide selective coverage for self-monitoring devices and insulin pumps. This varies according to type of diabetes, treatment regimen, complications, pregnancy, or age – with children and young people usually enjoying the most generous coverage. Most countries also limit the quantity of consumables covered for each category of people. Only Albania offers no coverage at all for self-monitoring devices (pumps are not available). These different criteria for coverage are usually additional to the prescription criteria described above (see Availability).

Most people with diabetes living in Israel, Albania and Serbia have to pay a share of their diabetes treatment out-of-pocket via co-payments, prescription fees and/or in order to complement the quantity of consumables covered by the health insurance scheme. The occasional shortages mentioned above (see Accessibility) can also result in occasional out-of-pocket expenditure, as people may be forced to source their diabetes products from a supplier that is not covered by the health insurance system. An estimate of annual out-of-pocket spending on diabetes products can be found in the country profiles and Annex. Variations between different categories of people with diabetes living in the same country have also been reported in Serbia.

“Until the new health insurance system was in place, associations used to run programmes to provide insulin and supplies to those who weren’t covered. As the new system is supposed to cover everyone, many of these programmes have stopped. However, the implementation of this reform needs to be improved because some people aren’t registered in the health system and thus, are de facto not covered by the national insurance scheme.”

A response from Turkey
Turkey and Israel. These differences may be due to the various degrees of coverage provided for each category of people with diabetes, and may also result from gaps in the health insurance scheme: in Turkey, for instance, the health insurance scheme formally provides prescribed diabetes products free of charge. However, uneven implementation of the scheme can result in a lack of coverage for some people. Most countries in the sub-region have mechanisms in place that protect some or all people affected by chronic disease from high out-of-pocket expenditure on healthcare. These mechanisms include additional benefits or subsidies for certain categories of people, such as disability benefits for people with complications in Albania or free diabetes supplies for children in Turkey; or control on certain healthcare-related expenses, such as a quarterly ceiling on pharmaceutical expenses in Israel. However, in most countries in the sub-region, these mechanisms have yet to be extended to all people encountering affordability issues.

Yet all the countries have mechanisms in place that limit the cost of diabetes to the health system. As mentioned above, stipulations for prescribing have a cost-containment function. Additionally, most countries regulate the price of at least some diabetes products (see also Annex): international reference pricing for instance appears to be used in at least three countries; and the regulation of mark-ups throughout the supply chain is implemented in most countries of the sub-region. Turkey and TFYR Macedonia have also designed their coverage schemes to promote lower-priced brands in certain categories of diabetes products. However, such mechanisms first require multiple brands to be available for each type of product, which is apparently not the case throughout the sub-region. Moreover, concerns were raised in Turkey about the selection process of the product chosen as a reference, and the guarantees this process provides to people with diabetes.

Although affordability appears to remain the main barrier to access to diabetes products, most countries in the sub-region have established, or are developing, mechanisms to mitigate the impact of this barrier on some or all population groups. Thus, this context of on-going reform of health systems should be born in mind when assessing each country’s current performance. In at least four of the countries, diabetes associations have taken part in the development of formal or informal mechanisms to identify these different issues and raise them before health institutions.

References
1 Global health observatory data repository, 2013
2 IDF, 2011
3 “Regulatory policy of the single market: international aspects”, 2013
4 Trade Policy: Countries and regions/Western Balkans, 2013
6 Dawes, S., Ellis-Gowland, J., Wallymahmed, M., 2013

Note: references related to individual countries can be found on the country profiles
EASTERN EUROPE
Access to medicines and medical devices in the Commonwealth of Independent States

Although all the countries inherited the same type of health system from the Soviet era, the capital and resources for health available to each of them at independence differed greatly from one country to another – as did the constraints on their health systems. Additionally, the impact of diabetes on the health systems varies widely, as this sub-region shows some of the highest and lowest diabetes prevalence rates in the European Region. In this context, careful consideration is needed when assessing each country’s achievements regarding access to diabetes medicines and devices.

Table 1: Key health expenditure figures (2011)

<table>
<thead>
<tr>
<th>Country</th>
<th>Total health expenditure per capita</th>
<th>Public spending in total health expenditure</th>
<th>Private spending in total health expenditure</th>
<th>Proportion of total government expenditure on health</th>
</tr>
</thead>
<tbody>
<tr>
<td>Armenia</td>
<td>USD 141.50</td>
<td>35.8%</td>
<td>64.2%</td>
<td>5.8%</td>
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<td>Azerbaijan</td>
<td>USD 356.90</td>
<td>21.5%</td>
<td>78.5%</td>
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<td>Belarus</td>
<td>USD 307.10</td>
<td>70.7%</td>
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<td>Georgia</td>
<td>USD 328.30</td>
<td>22.1%</td>
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<td>Kazakhstan</td>
<td>USD 454.90</td>
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<td>Kyrgyzstan</td>
<td>USD 71.30</td>
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<td>Moldova</td>
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<td>Russian Federation</td>
<td>USD 806.70</td>
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<td>Ukraine</td>
<td>USD 263.00</td>
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<td>Uzbekistan</td>
<td>USD 88.40</td>
<td>51.4%</td>
<td>48.6%</td>
<td>8.5%</td>
</tr>
</tbody>
</table>

Graph 1: Diabetes comparative prevalence (2011)

Additionally, the impact of diabetes on the health systems varies widely, as this sub-region shows some of the highest and lowest diabetes prevalence rates in the European Region. In this context, careful consideration is needed when assessing each country’s achievements regarding access to diabetes medicines and devices.

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* Although nine of these countries belong to the same regional organisation (Commonwealth of Independent States), this has no authority for health matters, which remain the responsibility of each individual country.

* Although Georgia is no longer part of this regional group, it shares a common heritage and other health characteristics – thus, it was included in this sub-regional group.
Availability

Registration and marketing have been identified as a primary obstacle to access. In Kyrgyzstan and Uzbekistan, some of the surveyed products were not registered (and as such, they could not be marketed), or their current status could not be determined. In Georgia, some occasional disruptions due to registration renewal were also reported, while in Moldova and Armenia the actual presence on the market of certain products could not be confirmed. Lengthy and complex registration procedures may play a role in the delay of a product launch or its introduction in certain national markets. However, other factors appear to play a role. Indeed, this difficulty seems to be shared by other, better-supplied countries in the sub-region, such as Kazakhstan. Given the low manufacturing capacities in the affected countries, and their subsequent dependency on foreign manufacturers, the size and attractiveness of the national market may suggest a different reason for these availability issues.

Other factors, such as prescription guidelines and, above all, selection for public supply, appear to further constrain the range of products available to people with diabetes. Nine out of the 10 countries in this sub-region report having such guidelines for diabetes treatment, while the other, Armenia, is reported to be developing guidelines. Guidelines may impact on access to diabetes products in various ways. In terms of prescribing, they can, for example, earmark certain products for a certain category of people with diabetes and/or only authorise certain healthcare professionals to prescribe them. In Azerbaijan, Russia and Ukraine, insulin analogues must be prescribed primarily to children and, in two of these countries, to pregnant women, while Georgia specifies that insulin analogues should be prescribed as a second-line treatment. The same type of specifications exists in Moldova for insulin pumps, which should be prescribed mainly to children. As for prescribers, at least three countries – Georgia, Belarus and Uzbekistan – report that only specialist doctors can prescribe certain diabetes medicines, mainly insulin.

However, the manner in which these directives and guidelines are implemented varies across the sub-region. We can assume that the actual constraints they represent also differ.

Regarding public supply, it appears that most of the supplies prescribed are provided publicly. As such, the choices available to prescribers and people with diabetes are influenced, if not constrained, by procurement decisions made by the authorities. In countries where most of the medical supply and distribution chain has been privatised, the supply of diabetes products stands out: in most of these countries, at least some supplies remain publicly procured and/or provided. Public supply is based either on national lists of essential medicines and/or on the list of products covered by national programmes, where these exist. Therefore, the range of publicly supplied products differs widely across the region: from only a handful of pharmaceutical products to larger packages, including medicines and devices, with multiple types of product per category. The supply of at least one type of insulin appears to be secure, as it is procured principally via public tenders, and in most countries of the region, publicly supplied. There are greater disparities between countries in the case of oral medication and medical devices. Insulin, and in some countries, injecting devices, usually depend on national budget and state provision. But responsibility for public provision of oral medication and other supplies, where these are publicly provided, has been decentralised to regional authorities or individual healthcare facilities in at least five countries. In such cases, publicly supplied products, which are the most widely used, may vary within the country and cause local inequalities in access.

Publicly supplied products are fully or partially paid for by the government or mandatory health insurance. Hence, the question of public supply is not only closely associated with affordability (see Affordability) but also the financial capacity and sustainability of health systems; and as shown in Table 1, national resources for health vary widely across this sub-region. Public supply also may be an economic and a protectionist issue; it has been suggested that the domestic preference applied in Ukrainian and Belarusian public tenders are intended to support the development of the national pharmaceutical and medical industries.
Access to diabetes medicines and devices is thus constrained at the national level by those three factors: registration and marketing, national guidelines and selection in public supply. Each of them contributes to the limited range of products from which healthcare professionals and people with diabetes are able to choose. However, the barriers to access in this sub-region appear to be even greater regarding the accessibility and affordability of diabetes products.

**Accessibility**

For people with diabetes, the first step along the path toward access to the medicines and medical devices they need is to obtain a prescription. Access to an appropriate prescriber is crucial. All countries in the sub-region report progress in this field. However, in a region where diabetes care primarily remains in the hands of specialist doctors, people living in six of the countries – Armenia, Belarus, Georgia, Kazakhstan, Moldova, Russia – still face a challenging situation. Most of them face overall shortages in qualified healthcare personnel trained in diabetes care, and the unequal distribution of such professionals across the country was an issue in Armenia, Georgia, Kazakhstan and Russia. Available human resources are also stretched by limitations applied to prescribing, which usually require people to visit their doctor once a month to renew their prescription, regardless of their health status. Moreover, those doctors often are the main points of diabetes advice and information. Therefore, difficulties accessing a prescribing doctor also impacts on people's knowledge about their treatment and how to use prescribed products – an essential component of diabetes self-management. Various initiatives have been implemented to tackle these difficulties. Offering diabetes care at the primary care level, in line with WHO recommendations, seems to be the main one: mobile endocrinology clinics in Russia; specialised consultations in local health centres in Uzbekistan; training in diabetes care for family doctors in Kazakhstan. Allowing doctors to prescribe for several months at a time, as it is the case in Belarus, may also contribute to a reduction in the burden on healthcare professionals.

In most of the countries, some medicines or devices may be provided at consultations or at the healthcare centre. Nevertheless, most people still have to visit a pharmacy for some or all of their diabetes supplies. Compared with access to a prescriber, access to a pharmacy seems to be less of an issue. However, even this may be a challenge in certain rural or remote areas of Georgia, Kyrgyzstan and Moldova. Also, access to a product is dependent on it being in stock at the time of the visit.

The supply of insulin in particular, as well as diabetes products in general, is said to have improved in all countries in the sub-region. A number of countries, including Russia and Kazakhstan, are undertaking initiatives to develop and strengthen their supply chain further. However, most countries still report recurring shortages of inadequate supply. At least six out of the 10 countries report shortages while all the others mention strong constraints on the supply of diabetes medicines and devices. Dispensing units appear to be undersupplied in five countries, either because of inadequate forecasting of needs (for example, in Armenia and Azerbaijan) or due to insufficient funding (in Ukraine, and Azerbaijan). Delays either at the procurement level or down the supply chain may also be possible causes for the shortages faced in Azerbaijan, Kazakhstan, Moldova and Ukraine. Concerns were also expressed about the capacity of some national supply chains to ensure and preserve the quality of diabetes products. In the countries where shortages do not seem to be a major challenge, people with diabetes face other difficulties. Firstly, even if the different categories of products are present at all times at the point of dispensation, the types and brands of product in each category are not constant. Thus, healthcare professionals are said to adapt some patient regimens to the types or brands available. This was reported in Armenia, Kyrgyzstan and Uzbekistan. Moreover, as almost all of these countries rely to some extent on public procurement for diabetes products, supply depends on yearly public tenders, a system that does not take into account the

"Every year, all healthcare facilities estimate the type and quantity of diabetes medicines they will need in the coming year and send these estimates to the Government for procurement. But the estimations aren't correct; they don't take into account people who will be diagnosed during that year. As a result, supplies run short."

A response from Azerbaijan
difficulties arising from *substituting* one medication or device for another. As a result, the brands and sometime types of publicly provided supplies may change from one year to another. Generally speaking, public tendering for diabetes supplies raises quite a few questions: many stakeholders expressed their concerns over the fact that tenders may give priority to budgetary considerations over other factors – such as quality.

The extent to which these difficulties affect both public and private supply could not be assessed systematically. However, it would appear that reported difficulties were mostly relating to products that are supposed to be provided publicly. Even if alternative sources of supply may be available in the private sector, in most of these countries the cost of privately purchased products is covered entirely by people with diabetes (see Affordability). Additionally, although a black market for diabetes products is reported not to be a major issue in this region, recurring shortages associated with poor capacity of regulatory authorities to control the market put people at risk of being forced to seek illicit supplies in a number of countries.

Due to their chronic condition, people with diabetes need a reliable and uninterrupted supply of medicines and medical devices. Yet shortages appear to be among the main barriers to access to diabetes products in a number of countries in the sub-region. Many people with diabetes who face these difficulties remain without a new supply of at least some of the products they needed for days or weeks. Besides adherence issues, which could not be studied in this publication, recurring interruptions or changes in treatment are likely to make it more difficult for people with diabetes to keep their condition under control, thus increasing the risk of potentially life-threatening complications. Such consequences are sometimes not fully taken into account by decision-makers when formulating health policies, specifically for diabetes. Disrupted supply in the public sector is also synonymous with further expenditure for people with diabetes.

**Affordability**

The affordability of healthcare is a serious issue across the sub-region and diabetes treatment is no exception. Affordability appears to be among the principal barriers to access in at least seven countries. Limited coverage by health systems, gaps between eligibility and the products that are actually delivered, and high prices all seem to contribute to this problem at various levels.

“Financial problems are a major barrier: everything, or almost everything, is paid out of people’s pocket.”

A response from Georgia

First of all, the list of medicines and devices that receive some public coverage varies a great deal from one country to another. An overview of national coverage for the surveyed products can be found on each country profile. However, some common features have been identified. At least one type of human insulin is provided free of charge in all the countries in this sub-region, while insulin analogues – where they are covered – are usually only provided free of charge to certain categories of people. Regarding oral medications, the majority of countries appear to offer some coverage for a few types of medicine. However, the range of oral medicines covered varies between countries and in at least four, coverage differs within countries, as these aspects are the responsibility of regional authorities.

In general, medical devices seem to have lower coverage: fewer countries offer financial support for devices and those that do usually cover specific groups of people only and/or a limited number of consumables per year. Significant differences in coverage exist between devices. For example, insulin pumps are reportedly covered in only a couple of countries, mainly for children. Insulin pens benefit from some kind of coverage for children at least in seven countries. Overall, children and, in some countries, pregnant women, tend to receive more comprehensive coverage. Belarus and Uzbekistan have also implemented measures to provide further financial support to people with low incomes and/or people registered as disabled. In some areas, support or additional free supplies may be available from diabetes associations and/or international aid programmes, but not at the national level. Nevertheless, it should be kept in mind that in all the countries in this sub-region, people with diabetes are, due to their condition, one of the few categories of people that can benefit from some kind of support from the public health system for outpatient medicines and devices.

A share of the cost of diabetes supplies would appear to remain the responsibility of people with diabetes, especially adults, in all these
Out-of-pocket spending on diabetes medicines and devices may supplement shortfalls in coverage by the health system, paying for supplies that are not covered and out of the necessity to overcome supply issues in the public sector. The elements described above are based on the apparent entitlement of people with diabetes in the sub-region under current legislation. However, gaps remain between legal entitlement and reality. As described in the previous section (Accessibility), inadequate or under-supply remains a pressing issue in most countries. It appears that in at least five of the countries, the list of products effectively dispensed free of charge to people with diabetes locally may be far shorter than any legal entitlement would suggest. Rationing of free supplies to cope with demand was reported Uzbekistan and Azerbaijan. For people with diabetes, such scarcity of medicines presents an unenviable choice of either interrupting treatment for a while, or paying for products out of the household budget, which can constitute significant burden.

The price of diabetes medicines and devices varies across a range of products and also between countries (see Annex). Additionally, some price variations are likely to exist within countries. Based on the literature, the prices of diabetes supplies in Armenia, Kazakhstan and Moldova are considered high compared to those in neighbouring countries and/or international references. Importantly, unlike most of their Western European counterparts, only a few countries in this sub-region regulate the prices of medical products. Based on available evidence, only four countries (Belarus, Russia, Ukraine and Uzbekistan) currently apply some kind of price regulation on medicines (either on prices themselves or on some of their components, such as distributors’ mark-ups). Armenia and Azerbaijan have announced the forthcoming application of similar regulations. Current price regulations do not apply equally to all medicines or across all sectors. For example, in Belarus strict price control only applies to the public sector, while only mark-ups are limited in the private sector. In Russia and Uzbekistan, price regulations apply only to the medicines included in the national list of essential medicines. As for medical devices, it was not possible to determine whether their price was regulated in any way. Additionally, while non-branded diabetes products seem to be available throughout most of the sub-region, it appears that only Belarus applies a clear policy to promote their use.

The contribution of each of these factors to the overall affordability issue could not be determined precisely and is likely to vary across the sub-region. However, it seems that they all add to the financial burden of diabetes on those affected. It should also be remembered that the costs cited above represent only a portion of the actual costs of diabetes; they do not include healthcare costs, costs due to complications or those associated with the behavioural changes that having diabetes entails.

References
1 Global health observatory data repository, 2013
2 IDF, 2011
3 Rechel B. et al., 2013
4 Rechel, B., & McKee, M., 2009
5 Carey M., Doherty Y., 2012
6 WHO, 2002

Note: references related to individual countries can be found on the country profiles
COUNTRY PROFILES
NORTH-WEST EUROPE
From the survey
- The vast majority of the respondents reported encountering no difficulties obtaining their medicines and medical devices.
- Education or information about treatment was received almost universally among surveyed people with diabetes but was far less frequent among their relatives.
- Although some fees apply to medicines, this was not identified as a major issue by respondents or the Austrian Diabetes Association.

Key background information: country health system

Healthcare expenditure profile (2011)^2
Total health expenditure per capita: USD 5,280.40
Proportion of government expenditure on health: 15.9%

Health system overview
- Austria’s mandatory health insurance system, administered by more than 20 health funds, covers the whole population.\(^3\)
- The package of benefits is defined by law as well as through negotiations between the different stakeholders.\(^2\) Healthcare provision is the responsibility of each region.\(^3\)
- Medicines and medical devices are supplied principally by private actors, according to the Federal Ministry of Health regulations – in line with EU regulations.\(^3\) A specialised agency ensures the application of these regulations.\(^3,4,9\)
- A quality issues reporting system is in place.\(^6\)

Diabetes prevalence (2011)^1,6
IDF Atlas National Data
9.1% of 20-79 year-olds
Austrian Diabetes Report 2011: 8% to 9%

Diabetes care procedure
- Prescriptions are provided mainly by GPs.\(^6\)
- Physicians and diabetes nurses are the principal points of diabetes information and advice.\(^6\)
- Diabetes products are dispensed mostly at pharmacies. A reduced number of products may also be distributed at outpatient clinics or hospitals.\(^5,6\)

Guidelines, specific prescription criteria and patterns of use
- Austria has guidelines for diabetes care.\(^1\)
- For medicines, prescription criteria are related to reimbursement classification: depending on the “box” into which medicines have been classified, these may be prescribed without additional criteria, for specific indications only, or require ex-ante approval from health funds.\(^4\)
  - Some newer oral and injectable medications require authorisation prior to prescription and can be prescribed only to people who are failing to achieve good glycaemic control with other therapies.\(^6\)
  - Some long-acting insulin analogues can be prescribed only to certain people with diabetes (for example, people with type 2 diabetes with nocturnal hypoglycaemia).\(^2\)
- The prescription of medical devices is also affected by reimbursement:
  - Pens are the most widely used insulin injection devices.\(^7\) Pumps are mainly prescribed to: people with type 1 diabetes;\(^5,6\) women during pregnancy; people with type 2 diabetes who do not achieve good glycaemic control with conventional insulin therapy, people with certain complications, severe hypoglycaemia or hypoglycaemia unawareness.\(^6\)
  - Regarding blood glucose test strips for people who are not on insulin or oral medications that have associated risks of hypoglycaemia, the prescriber is obliged to justify their prescription.\(^6\)
- According to the Austrian Diabetes Association,\(^1\) these constraints on prescription represent the key restraining issue in people’s access to medical devices, and especially to new medicines.
  - This Association considers that the “box” system applied to medicines significantly delays access to new medications. It involves lengthy procedures until the medicine is effectively available to people and tight prescription criteria apply for a prolonged period.\(^1\)
The available evidence suggests that for people living with diabetes accessibility is not the main barrier to obtaining medicines and medical devices, no particular difficulties were reported in this regard.5,6

- Although most people with diabetes seem to make some out-of-pocket expenditure, this appears not to be considered a barrier.5,6
  - All prescribed medicines require the payment of a prescription fee of approximately EUR 5 to 6 per pack (USD 6.5 to 8).5,6 This fee has increased over the last few years.5 However, a ceiling on prescription-related payments is applied to people affected by chronic disease.6
  - According to respondents to our survey,5 the median monthly out-of-pocket payment for diabetes medicines and medical devices was EUR 40 (USD 52) — EUR 480 (USD 623) per year. This constitutes 2% of the average Household Net Adjusted Disposable Income and as much as 5% for the least wealthy 20% of households.
- Based on collected responses,5 it appears that most people with diabetes are using branded products, and that the choice of brand is made largely by healthcare providers.6
  - No regulation specifically encourages the use of non-branded and/or low-priced products. However, the reimbursement system and associated prescription criteria were designed as a mean to contain costs.5,6
- All medicines applying for reimbursement are submitted to a pricing procedure, which is carried out by the Ministry of Health, with the advice of a pricing committee that includes representatives of relevant federal ministries and social partners. Maximum prices are based on average prices in EU countries, using reference pricing. Health funds also carry out further negotiations with manufacturers. The mark-ups applied by wholesalers and pharmacists are capped for all medicines according to a regressive scheme.4,8,9 In terms of taxation, medicines are exempt from import taxes but submitted to a reduced VAT of 10%.6 The price of components for medical devices could not be assessed.

Financial coverage

Any decision regarding the reimbursement of a product is made by a federation representing the health funds, and is based on the recommendations of an advisory commission. This commission includes scientific experts and representatives of health funds and social partners.4,8,9 For medicines, the decision is made based on therapeutic value and pharmacoeconomic evaluation.4,9 The cost to the user of all medicines included in the reimbursed list is fully covered4,9 but an additional fixed prescription fee is applied.

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin and anti-diabetes medications</td>
<td>Free5,6 (prescription fees apply)</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free5,6 (prescription fees apply)</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free5,6</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free5,6</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free5,6</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Free but limited to 50 strips per quarter for people who are not on insulin or oral medications that have associated risks of hypoglycaemia.5,6</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free5,6</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

Looking ahead

Although reimbursement is subject to the tight control placed on the allocation of financial resources, it has not as yet suffered from the economic crisis. Associations are not formally included in decisions over reimbursement but have been able to engage in discussions over improved public coverage for certain types of products.6

Additionally, since 2007 some regions have launched diseases management programmes, which have had a positive impact on access to medicines and medical devices.5

References

1 EURADIA, FEND, IDF, & PCDE. (2011).
2 Global health observatory data repository. (2013).
4 WHOCC PPRI, 2011.
Healthcare expenditure profile (2011)

Total health expenditure per capita: **USD 4,962.50**
Proportion of government expenditure on health: **15.1%**

Health system overview
- Belgium's mandatory health insurance, administered by multiple sickness funds, covers the whole population.
- The Ministry of Social Affairs and Public Health, advised by the National Institute for Health and Disability Insurance (NIHDI), defines the basic package of benefits that must be provided by all sickness funds. However, each of them — and other private health insurance companies — may also offer additional coverage to their clients.
- Medicines and medical devices are provided principally through the private sector to points of dispensing, according to the Ministry of Social Affairs and Public Health regulations — in line with EU regulations. A specialised agency ensures that these regulations are applied.
- A quality issues reporting system is in place.

Diabetes prevalence

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.6% of 20-79 year-olds (2011)</td>
<td>Official records (2013): 600,000 diagnosed people Including 10% of people with type 1 diabetes</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are provided by GPs and/or diabetologists (depending on treatment regimen).
- Diabetes nurses, GPs and diabetes associations are the main points of diabetes information and advice.
- Dispensation of diabetes medicines occurs mostly at pharmacies, which can also be located within healthcare facilities. Medical devices can be dispensed at pharmacies, hospitals or by associations (see Availability).

Presence of products at national level:
- At least one product from each of the categories surveyed was reported authorised for sale and effectively present in the country.

Guidelines and specific prescription criteria
- Belgium has guidelines for diabetes care.
- The prescription of most diabetes medicines is left to the prescriber's professional assessment of each person's condition.
- The prescription of certain medical devices is closely related to reimbursement as they are only available through conventions integrated into care pathways. Only certain hospitals with authorisation from NIHDI can offer these conventions.
- Conventions for pump therapy are only available to children, pregnant women and people with type 1 diabetes whose condition cannot be properly managed with regular insulin therapy.
- Conventions for blood glucose monitoring are only available to people treated with insulin or incretin injections. The number of strips covered depends on the category mentioned above.
- The holistic approach of care pathways makes that the various parties involved have care requirements throughout the process. The person issued with a device through a convention is entitled to receive education and regular check-ups. They must attend these sessions and may have to meet certain treatment targets to have their convention renewed.
- Although conventions are being progressively extended to new technologies and/or categories of people, this process is limited by strong budgetary constraints.

Use
- Only a third of people diagnosed with diabetes are treated with insulin. Most of these people use pens to inject insulin.
- The principal treatment given to other people with diabetes could not be assessed.
Access to treatment

- To address the issue of the insufficient number of diabetologists, care and treatment for people on oral medications or less than two insulin injections per day have been transferred to GPs.6
- The inclusion of education in care pathways (see Availability) has helped to ensure that people get proper information about their treatment.

Stock and shortages

- Although some stock issues arose around insulin in 2012, alternatives were found with healthcare professionals in order to avoid any adverse impact on people with diabetes.6,7

Insulin and Anti-diabetic medication Free/Fully reimbursed1,5,6,7

- Medication for hypoglycemia Fully or partially reimbursed5

- Pens and related supplies Only pens are free/fully reimbursed5,6

- Syringes and needles Partially reimbursed (only disposable syringes with integrated needles are available) 6

- Pumps and related supplies* Free/Fully reimbursed1,5,6 (see availability for criteria)

- Blood glucose test strips and meters* Free/Fully reimbursed1,5,6 (see availability for criteria) but a limited number of strips are covered according to the person’s condition10

- Ketones test strips Free/Fully reimbursed6

* These medical devices are only reimbursed through as part of conventions (see Availability)
Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

References

1 EURADA, FEND, IDF, & PCDE. (2011).
2 Global health observatory data repository. (2013).
4 PPRI & WHO. (2011)
5 IDF-Europe Access survey (2013)
6 ABD (personal communication) (2013)
7 VDV (personal communication) (2013)
9 PPRI 2013
10 Diabète (n.d.)
12 EFPIA (personal communication) (2012)
About the data
We were not able to collect a large number of responses in this country. Thus, the information presented below is based mainly on a review of the literature and exchanges with the national diabetes association.

Healthcare expenditure profile (2011)
- Total health expenditure per capita: USD 6,647.70
- Proportion of government expenditure on health: 16.4%

Health system overview
- In the Danish National Health System, responsibility for healthcare is shared between the national, regional and local authorities.
- Medicines and medical devices are provided through a mixed system: products provided by healthcare facilities are publicly procured, while others are supplied by private actors. Both sectors have to comply with Ministry of the Interior and Health policy, in line with EU regulation. A specialised agency ensures the application of those regulations.
- Although a quality-monitoring system seems to be in place, quality control is mainly carried out prior to distribution.

Diabetes prevalence (2011)
- 7.5% of 20-79 year-olds
- Official records: 250,000 people including 10% people with type 1 diabetes

Diabetes care procedure
- For people with type 1 diabetes, prescriptions are provided by specialists; for people with type 2 diabetes, by GPs.
- Prescribers, along with diabetes nurses and social workers are the main points of diabetes information and advice.
- Diabetes products are dispensed mostly at healthcare facilities or pharmacies. Some local authorities delegate the delivery of certain medical devices to private contractors.

Presence of products at national level
- At least one product from each of the surveyed categories was reported authorised for sale and effectively present in the country.

Guidelines and specific prescription criteria
- Denmark has national guidelines for diabetes care.
- Only specialists can prescribe insulin pumps.
- Metformin is the first line of pharmaceutical treatment for people with type 2 diabetes.
- Some newer diabetes medicines (that were not included in this survey like GLP-1 agonists) also follow specific prescription requirements.

Use
- Prescription and use is regulated through reimbursement.
- The National Quality Register allows close monitoring of prescription practices.
Access to treatment

• The provision of education and information about treatment is the responsibility of each regional authority, giving rise to differences across regions.6
• Local access to pump therapy is limited by many factors.
  o Although insulin pumps are covered by the national budget, pump therapy has no specific budget line; each healthcare facility decides on the proportion of their budget to be allocated to pump therapy.6
  • These differences in budget allocation lead to long waiting lists for pumps.6
  o The uptake of pump therapy is also limited by the lack of healthcare professionals trained for this therapy.6

Stock and shortages

• In terms of medical devices, the number of brands available per category of products varies from region to region, as it is constrained by municipal tenders.6 Only certain brands are fully reimbursed, others are covered to the level agreed on in each municipality’s tenders.6

Insulin and anti-diabetes medication

• Partially reimbursed5,6

Medication for hypoglycaemia

• Partially reimbursed5

Pens and related supplies

• Pens are free1,6
  • Needles are free or partially reimbursed5,6

Syringes and needles

• Free1,6

Pumps and related supplies

• Free5,6 (see criteria in Availability)

Blood glucose test strips

• Free up to the level negotiated in public tenders5,6 but with a 150 strips-per-year limit for people with type 2 diabetes on oral medications.5,6

Glucometers

• Partially covered1,6

Ketone test strips

• Free or partially covered5,6

Financial coverage

Reimbursement for products depends on the target condition. The Danish Medicines Agency (DKMA) decides on reimbursement for both medicines and medical devices, according to the Reimbursement Committee's recommendations.2 For medicines, the key criteria are therapeutic value and cost-effectiveness. Their degrees of reimbursement depends on the medicines (with a set reimbursed amount per class)3,4 and individual expenses (the higher the expenditure per year, the higher the degree of reimbursement).3 Depending on the medical device, the level of reimbursement is either fixed (100% for “treatment aid”) or vary according to the decision of the local authority decision.6

Affordability

• An estimate of monthly out-of-pocket expenditure on diabetes products could not be obtained. Although most people would pay a part of treatment out-of-pocket, systems exist to avoid high expenditure.5
  • People with a chronic condition who have to spend more than DKK 3,710 (USD 647) per year are eligible to full reimbursement for any further expenditure on medicines. Their doctor must apply for this full reimbursement.6
  • Additionally, people with a low income may receive additional financial support.6
  • For prescribed medicines, pharmacies are obliged to suggest the lowest price medicine in each category. For medical devices, the brand is chosen by the prescriber together with the person with diabetes – and also may be constrained by public tenders.6
  • There is no price-setting mechanism in place6 but the prices of medicines and medical devices are influenced by degrees of reimbursement and/or public tenders. The price of medicines must also be reported to the Danish Medicines Agency (DKMA).1,6 According to the industry, a 25% VAT is applied to all medicines.8

References

1 EURADA, FEND, IDF & PCDE. (2011).
2 Global health observatory data repository. (2013)
3 Olejaz, M. et al. (2012)
4 PPRI & WHO. (2011)
5 IDF-Europe Access survey (2013)
6 Danish Diabetes Association (personal communication), (2013)
8 Danish Diabetes Association (2013)
9 National Board of Health (2012)
10 EFPIA (personal communication) (2012)
Healthcare expenditure profile (2011)²
Total health expenditure per capita: **USD 3,200**
Proportion of government expenditure on health: **19.3%**

Health system overview
- The Faroe Islands has a **National Health Insurance** system.¹
- As the Faroe Islands are an autonomous territory of the Kingdom of Denmark, regulatory powers are shared between the Faroese government and the Danish government. Healthcare provision is the responsibility of the Faroese authorities.¹,⁴

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th></th>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.5% of 20-79 year-olds</td>
<td></td>
<td>13.1% of 40-79 year-olds</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are provided mostly by GPs.¹
- GPs and nurses are the main points of diabetes information and advice.¹
- Diabetes supplies are dispensed mostly at public pharmacies. Some medical devices can be dispensed at healthcare facilities.¹

Guidelines and specific prescription criteria
- The Faroe Islands recently adopted a National Diabetes Action Plan, which includes guidelines for diabetes care.⁵

Use
- Insulin pumps are primarily used among people with type 1 diabetes, 26% of whom are currently using a pump.⁵
- Newer oral medications are used as second- or third-line treatments for people with type 2 diabetes, in combination with insulin.⁵

About the data
We were not able to collect a large number of responses in this autonomous territory. Thus, the information presented below is based mainly on a review of the literature and exchanges with the national diabetes association.
**Access to treatment**

- Access to specialist care is limited by the lack of endocrinologists in the autonomous territory. Only one doctor has specialist training in diabetes.
- However, people with diabetes receive education and information about their treatment from their GPs. GPs also have access to Danish patient education leaflets, which they can disseminate.

**Stock**

- No specific issues have been reported regarding stocks or supply of diabetes medicines and medical devices.

**Insulin and anti-diabetes medication**
- Partially covered

**Medication for hypoglycaemia**
- Not covered — 100% paid for by the person with diabetes

**Pens and related supplies**
- Partially reimbursed

**Syringes and needles**
- Partially reimbursed

**Pumps and related supplies**
- Pump — free
- Supplies — partially reimbursed

**Blood glucose test strips and meters**
- Partially reimbursed

**Ketone test strips**
- Partially reimbursed

*Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.*

**Affordability**

- Although the National Health Insurance covers most of the costs of diabetes medicines and medical devices, it appears that at least some people have to pay a part of treatment out-of-pocket. An estimate of monthly out-of-pocket expenditure on diabetes products could not be obtained through the survey. According to the Faroese Diabetes Association, people with diabetes have to pay at least EUR 25–30 (USD 32–39) per month, on the top of the monthly contribution to the National Health Insurance System — about EUR 33 (USD 43) per month. They have a ceiling for out-of-pocket expenditure on medicines for children under 18 and pensioners. All people with diabetes can apply for additional allowances to cover therapeutic diet-related expenses. Pharmacies are compelled by law to offer the lowest-priced option for each prescribed medicine. The price of components medicines and medical devices could not be assessed. However, the pricing system in the Faroe Islands is similar to the system applied in Denmark.

**Financial coverage**

- Insulin and anti-diabetes medication
  - Partially covered
- Medication for hypoglycaemia
  - Not covered — 100% paid for by the person with diabetes
- Pens and related supplies
  - Partially reimbursed
- Syringes and needles
  - Partially reimbursed
- Pumps and related supplies
  - Pump — free
  - Supplies — partially reimbursed
- Blood glucose test strips and meters
  - Partially reimbursed
- Ketone test strips
  - Partially reimbursed

**Looking ahead**

Healthcare expenditure profile (2011)²
Total health expenditure per capita: **USD 4,325.50**
Proportion of government expenditure on health: **12.1%**

Health system overview
- The National Health Insurance covers certain services, such as outpatient drugs, but healthcare provision is municipalities' responsibility.³
- Medicines are provided by private actors; reimbursed medical devices are purchased by public healthcare facilities from private wholesalers.³,⁶ The private sector has to comply with Ministry of Social Affairs and Health (MoSAH) regulations – in line with EU regulation.³ A specialised agency ensures the application of those regulations.³,⁷
- A quality issues reporting system is in place.⁶

Diabetes prevalence (2011)¹
<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.7% of 20-79 year-olds</td>
<td>National estimate: <strong>10%</strong> of the adult population Including 280,000 people with type 2 diabetes and 40,000 with type 1 diabetes</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Most prescriptions are provided by GPs; specialists prescribe for around half of all people with type 1 diabetes.⁴
  - Prescribers function also as the main points of diabetes information and advice.⁴
- Diabetes medicines tend to be dispensed at pharmacies, while medical devices are dispensed largely at healthcare facilities.⁵,⁶

About the data
We were unable to collect a large number of responses in this country. Thus, the information presented below is based mainly on a review of the literature and exchanges with the national diabetes association.

### Availability
- At least one product from each of the categories surveyed was reported authorised for sale and effectively present in the country.⁵

### Guidelines and specific prescription criteria
- Finland has national guidelines for diabetes care.¹

### Use
- The provision of medical devices is the responsibility of the municipalities. Some municipalities apply further prescription criteria.⁴
- Insulin pumps are mainly used in children and young adults but their uptake is constrained by municipal budgetary limitations.⁶
Access to treatment

- Physical access to prescribers and dispensers appears not to be a problem.\(^3,6\)
- Although all people with diabetes are eligible to education about their treatment, the quality of information varies between municipalities and is often limited to basic product use.\(^6\)

Stock

- In order to prevent shortages, wholesalers have to maintain a minimum level of stock at all times.\(^3\)

- An estimate of monthly out-of-pocket expenditure for diabetes products could not be obtained. However, while medicines are equally covered across the country thanks to a national legislation, the coverage of medical devices seems to vary between municipalities.\(^6\)
- While people previously did not face reimbursement differences based on their type of diabetes, the reimbursement of insulin analogues for people with type 2 diabetes is currently being reassessed and may be reduced.\(^6\)
- A few non-branded diabetes products seem to be on the market, and to be limited to certain categories of products.\(^5,6\) Although policies exist to encourage the use of the lowest-price products, brands are mainly decided by prescribers, who are informed and advised in persuasive terms by industry representatives.\(^6\)
- Although not formally regulated, the pricing of all reimbursed medicines is controlled by reimbursement levels. It is negotiated with the institution in charge of reimbursement – which is only granted if a "reasonable" wholesale price is accepted.\(^7\) The mark-ups applied by wholesalers are regulated in the same way. Mark-ups applied by pharmacies are regulated through a mixed system, including both fixed fees and a regressive scheme. The VAT rate applied to medicines was raised recently to 9%.\(^8\) The price of components for medical devices could not be assessed.

Financial coverage

People with diabetes, and those with certain other diseases, are entitled to increased reimbursement rates.\(^6,7\) An independent body under the MoSAH decides on reimbursments for medicines while the NHI makes the payments. For medicines, decisions regarding reimbursement are based on therapeutic value, the severity of the target illness, and price – which is assessed through external and internal reference pricing.\(^7\) However, diabetes associations report that price evaluation lacks transparency and may give priority to cost-containment over other criteria.\(^6\)

The coverage of medical devices is the responsibility of each municipality.\(^6\) Alongside the reimbursement summarised below, a fixed dispensation fee of EUR 2-3 (USD 2.60-3.90) is applied at each visit to a pharmacy.\(^3,6,7\)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin and anti-diabetes medication</td>
<td>Free(^1,4)</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free(^1,4)</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free or subsidised, depending on the municipality(^1,4)</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free or subsidised, depending on the municipality(^1,4)</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free or subsidised, depending on the municipality(^1,4)</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Free or subsidised, depending on the municipality(^1,4)</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free or partially covered(^6)</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

References

1. EURADA, FEND, IDF & PCEO. (2011)
2. Global health observatory data repository. (2013)
4. PPI & WHO (2011)
5. IFP–Europe Access survey (2013)
Healthcare expenditure profile (2011)\textsuperscript{2}

Total health expenditure per capita: \textbf{USD 4,952}

Proportion of government expenditure on health: \textbf{15.9\%}

Health system overview

- The National Health Insurance System, administered by the National Union of Health Insurance Funds, covers the whole population.\textsuperscript{3}
- The French National Authority for Health develops recommendations for the Ministry Of Health and the National Union of Health Insurance to define the care package.\textsuperscript{3}
- Medicines and medical devices are supplied principally by private actors, according to the Ministry of Health regulations – in line with EU regulations. A specialised agency ensures that these regulations are applied.\textsuperscript{4,5}
- A quality issues reporting system is in place.\textsuperscript{5,6} However, further to recent scandals revealing the system’s weaknesses, it is being reformed.\textsuperscript{6}

Diabetes prevalence\textsuperscript{1}

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
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</table>

Diabetes care procedure

- Prescriptions are provided mainly by GPs and, to a lesser extent, diabetologists, who tend to focus on more complex cases.\textsuperscript{6}
- These doctors, along with associations and pharmacists, are the main points of diabetes information and advice.\textsuperscript{6}
- Most diabetes supplies are dispensed at pharmacies, except for insulin pumps, which are dispensed by specific contractors.\textsuperscript{5,6,9}

From the survey

- The majority of the respondents reported encountering no difficulties obtaining their medicines and medical devices.
  - The few stock issues reported appeared to have limited impact on people’s treatment, and these problems were usually resolved within a few days.
  - On the other hand, it seems that a small portion of people with diabetes still face affordability issues, despite the existing scheme, which offers free access to healthcare and treatment for people with a chronic disease.
- Diabetes education and information about treatment were provided almost universally among the people with diabetes surveyed but was far less frequent among their relatives.
- The low number of respondents with types of diabetes other than type 1 diabetes makes it difficult to discuss access for all people with diabetes.

**Key background information:** country health system

**Key diabetes data**

**Availability**
Access to treatment

- Because the initiation of pump therapy requires the person to be hospitalised for few days, some areas may have waiting lists for such a therapy. However, according to the French Diabetes Association, this waiting time remains limited.
- Like people with other health conditions, some people with diabetes are facing growing difficulties accessing prescribers – either because of the lack of doctors in certain areas, or because of the cost (cost of travel, overrun fees applied by certain physicians).

Stock and shortages

- A small number of stock issues have arisen due to delays along the supply chain, which is becoming increasingly strained. However, according to the French Diabetes Association, these events remain very rare.
- Additionally, these issues do not appear to impact on treatment, also because people usually have a small safety stock at home.

Insulin and anti-diabetes medication

- Free
- Medication for hypoglycaemia
- Free
- Pens and related supplies
- Free
- Syringes and needles
- Free
- Pumps and related supplies
- Free
- Blood glucose test strips and meters
- Free but limited to 200 strips per year for people treated with the oral medications that have low related risks of hypoglycaemia
- Ketone test strips
- Free

Ketone test strips are lent free-of-charge to people with diabetes by the contractors.

*Please note that the information above presents only a summary of the reimbursement system and may not apply to individual cases.

Affordability

- The majority of respondents reported having access to diabetes medicines and medical devices at no cost, due to the Long-Term Illness Scheme. But the French Diabetes Association estimates that about a third of people with diabetes using medicines and medical devices (and therefore eligible to free supplies) are not enrolled on the Scheme.
- People with type 2 diabetes are the most affected by this gap in the system. However, the causes of this problem are unclear and require further research.
- This gap may explain the findings of a recent survey from the pharmaceutical industry involving people with type 2 diabetes, which found that about 20% of them could not afford their medication and/or their blood glucose-monitoring devices. However, these findings were not confirmed by the French Diabetes Association.
- It appears that few non-branded products are available on the market.
- The choice of the brand of medical device is determined jointly by the healthcare providers and the person with diabetes. If the choice is open to the person with diabetes, it appears that the doctor’s advice remains key in this decision.
- The prices of all reimbursed medicines and medical devices are regulated centrally via negotiations with the manufacturers. Pricing is included in the procedure for reimbursement. Additionally, the mark-ups applied by wholesalers and pharmacists are regulated by the Ministry of Health and the Ministry of Finance, mainly through a regressive scheme. Finally, a reduced VAT rate of 2.1% is applied to all diabetes products. So far, the reforms applied to the pricing and reimbursement of medicines have not affected medication for diabetes.

Financial coverage

Expert committees and the National Authority for Health advise the Ministry of Health on which medicines and medical devices should be reimbursed. Criteria include clinical and therapeutic benefits as well as added value compared to existing technologies or medicines. Based on this assessment, and after the Ministry’s decision has been made, the National Union of Health Insurance Funds decides the rate of reimbursement. Under the Long-Term Illness Scheme, medicines and medical devices for diabetes are fully covered by the mandatory health insurance system and people are exempt from dispensing fees. However, in order to enrol on the Scheme, the prescriber must apply (on the patient’s behalf) to the person’s health insurance fund. Please note that the table below presents a level of reimbursement assuming that the person has registered with the Long-Term Illness Scheme.

Looking ahead

Although some financial cuts and cost-containment measures may be implemented in the near future, diabetes should be protected, with the current financial protection being maintained.

References
1 EURADA, FEND, IDF, & PCDE. (2011)
2 Global health observatory data repository. (2013)
3 Chevreul, K. et al., (2010)
4 PPRI & WHO (2011)
5 IDF-Europe Access survey (2013)
6 Association Française des Diabétiques (personal communication) (2013)
9 Association Française des Diabétiques. (2013)
10 Sulmont, V., et al. (2011)
Healthcare expenditure profile (2011)²
Total health expenditure per capita: **USD 4,875**
Proportion of government expenditure on health: **18.5%**

Proportion of government expenditure on health
- Public expenditure: 25%
- Private expenditure: 75%
Out-of-pocket expenditure represents 51.4% of private spending on health

Health system overview
- Germany’s health insurance system, administered by multiple health funds, covers most of the population.³
- The package of benefits is defined by the Federal Joint Committee (FJC), which includes representatives of health funds and healthcare providers. The FJC is under the authority of the Ministry of Health.³
- Medicines and medical devices are supplied principally by private actors,⁵ following FJC regulations – and in line with federal and regional laws, and EU regulations.⁴ A specialised agency supports the FJC in these tasks.³
- A quality issues reporting system is in place.⁵

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th>IDFAtlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>8%</td>
<td>9% of people over 18</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions for most people with type 2 diabetes are provided by GPs; diabetologists prescribe mainly for people with type 1 diabetes and people with type 2 diabetes with complications or complex cases.⁶
- Diabetes nurses are the principal point of diabetes information and advice. The Internet and peer groups are also becoming important sources of information.⁷
- Diabetes medicines are usually dispensed at pharmacies. Medical devices may be dispensed at pharmacies but are also commonly obtained online.⁵,⁶

Presence of products at national level
- At least one product from each of the categories surveyed appeared to be authorised for sale and effectively present in the country.⁵,⁶
  - However, Germany’s new pricing and reimbursement policy (see Affordability) is leading to the withdrawal of certain newer medicines (like a DPP4 inhibitors) by their manufacturers — where no agreement can be found on the reimbursement price.⁴,⁶

Guidelines and specific prescription criteria
- Germany has guidelines for diabetes care.¹
- Prescription criteria are directly related to reimbursement and prices (see also Affordability). The health funds decide on the criteria and prices according to which they cover products for each category of people.⁶
  - In recent years, health funds have tended to apply further criteria, especially on newer medicines and technologies.⁶
  - Additionally, certain therapies like insulin pump therapy have to be requested and justified by the diabetologist. This application is assessed by the health fund.⁶
    - These evaluations are not carried out in the same way across health funds. Thus the likelihood of having a request for reimbursement rejected varies.⁶

Use
- Although it may depend on their type of diabetes, most people treated with insulin seem to use insulin analogues and insulin pens. Pumps are under specific procedure (see above) and primarily prescribed to people with type 1 diabetes.⁵
- Metformin appear to be the most widely prescribed oral medication, and is used mainly by people with type 2 diabetes.⁵
- Blood glucose-testing devices seem to be mainly prescribed to people treated with insulin (regardless of their type of diabetes — see Affordability) while ketone test strips appear to be primarily prescribed to people with type 1 diabetes.⁵

From the survey
- The majority of the respondents reported encountering no difficulties obtaining their medicines and medical devices.
  - However, the very low number of respondents with types of diabetes other than type 1 diabetes makes it difficult to discuss access for all people with diabetes in Germany.
- Education or information about treatment was received almost universally among people surveyed with diabetes but was far less frequent among their relatives.

Key background information: country health system
- **GERMANY**
- **From the survey**
  - **Key diabetes data**
  - **Diabetes prevalence (2011)**²
  - **Diabetes care procedure**
  - **Presence of products at national level**
  - **Guidelines and specific prescription criteria**
  - **Use**
Accessibility

• The available evidence suggests that for people living with diabetes accessibility is not the main barrier to obtaining medicines and medical devices.5,6

• A 2013 study from the industry found high participation rates in diabetes education programs among German people with diabetes.11 DiabetesDE reports that in 2011, 3.6 million people with type 2 diabetes and 147 thousand people with type 1 diabetes took part in structured disease management programs.6

Affordability

• It appears that the main source of out-of-pocket expenditure for diabetes products is the 10% fee applied to most products, which cannot exceed 1% of a person’s income per year.6

o Some providers (including online companies) do not apply this fee.6

o According to respondents with type 1 diabetes,6 the median monthly out-of-pocket expense for diabetes medicines and medical devices was EUR 11.50 (USD 15), or EUR 138 (USD 179) per year. This constitutes 0.6% of the average Household Net Adjusted Disposable Income, or 1.4% for the least wealthy 20% of households.

• Few non-branded products seem to be available on the market. However, it appears that most people with diabetes use branded products. That choice of brand is made largely by healthcare providers.5

• It appears that the prices of most diabetes products (including all diabetes medicines) are regulated.6 Pricing for products covered by health funds is directly tied to reimbursement policy and reimbursement price (see Table). In recent years, a number of cost-containment measures have been applied to reimbursable medicines.6

o The new pricing and reimbursement policy, which aims at containing pharmaceutical expenditure, has triggered debates over the assessment methodology being used. It has also raised concerns over companies withdrawing or not introducing new products in Germany – as happened with a DPP4 inhibitor.6

o The reimbursement prices of diabetes medicines like insulin analogues have been cut.6

o Although the mark-ups applied by wholesalers and pharmacists are regulated, different schemes are applied depending on the type of product, and have also been the subject of a recent reform.8,10

Financial coverage

The FJC, advised by the specialised agency mentioned above, decides on reimbursement and fixes reimbursement prices.6 For medical devices, the decision is based on price and therapeutic value, while the reimbursement price is based on reference pricing.7 Reimbursement policy for medicines was changed recently and is now based on a benefit assessment: in order to receive higher reimbursement prices (set through negotiation) manufacturers of new medicines have to prove that their products offer additional clinical benefits beyond those already on the market. If they fail to do so, the reimbursement price is set using internal and external reference pricing.6,8

Diabetes products are classified in the category with the lowest fee – 10% of the reimbursement price with a cap of EUR 10 (USD 13) per package.6 Children are exempt.6

<table>
<thead>
<tr>
<th>Drug Group</th>
<th>Fee/Exemption</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin and anti-diabetes medication*</td>
<td>Free/Exempt (fees apply)</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free/Exempt (fees apply)</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free/Exempt (fees apply)</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free/Exempt (fees apply)</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free/Exempt (fees apply)</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Only people treated with insulin receive this equipment free of charge; limits are applied to strips. Otherwise, not covered — 100% paid for by the person with diabetes.</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free/Exempt (fees apply)</td>
</tr>
</tbody>
</table>

*See above about DPP4 inhibitors

References

1 EURADA, FEND, IDF, & PCDE. (2011)
2 Global health observatory data repository. (2013)
4 “Association of Statutory Health Insurance Funds”. (2013)
5 IDF-Europe Access survey (2013)
6 Diabetes DE (personal communication) (2013)
7 IMS, (2012)
8 Vogler, S. et al. (2011) Southern Med Review
9 Janssen Pharmaceutical Companies. (2013)
11 Willaing, I., et al. (2013)
Healthcare expenditure profile (2011)

Total health expenditure per capita: **USD 3,985.90**
Proportion of government expenditure on health: **15.4%**

Health system overview
- Iceland’s mandatory health insurance, administered by the Icelandic health insurance, covers the whole population.
- The package of benefits is defined by law.
- Medicines and most medical devices are supplied by private actors, according to the Ministry of Welfare’s regulations. Under the European Economic Area Agreement, these regulations and EU’s ones have been harmonised to facilitate market access. A specialised agency ensures that these regulations are applied. Some medical devices like insulin pumps are directly supplied by the private companies under contract with the state.
- A quality issues reporting system is in place.

Diabetes prevalence (2011)

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.9% of 20-79 year-olds</td>
<td>No data</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are provided by GPs or specialists at diabetes clinics, according to a person’s condition.
- Doctors, diabetes nurses and associations, as well as the manufacturers of medical devices, serve as the main points of diabetes information and advice.
- Diabetes products are dispensed mostly at pharmacies, except insulin pumps and associated supplies, which are directly dispensed by the company — under state contract.

Presence of products at national level
- At least one product from each of the categories surveyed appears to be authorised for sale and present in the country.

Guidelines and specific prescription criteria
- Iceland has guidelines for diabetes care.
- The level of care and facility (GP or specialised clinic) is defined by these guidelines (see also Accessibility).
- Specific prescription criteria could not be assessed. However, it appears that these are closely related to reimbursement (see Affordability).

Use
- Pens remain the most widely used insulin injection device.
- Pumps are mainly offered to children with type 1 diabetes.
- People with type 2 diabetes are mainly treated with metformin or insulin.
- Lifestyle changes and blood glucose monitoring remain the first line of treatment for women with gestational diabetes. Only insulin is used as a second line.
ICELAND

Access to treatment

- The small Icelandic population living in rural areas may still face difficulties accessing diabetes clinics.
  - Although trips to the clinic may be financed by the health system, some people still do not have access to a clinic due to the distance and journey time.6
  - Access to information and education differs according to the care setting (GP vs. diabetes clinic), and depends primarily on individual healthcare providers and associations.6

Stock and shortages

- The proportion of the state budget allocated to insulin pumps is being reduced. Thus, it is giving rise to growing waiting lists.6
- The supply of diabetes products relies entirely on imports. The 2008 financial crisis caused some stock issues when imports were hampered by the difficulties involving the banks. However, these challenges were resolved and no further stock issues have been reported.6

Insulin and anti-diabetes medication

- Partially covered6
- Partially covered6
- Only pens are fully covered
- Partially covered6
- Fully covered but limited to 50 strips per year for people with type 2 diabetes6
- Unknown

Financial coverage

The Ministry of Welfare decides on all reimbursements. Reimbursement of medicines (i.e. full, partial or no reimbursement) is based on the therapeutic classification of each drug. Reimbursement of many categories of medicines changed recently, including for diabetes medicines. Reimbursement itself is based on the lowest priced product in each category.6

Access to treatment

- As a result of the economic crisis, the reimbursement system for medicines was changed, raising existing co-payments and/or introducing new ones.5,10
  - While insulin and anti-diabetes medications previously were provided free of charge,4,11 they have not been included in the new list of medicines exempted from co-payments.6
  - A EUR 300 (USD 390) ceiling on out-of-pocket payments for medicines has been created, with lower ceilings for certain groups like pensioners. Additionally, people with a low income may apply for social benefit to cover some of the co-payments for medicines but this application for refund can be made at least three months after the person has made the payment.6
  - This system was implemented recently, its impact on people’s access to medicines could not be assessed.
  - Additionally, some co-payments are required for most medical devices and consumables (see Table).6
  - Like for other health conditions,1 it appears that mainly branded diabetes products are available on the market.6 The number of brands available per category of product, which are all imported, appears to be limited (see also Accessibility).6
  - The prices of diabetes medicines and medical devices are regulated by the Ministry of Welfare.6 For medicines, pricing methodologies vary according to the type of product but are based principally on external reference pricing.6,8 The mark-ups applied by wholesalers are open but constrained by the prices set previously. Pharmacists’ mark-ups are regulated under a mixed scheme (fixed fee plus percentage of price).6,7 According to the pharmaceutical industry, the standard VAT rate of 25.5% is applied to all medicines.10
  - The price of medicines in Iceland is considered high, because of Iceland’s market size.6 However, recent reforms are aimed at reducing prices.5,6,11

Affordability

- As a result of the economic crisis, the reimbursement system for medicines was changed, raising existing co-payments and/or introducing new ones.5,10
  - While insulin and anti-diabetes medications previously were provided free of charge,4,11 they have not been included in the new list of medicines exempted from co-payments.6
  - A EUR 300 (USD 390) ceiling on out-of-pocket payments for medicines has been created, with lower ceilings for certain groups like pensioners. Additionally, people with a low income may apply for social benefit to cover some of the co-payments for medicines but this application for refund can be made at least three months after the person has made the payment.6
  - This system was implemented recently, its impact on people’s access to medicines could not be assessed.
  - Additionally, some co-payments are required for most medical devices and consumables (see Table).6
  - Like for other health conditions,1 it appears that mainly branded diabetes products are available on the market.6 The number of brands available per category of product, which are all imported, appears to be limited (see also Accessibility).6
  - The prices of diabetes medicines and medical devices are regulated by the Ministry of Welfare.6 For medicines, pricing methodologies vary according to the type of product but are based principally on external reference pricing.6,8 The mark-ups applied by wholesalers are open but constrained by the prices set previously. Pharmacists’ mark-ups are regulated under a mixed scheme (fixed fee plus percentage of price).6,7 According to the pharmaceutical industry, the standard VAT rate of 25.5% is applied to all medicines.10
  - The price of medicines in Iceland is considered high, because of Iceland’s market size.6 However, recent reforms are aimed at reducing prices.5,6,11

Financial coverage

The Ministry of Welfare decides on all reimbursements. Reimbursement of medicines (i.e. full, partial or no reimbursement) is based on the therapeutic classification of each drug. Reimbursement of many categories of medicines changed recently, including for diabetes medicines. Reimbursement itself is based on the lowest priced product in each category.6

### References

1. EURADA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
4. PPRI & WHO (2011)
8. EFTA. (2013)
10. Icelandic Medicine Pricing and Reimbursement Committee (IMPRC). (2013a)
11. Icelandic Medicine Pricing and Reimbursement Committee (IMPRC). (2013b)
12. EFPIA (personal communication) (2012)
About the data
We were not able to collect a large number of responses in this country. Thus, the information presented below is based mainly on a review of the literature and exchanges with the national diabetes association.

Healthcare expenditure profile (2011)²
Total health expenditure per capita: **USD 4,542.40**
Proportion of government expenditure on health: **13.5%**

Health system overview
- The central state-funded and -organised health system – which is currently administered by a single agency called the Health Service Executive (HSE) – is being reformed into a national Health insurance system.⁷
- The HSE, under the supervision of the Minister for Health and Children, defines benefits and conditions of access to health services.³
- Most medicines and medical devices are supplied by private actors, according to Department of Health and Children’s standards and regulations, and in line with EU regulation.³,⁴ A specialised agency ensures the application of those regulations.³,⁴
- A quality issues reporting system is in place.³

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th>Source</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDF Atlas</td>
<td>6.1% of 20-79 year-olds</td>
</tr>
<tr>
<td>National Data</td>
<td>No data</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are provided by GPs and diabetes teams in hospitals.⁵
- Healthcare professionals’ associations and the pharmaceutical industry have been identified as major sources for diabetes information and advice in Ireland.⁶
- Diabetes medicines are dispensed mostly at pharmacies; medical devices can be dispensed at public healthcare facilities or pharmacies.⁵,⁶

Presence of products at national level
- At least one product from each of the categories surveyed seem to be authorised for sale and effectively present in the country.¹,⁵

Guidelines and specific prescription criteria
- Ireland has national guidelines for diabetes care.¹
- No specific criterion applies to the prescription of diabetes medicines and medical devices, which is left to the diagnosis and evaluation of the healthcare professional.⁶

Use
- Pattern of use for other diabetes products could not be assessed for this country.
Access to treatment
• Access to specialist care remains challenging in remote areas. Additionally, as education and information are also provided mainly in specialised centres and hospitals, access to information about treatment is poor.\(^1\,^6\)

Stock and shortages
• According to the Diabetes Federation of Ireland, people with diabetes are not particularly affected by out-of-stock issues.\(^6\)

Affordability
• Based on available information,\(^1\,^5\,^6\) it appears that the majority of people do not have to pay any out-of-pocket expenditure for their diabetes medicines and medical devices.
• The choice of brand is made by prescribers,\(^6\) who seem to prescribe mostly branded products.\(^5\,^6\) However, a new law to allow substitution of branded medicines to non-branded ones at pharmacy level is being discussed.\(^6\)
• The prices of reimbursed medicines are negotiated with the pharmaceutical industry.\(^4\) With the financial crisis, Ireland negotiated successive price reductions on medicines. The margins established by wholesalers and pharmacies have been reduced while external reference pricing is being implemented.\(^5\) Price components for medical devices could not be assessed.

Financial coverage
People with diabetes are eligible to the Long-Term Illness Scheme, which ensures access to a list of health services free of charge.\(^3\,^4\) The HSE decides on whether a product should be reimbursed,\(^4\) based on a pre-established list of reimbursed substances.\(^4\) The level of reimbursement for medicines is based on the price negotiated with the industry.\(^4\)

<table>
<thead>
<tr>
<th>Product</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin and anti-diabetes medication</td>
<td>Free(^1)</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Not covered — 100% paid for by the person with diabetes(^5)</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free or partially covered(^1)</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Not known</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free(^5)</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Free(^1)</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free(^7)</td>
</tr>
</tbody>
</table>

Please note that the information above presents only a summary of the reimbursement system and may not apply to individual cases.

Looking ahead
Ireland is currently reforming its health system. While protecting the current health and treatment rights of people with diabetes in Ireland, it is hoped that this reform might address the difficulties faced by some people regarding access to specialist care and education.\(^6\)

References
1 EURADA, FENH, IFE, PCDE. (2011)
2 Global health observatory data repository. (2013)
4 Elliott, D., & Byrne, G. (2007)
5 IDF—Europe Access survey (2013)
6 Diabetes Federation of Ireland (personal communication) (2013)
7 Health Ministers Publish Future Health (2013)
Healthcare expenditure profile (2011)²

Total health expenditure per capita: USD 8,797.64
Proportion of government expenditure on health: 15.5%

Health system overview
- The mandatory Health Insurance System, administered by four Health Insurance Funds, covers the entire population.⁵,⁶
- The healthcare package is defined by law.⁷
- Medicines and medical devices are mainly supplied by private actors, according to Ministry of Health regulations — and in line with EU regulation.⁷
- The existence of a quality issues reporting system could not be confirmed.

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.6% of 20–79 year-olds</td>
<td>No data</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are provided by diabetologists and GPs, who also function as the main points of diabetes information and advice.⁶
- Diabetes products are dispensed mostly at pharmacies.⁵,⁶

Presence of products at national level
- At least one product from each of the categories surveyed seem to be authorised for sale and effectively present in the country.⁵,⁶

Guidelines and specific prescription criteria
- Luxembourg has national guidelines for diabetes care.¹
- It appears that specific prescription criteria mainly apply to medical devices and are closely related to reimbursement (see also Affordability).
  - Prior to the prescription of an insulin pump, a medically justified recommendation for pump therapy must be submitted by a diabetologist to the person’s health insurance fund.⁹ Pumps are prescribed mainly to people with type 1 diabetes.⁶
  - Glucometers are limited to one per family, distributed every five years.¹

From the survey
- The majority of people with diabetes reported no difficulties obtaining their diabetes medicines and devices.
- Education and information about treatment was almost universal among the people with diabetes surveyed but far less frequent among their relatives.
- The disproportionately low number of respondents with a type of diabetes other than type 1 diabetes makes it difficult to discuss access for the entire diabetes population.
No difficulties were reported regarding accessibility, suggesting that accessibility is not the main barrier to medicines and medical devices for people living with diabetes in Luxembourg.5

Insulin and anti-diabetes medication Free/Fully reimbursed1,6,10
Medication for hypoglycaemia Free/Fully reimbursed5
Pens and related supplies Free/Fully reimbursed1,6
Syringes and needles Free/Fully reimbursed1,6
Pumps and related supplies Free/Fully reimbursed (see Availability for criteria)1,6
Blood glucose test strips Free/Fully reimbursed1,6
Glucometers Only people on insulin receive these free of charge (see Availability for criteria)5
Ketone test strips Only urine test strips are fully reimbursed5

Please note that the information above presents only a summary of the reimbursement system and may not apply to individual cases.

Financial coverage

Decisions over reimbursement are made by the Committee of Health Insurance Funds.7
A reference price for reimbursement was introduced in 20108 leading to shortfalls on the retail price, which are now paid out-of-pocket by people with diabetes.6

<table>
<thead>
<tr>
<th>Product</th>
<th>Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin and anti-diabetes medication</td>
<td>Free/Fully reimbursed1,6,10</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free/Fully reimbursed5</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free/Fully reimbursed1,6</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free/Fully reimbursed1,6</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free/Fully reimbursed1,6</td>
</tr>
<tr>
<td>Blood glucose test strips</td>
<td>Free/Fully reimbursed1,6</td>
</tr>
<tr>
<td>Glucometers</td>
<td>Only people on insulin receive these free of change (see Availability for criteria)5 Otherwise, not covered – 100% paid for by the person with diabetes6</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Only urine test strips are fully reimbursed5 Some other supplies may be donated to certain categories of people Otherwise, not covered — 100% paid for by the person with diabetes6</td>
</tr>
</tbody>
</table>

Looking ahead

The policy promoting low-priced products across the Luxembourgian health system which has been recently implemented, is likely to be strengthened and more developed in the coming years.6

References
1 EURADA, FENO, IDE, & PCDE. (2011)
2 Global health observatory data repository. (2013)
3 Consbruck, R. (2009)
4 PPRI. (2007)
5 IDF-Europe Access survey (2013)
6 Association Luxembourgeoise du diabète (personal communication) (2013)
7 Système et politique de santé. (2013)
8 Luxembourg Government. (2010)
9 Institutions de sécurité social luxembourgeoise. (2013)
10 Liste positive des médicaments. (2013)
**Healthcare expenditure profile (2011)**

Total health expenditure per capita: **USD 5,994.99**

Proportion of government expenditure on health: **20.6%**

**Health system overview**
- The mandatory health insurance system is administered by private insurance companies and covers almost the whole population.
- The basic package of benefits is defined by the government but insurers can offer additional benefits.
- Medicines and medical devices are supplied by private actors, according to government’s regulations — and in line with EU regulation. Specialised agencies ensure the application of those regulations.
- Supply channels for medical devices are also affected by the contracts between health insurers and suppliers.
- A quality issues reporting system is in place.

**Diabetes prevalence**

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
</table>

**Diabetes care procedure**
- Diabetes supplies are prescribed by physicians and diabetes nurses.
- Diabetes nurses and pharmacists are the main points of diabetes information and advice.
- Diabetes medicines are dispensed mostly at pharmacies. Medical devices are dispensed through various outlets depending on the different health insurers’ contracts with providers.
- A quality issues reporting system is in place.

**Key background information: country health system**

- The majority of people with diabetes did not report any difficulties obtaining their diabetes medicines and devices.
  - However, the range of products available to individual people is strongly influenced by their health insurers.
  - A small number of stock issues were reported, principally affecting medical devices, which were resolved within a few days.
  - People report no obligation to pay for most of their medicines but some payments are required for testing devices.
- The provision of diabetes education and information about treatment was almost universal among the people with diabetes surveyed but much less common among their relatives.
- The low number of respondents with diabetes other than type 1 diabetes makes it difficult to discuss access for these groups, including those with type 2 diabetes.

**Guidelines and specific prescription criteria**
- The Netherlands has guidelines for diabetes care.
- Certain devices, such as glucometers, can be prescribed by diabetes nurses.
- Prescribing is influenced by the health insurances (see also Affordability): a list of preferred medicines is issued by each health insurance company.
- Reimbursement is also a mean to contain prescription and use of medicines and medical devices (see Affordability).

**Use**
- The survey found that of the people on insulin, more were treated with human insulin than with analogues, and that pens are the most widely used insulin injection devices.
The available evidence suggests that accessibility is not a major barrier to medicines and medical devices for people living with diabetes.5

- However, as mentioned above, some stocks issues were reported, mainly affecting medical devices:5
  - Users of one brand of pump supplies were forced to switch to another brand due to shortages of pumps supplies for this particular brand.6

Insulin and anti-diabetes medication Free/Fully reimbursed1,5
Medication for hypoglycaemia Depending on the medicine, free/fully reimbursed or not covered5
Pens and related supplies Free/Fully reimbursed1,5
Syringes and needles Free/Fully reimbursed1,5
Pumps and related supplies Free/Fully reimbursed1,5
Blood glucose test strips and meters Free of charge only to people on insulin – limited number of strips
  Otherwise, not covered – 100% paid for by the person with diabetes 5,6
Ketone test strips Free of charge only to people with type 1 diabetes
  Otherwise, not covered – 100% paid for by the person with diabetes5,6

Please note that the information above presents only a summary of the reimbursement system and may not apply to individual cases.

References
1  EURADA, FEND, IDF, & PCDE. (2011).
2  Global health observatory data repository. (2013)
3  Schäfer, W. et al. (2010)
4  PPRI & WHO (2011)
5  IDF-Europe Access survey (2013)
6  Diabetes Vereniging Nederland (personal communication) (2013)
7  Dutch Ministry of Public Health & PPRI. (2013)

Looking ahead
The Netherlands’ Diabetes Association worries that further criteria will be applied to the prescription of diabetes medicines and medical devices. Certain new technologies not included in this survey are already submitted to such criteria.8

Additionally, latest therapies are also about to be re-evaluate, which may impact their reimbursement by health insurances.9

Financial coverage
The Ministry of Health, advised by the specialised independent body responsible for health insurance, makes decisions on reimbursement. For medicines, this is based on medical, therapeutic and pharmacoeconomic criteria.4 Depending on the results of this evaluation, medicines are either fully reimbursed, reimbursed up to a maximum price set through internal reference pricing, or not reimbursed (with the basic insurance package). The reimbursement process is managed by each person’s health insurance company.5

The table below only represents reimbursement levels included in the basic health package. However, some people may benefit from more comprehensive coverage, depending on their insurers.5,5

<table>
<thead>
<tr>
<th>Item</th>
<th>Financial coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin and anti-diabetes medication</td>
<td>Free/Fully reimbursed1,5</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Depending on the medicine, free/fully reimbursed or not covered5</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free/Fully reimbursed1,5</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free/Fully reimbursed1,5</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free/Fully reimbursed1,5</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Free of charge only to people on insulin – limited number of strips</td>
</tr>
<tr>
<td></td>
<td>Otherwise, not covered – 100% paid for by the person with diabetes 5,6</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free of charge only to people with type 1 diabetes</td>
</tr>
<tr>
<td></td>
<td>Otherwise, not covered – 100% paid for by the person with diabetes5,6</td>
</tr>
</tbody>
</table>

Please note that the information above presents only a summary of the reimbursement system and may not apply to individual cases.
About the data
We were not able to collect a large number of responses in this country. Thus, the information presented below is based mainly on a review of the literature and exchanges with the national diabetes association.

Healthcare expenditure profile (2011)\(^2\)
Total health expenditure per capita: **USD 8,987.26**
Proportion of government expenditure on health: **17.7%**

Health system overview
- The mandatory health insurance, administered by the National Insurance Scheme (NIS), covers all residents.\(^3\,7\)
- Healthcare provision is the responsibility of local authorities.\(^7\)
- Medicines and medical devices are supplied by private actors, regulated and controlled by specialised agencies.\(^7\,8\,9\) Norway recognises EU regulations regarding medicines and medical devices.
- A quality issues reporting system is in place.\(^6\)

Key diabetes data

### Diabetes prevalence\(^1\)

<table>
<thead>
<tr>
<th></th>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5.9% of 20-79 year-olds (2011)</strong></td>
<td><strong>Official estimates: 192 000 people</strong> Including ≈ 20% people with type 1 diabetes (2006 rate)</td>
<td></td>
</tr>
</tbody>
</table>

### Diabetes care procedure
- Prescription are provided by GPs and specialists, who also function as the main points of diabetes information and advice.\(^6\)
- Diabetes products are dispensed mainly at pharmacies.\(^5\,8\)

Out-of-pocket expenditure represents 94.6% of private spending on health

Presence of products at national level
- At least one product from each of the categories surveyed was reported authorised for sale and present in the country.\(^1\,8\)

Guidelines and specific prescription criteria
- Norway has national guidelines for diabetes care.\(^1\)
- Newer medications are subject to specific prescription criteria.\(^7\)

Use
- Patterns of use could not be assessed
No issues were reported concerning access to treatment, or regarding stocks of diabetes supplies.

**Financial coverage**

For medicines, the Norwegian Medicine Agency decides on eligibility for reimbursement. Only medications for chronic or long-term illnesses are reimbursed. As well as an assessment of their therapeutic use, a cost-effectiveness analysis of all drugs is compulsory in the reimbursement process. Medicines are reimbursed only for specific indications.

<table>
<thead>
<tr>
<th>Item</th>
<th>Reimbursement Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin and anti-diabetes medication</td>
<td>Fully or partially reimbursed¹,⁵,⁶</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Fully or partially reimbursed¹,⁵,⁶</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Fully or partially reimbursed¹,⁵,⁶</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Fully or partially reimbursed¹,⁵,⁶</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Fully reimbursed¹</td>
</tr>
<tr>
<td>Blood glucose test strips</td>
<td>Fully or partially reimbursed¹,⁵,⁶</td>
</tr>
<tr>
<td>Glucometers</td>
<td>Not covered — 100% paid for by the person with diabetes⁵</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Fully reimbursed¹,⁵</td>
</tr>
</tbody>
</table>

Please note that the information above presents only a summary of the reimbursement system and may not apply to individual cases.

**References**

1. EURADIA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
4. PPRI & WHO (2011)
5. IDF-Europe Access survey (2013)
7. Festøy, H. et al. (2011)
**Healthcare expenditure profile (2011)**
Total health expenditure per capita: **USD 5,330.77**
Proportion of government expenditure on health: **14.8%**

**Health system overview**
- In the Swedish National Health System, responsibility for healthcare is shared between the national, regional and local authorities.
- Medicines and medical devices are provided through a mixed system: most pharmacies and healthcare facilities are state-owned but supplied by private actors.
- Both sectors have to comply with Ministry of Health and Social Affairs policy – in line with EU regulation.
- A number of quality-monitoring and control systems are in place.

**Diabetes prevalence (2011)**
<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.7% of 20-79 year-olds</td>
<td>National estimates: 2% to 4.5%</td>
</tr>
</tbody>
</table>

**Diabetes care procedure**
- Prescriptions are provided by a diabetes nurse, who is also the main point of diabetes information and advice.
- Diabetes medicines are dispensed mostly at pharmacies. Medical devices are also dispensed at pharmacies but can also be obtained at healthcare facilities or sent directly at home.

**Presence of products at national level**
- At least one product from each of the categories surveyed was reported authorised for sale and present in the country.

**Guidelines and specific prescription criteria**
- Sweden has national guidelines for diabetes care.
  - However, implementation depends on regional authorities, and varies from one region to another (see Accessibility).

**Use**
- People on insulin seem to use primarily human insulin.
- Pens remain the most widely used insulin injection device. Pumps are prescribed mainly to people with type 1 diabetes who are not meeting their treatment targets with regular insulin therapy.
- The use of self-monitoring devices seems to be higher among people with type 1 diabetes than among people with other types of diabetes.

**From the survey**
- Very few of the respondents reported having had difficulties obtaining their diabetes supplies within the last two years.
- The provision of diabetes education and information about treatment was almost universal among the people with diabetes surveyed but far less frequent among their relatives.
- Most of respondents reported not having to pay for their diabetes supplies.
- The very low number of respondents with diabetes other than type 1 diabetes makes it difficult to discuss access for all people with diabetes.
- No significant differences in access issues were reported between urban respondents and those living further from healthcare providers. Differences between administrative regions could not be assessed through this survey.
The implementation of guidelines and the range of products available to people with diabetes vary between regions. Some regions have chosen to apply further criteria to the prescription of glucose test strips, making them less easily accessible, especially for people with type 2 diabetes. Financial responsibility for insulin pumps was recently given to the regions. The Swedish Diabetes association fears that such additional criteria or new quotas may also be applied to these devices, and has been challenging this decision. Certain regions negotiate procurement contracts with their chosen suppliers. The number and types of brands available for each category of products thus vary from one region to another.

### Accessibility

- According to collected responses, the majority of people with diabetes do not make out-of-pocket payments to pay for their diabetes supplies.
  - Additionally, upper limits have been placed on co-payments for partially reimbursed medicines and devices: SEK 2200 (USD 330) and SEK 2000 (USD 300) per 12-month period.
  - Pharmacies are obliged to offer the lowest-price brand for prescription medicines.
- Some non-branded supplies seem to be available. The choice of brand is conditioned primarily by regional procurement (see Accessibility) and, to a lesser extent, the healthcare professional’s advice.
- The prices of reimbursed products are constrained by the cost-effectiveness analysis carried out for reimbursement. Distributors’ margins are negotiated with the manufacturer. The mark-ups made by pharmacies are regulated though a mixed system of flat and regressive fees, and a 25% VAT is applied.

### Affordability

Reimbursement in Sweden follows three main principles: equality, solidarity (more severe conditions are given priority), and cost-effectiveness. A national agency decides on eligibility of supplies for reimbursement. The decision primarily relies on a cost-effectiveness analysis. Reimbursement of medicines is based on the lowest-priced medicines in each group. For products that are partially reimbursed, reimbursement is not based on a fixed rate per product but on individual progressive expenditure levels per year: the higher the expenditure, the larger the reimbursement.

<table>
<thead>
<tr>
<th>Product</th>
<th>Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>Free</td>
</tr>
<tr>
<td>Anti-diabetic medication</td>
<td>Free or partially reimbursed</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free or partially reimbursed</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free</td>
</tr>
<tr>
<td>Blood glucose test strips</td>
<td>Free (see Accessibility)</td>
</tr>
<tr>
<td>Glucometers</td>
<td>Free or partially reimbursed</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free</td>
</tr>
</tbody>
</table>

*Please note that the information above presents only a summary of the reimbursement system and may not apply to individual cases.*

### Financial coverage

Reimbursement in Sweden follows three main principles: equality, solidarity (more severe conditions are given priority), and cost-effectiveness. A national agency decides on eligibility of supplies for reimbursement. The decision primarily relies on a cost-effectiveness analysis. Reimbursement of medicines is based on the lowest-priced medicines in each group. For products that are partially reimbursed, reimbursement is not based on a fixed rate per product but on individual progressive expenditure levels per year: the higher the expenditure, the larger the reimbursement.

### Looking ahead

The Supreme Administrative Court is to announce its decision regarding the re-classification of insulin pumps into the regional budgets. As further products are added to regional and local health budgets, further limitations to access may arise. The Swedish Diabetes Association fears that companies may lose interest in the Swedish market, and choose to delay or cancel the launch of new products in Sweden.

### References

1. EURADIA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
5. IDF-Europe Access survey (2013)
8. Apoteket (2013)
**Key diabetes data**

- **Diabetes prevalence (2011)**
  - **IDF Atlas National Data:**
    - 7.4% of 20-79 year-olds
  - No official data
  - National experts’ estimate: 5-6% of the population

- **Diabetes care procedure**
  - Prescriptions for people with type 2 diabetes are provided by a GP; endocrinologists prescribe for people with type 1 diabetes.
  - GPs, diabetes specialists, diabetes nurses and diabetes associations are the main source of diabetes information and advice.
  - Diabetes products are dispensed mainly at pharmacies and also at healthcare centres, hospitals and diabetes associations.

**Key background information: country health system**

- **Healthcare expenditure profile (2011)**
  - Total health expenditure per capita: **USD 9,120.81**
  - Proportion of government expenditure on health: **21%**

- **Health system overview**
  - Switzerland’s mandatory health insurance is administered by multiple public and private companies, and covers the entire population.
  - The main care package is defined by law at the federal level. However, implementation is the responsibility of each region.
  - The Federal Medicines Agency and the federal government share responsibility for authorising and licensing medicines and medical devices.
  - To facilitate pharmaceutical and medical device trade, an agreement allows for the mutual recognition of authorisation for medical devices, and of some certifications on the quality of medicines delivered by members of the European Economic Area. Once authorised, medicines and medical devices are supplied principally by private actors, according to federal government regulations and under the joint supervision of central and regional governments.
  - A quality issues reporting system is in place.

- **Availability**
  - At least one product from each of the surveyed categories was reported authorised for sale and effectively present in Switzerland.

- **Guidelines and specific prescription criteria**
  - Switzerland has guidelines for diabetes care. However, individual healthcare facilities seem to have some autonomy in terms of prescribing practices.
  - Certain medications – especially newer medicines – can be prescribed only by a specialist and/or only as a second- or a third-line treatment.
  - The consumption and prescription of medical devices is constrained by reimbursement (see Affordability).

- **Use**
  - Most people on insulin use insulin analogues, medication against hypoglycaemia and insulin pens. Insulin pumps are prescribed primarily to people with type 1 diabetes and their uptake varies from one diabetes centre to another.
  - The use of oral medication for people with diabetes other than type 2 diabetes is limited.
  - Although oral medication can be used to treat women with gestational diabetes, lifestyle change is the therapy of choice — then insulin if the behavioural intervention fails.
  - Self-monitoring devices can be prescribed to all people with diabetes but the quantity of consumables is limited by the reimbursement given by the health insurer.

**From the survey**

- Very few respondents reported difficulties accessing diabetes supplies.
  - Although some fees apply to all diabetes products, this was not identified as a major issue by respondents or the Swiss Diabetes Association.
  - Diabetes education and information about treatment was received almost universally among people with diabetes surveyed but was far less frequent among their relatives.

**Diabetes prevalence (2011)**

<table>
<thead>
<tr>
<th></th>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.4% of 20-79 year-olds</td>
<td>No official data</td>
<td>National experts’ estimate: 5-6% of the population</td>
</tr>
</tbody>
</table>

**Diabetes care procedure**

- Prescriptions for people with type 2 diabetes are provided by a GP; endocrinologists prescribe for people with type 1 diabetes.
- GPs, diabetes specialists, diabetes nurses and diabetes associations are the main source of diabetes information and advice.
- Diabetes products are dispensed mainly at pharmacies and also at healthcare centres, hospitals and diabetes associations.
The available evidence suggests that for people living with diabetes accessibility is not the main barrier to obtaining medicines and medical devices.1,4

- Although some stock issues due to delays at the manufacturer or wholesalers levels may affect specific products,6,9 alternatives can be offered to people with diabetes in order that their treatment is not impacted upon by these difficulties.6

### Financial coverage

The Federal Office for Public Health decides on reimbursement, according to efficacy, indications and cost-effectiveness.1 Although all the surveyed products are on the list of fully reimbursed products (see also Availability), a fee is applied to all diabetes medicines and medical devices.6 Reimbursements are made by the health insurance companies.

The table below presents only coverage offered by the basic care package without taking into account additional coverage through complementary health insurance.

| Product                        | Coverage
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin and anti-diabetes medication</td>
<td>Free5 but fees apply2,6</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free but fees apply3,6</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free5 but fees apply and a limit on needles may also apply2,6</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free but fees apply2,6</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free5 but fees apply2,6</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Free but fees apply2,6 – limit of 400 per year for people who are not on insulin2,6</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free but fees apply2,6</td>
</tr>
</tbody>
</table>

Please note that the information above presents only a summary of the reimbursement system and may not apply to individual cases.

### References

1 EURADA, FEND, IDF, & PCDE. (2011)
2 Global health observatory data repository. (2013)
3 “Prestations” (2012)
5 IDF-Europe Access survey (2013)
6 Swiss Diabetes Association (personal communication) (2013)
8 Huber C. (personal communication) (2013)
Diabetes prevalence

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
</table>

Health system overview
- The National Health Service (NHS) covers all residents.\(^1\)\(^4\)
- The care package is defined by the Ministry of Health of each nation (England, Scotland, Wales, Northern Ireland), and their regional representatives.\(^1\)\(^4\)
- Most medicines and medical devices are provided by private actors, according to Ministry of Health regulations — and in line with EU regulations.\(^3\) A specialised agency ensures the application of these regulations across all UK nations.\(^3\)\(^4\)\(^9\)
- A quality issues reporting system is in place.\(^3\)\(^4\)

Guidelines and specific prescription criteria
- The UK has national guidelines for the treatment of diabetes,\(^1\) developed by specialised bodies, such as the National Institute for Health and Clinical Excellence in England and Wales and the Scottish Medicines Consortium.\(^3\) However, recommendations may vary from one agency to another, and as a result, from one nation to another.\(^6\)
- Current guidelines recommend the use of newer medications, including insulin analogues and DPP4-inhibitors, mainly as second- or third-line treatment.\(^5\)\(^6\)
- Ketone test strips and medication for hypoglycaemia seem to be prescribed to certain categories of people on insulin (children, people with severe hypoglycaemia).\(^5\)\(^6\)
- The prescription of blood glucose test strips was redefined recently: test strips are provided primarily to people on insulin and/or during pregnancy. The prescription of test strips to people on oral medication depends on their doctor’s assessment. Rationing has been reported at the prescriber level (see Accessibility).\(^6\)
- Insulin pumps are prescribed primarily to people with type 1 diabetes, mainly children under 12, or children over 12 who are failing to reach their treatment targets with conventional insulin therapy, according to national guidelines.\(^6\)

Use
- Pens are the most widely used insulin injection device.\(^5\)\(^6\) Although many survey respondents reported using a pump,\(^3\) the use of these remains limited.\(^4\) In Scotland and Northern Ireland, funds have been created to support the uptake of pump therapy among children.\(^6\) However, this uptake is also limited by the lack of staff trained to use this technology.\(^6\)
- Metformin and sulphonylureas seem to be the most widely used oral medications for people with type 2 diabetes.\(^5\)\(^6\) It is estimated that about 30% of people with type 2 diabetes will be moved by their healthcare team to insulin therapy.\(^6\)
- The use of oral medication for gestational diabetes remains limited. This type of diabetes is primarily treated with lifestyle changes and close monitoring of blood glucose or insulin therapy.\(^4\)
**UNITED KINGDOM**

**Accessibility**

**Access to treatment**
- Due to budgetary constraints, local NHS services in England seem to be restricting the prescription of blood glucose test strips further than what the national guidelines recommend. Restrictions — and consequently, access — to these devices vary locally.
  - A recent survey by Diabetes UK found that 39% of people using self-monitoring devices reported being refused a prescription of blood glucose test strips, or having their prescription restricted — people with type 1 diabetes and people with type 2 diabetes alike.7

**Stock and shortages**
- People with diabetes find alternative for supplies, including going to their diabetes association to lobby on their behalf 5 or adapting their treatment regimen. 6 However, changing supplies can be an important source of stress for people with diabetes who seem to be reluctant to do so, leading to stock-piling behaviours.6
- Pressure on the supply chain and reductions in levels of stock have been cited as possible explanations for this situation.6,10

**Financial coverage**

Reimbursement is decided by specific bodies within the Department of Health, based on the recommendations of specialised bodies (NICE in England and Wales).9 Most products covered by the NHS are provided free of charge on prescription (see also Availability for criteria).2

<table>
<thead>
<tr>
<th>Supply Type</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin and anti-diabetes medication</td>
<td>Free1,5,6</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Some categories of people can get them free of charge, otherwise, not covered1,4</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free1,5,6</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free1,5,6</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free1,5,6</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Free for people with type 1 diabetes (see also Availability); otherwise, not covered1,6</td>
</tr>
<tr>
<td>Glucometers</td>
<td>Not covered by NHS, some donated by companies1,4</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free1,5</td>
</tr>
</tbody>
</table>

*Please note that the information above presents only a summary of the reimbursement system and may not apply to individual cases.*

**Affordability**

- According to collected responses, the majority of people with diabetes do not make out-of-pocket payments to pay for their diabetes supplies.
  - People with diabetes on insulin or oral medications are exempt from the prescription fee of GBP 7.85 (USD 12) but must apply for an exemption certificate to benefit from this.6
  - Despite NHS coverage, a 2013 survey from the pharmaceutical industry showed that 43% people with type 2 diabetes could not afford their blood glucose testing devices, while 28% could not afford their medication.8
- Although the availability and use of non-branded products are limited to certain categories of product only,9 there is a strong political will to support the development, marketing and use of such products (especially in the field of insulin).6
- Only supplies covered by NHS have their prices controlled. The pricing of branded medicines is negotiated between manufacturers and the NHS, with limits placed on the profits they can make. Maximum prices and amounts paid to dispensers are set for generic medicines covered by NHS. The price of medical devices is negotiated with manufacturers. Mark-ups applied by wholesalers and pharmacies are not regulated; these are negotiated between players involved in the supply chain, and are constrained by coverage offered by the NHS. Prescription medicines are exempt from VAT.9

**Looking ahead**

Costs and budget constraints are high on the political agenda. New pricing methods for medicines are also under discussion. Both raise concern as to the extent they may reduce people’s access to free diabetes products and new technologies.6

**References**

1. EURADIA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
5. IDF-Europe Access survey (2013)
7. Diabetes UK. (2013a)
9. PPRI & WHO (2011)
10. PCEU/GPUE. (2012)
SOUTH-WEST EUROPE
From the survey
- The very low number of respondents who are not treated with insulin made it difficult to assess access for these people.
- Diabetes education and information about treatment was universal among the people with diabetes surveyed but far less common among their relatives.
- Based on collected responses and discussions with the Croatian Diabetes Association, it appears that the main obstacle to access to medicines and devices is the rationing of diabetes products subsidised by the health insurance scheme.

Healthcare expenditure profile (2011)\(^2\)

Total health expenditure per capita: **USD 1,137.30**
Proportion of government expenditure on health: **17.7%**

Health System Overview
- Croatia’s mandatory health insurance scheme, administered by the Croatian Health Insurance Institute\(^8\) covers all citizens.\(^3\) Croatians are encouraged to purchase complementary health insurance to cover co-payments necessary for most health services.\(^3,6\)
- The package of benefits covered is defined by law.\(^3\)
- Most medicines and medical devices are supplied by private actors,\(^5\) according to the Ministry of Health and Social Welfare regulations – in line with EU regulations. The Ministry and a specialised agency share responsibility for the application of these regulations.\(^7,8\)
- A quality issues reporting system is in place.\(^5,6\)

Diabetes prevalence\(^1\)

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.6% of 20-79 year-olds (2011)</td>
<td>Official records: 9.2% of 20-79 years</td>
</tr>
<tr>
<td>6.1% of people of working age (2010)</td>
<td></td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions provided by GPs (or paediatricians), according to a treatment regimen defined by a diabetologist.\(^6\)
- These healthcare professionals are also the main points of diabetes information and advice.\(^6\)
- Diabetes products dispensed mostly at pharmacies, except pumps, which are dispensed at hospitals.\(^6\)

Key diabetes data

<table>
<thead>
<tr>
<th>Key background information: country health system</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Key diabetes data</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Availability</th>
</tr>
</thead>
</table>

Presence of products at national level
- At least one product from each of the categories surveyed appeared to be authorised for sale and present in the country.\(^5\)

Guidelines and specific prescription criteria
- Croatia has guidelines for diabetes care.\(^1\)
- It seems that, apart from insulin pumps, the prescription of most diabetes products is left to the judgement of the prescriber.\(^5\)
  - The few insulin pumps available (see below) are primarily given to children and pregnant women.\(^5\)
  - The use and prescription of diabetes medicines and devices is closely related to reimbursement (see Affordability).\(^5\)

Use
- Based on collected responses, it would appear that most of the people on insulin are using insulin analogues and insulin pens.\(^1\)
  - The use of insulin pumps remains limited. No part of the national budget is allocated to pumps, so their financing is dependent on the budget of each individual healthcare facility.\(^4\)
  - Because of these budget constraints, pumps are more widely offered in the capital city than in other areas.\(^6\)
- The main treatment for other people with diabetes could not be determined.
The available evidence suggests that for people living with diabetes accessibility is not the main barrier to obtaining diabetes supplies; no particular difficulties were reported in this regard.\(^5\,6\)

<table>
<thead>
<tr>
<th>Product</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>Free(^1,5,6)</td>
</tr>
<tr>
<td>Anti-diabetes medication</td>
<td>Depending on the medicine, free or partially covered(^1)</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free(^2)</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free(^3)</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free(^2)</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free for the first pump (see availability for criteria)(^4), the quantity of supplies is limited. The replacement of this first pump is paid by the person with diabetes at a subsidised price(^6)</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Free but the number of strips is limited according to age, treatment regimen and type of diabetes (from 50 to 1,000 per 6 months)(^3)</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free(^1)</td>
</tr>
</tbody>
</table>

Please note that the information provided above is only a summary of the reimbursement system and may not apply to individual cases.

Looking ahead

The financial situation of the Croatian Health Insurance Institute has led to fears of the Croatian Diabetes Association that further rationing may be applied to reimbursed diabetes supplies, starting with consumables (such as test strips and sharps). However, good relations and regular exchanges between diabetes organisations and the Croatian Health Insurance Institute enable these associations to express and discuss these concerns before changes come into effect.\(^5\)

References

1. EURADA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
4. PPRI & WHO (2011)
5. IDF-Europe Access survey (2013)
Healthcare expenditure profile (2011)²
Total health expenditure per capita: **USD 2,123.20**
Proportion of government expenditure on health: **6.9%**

Health system overview
- About 80% of the population has access to state-financed, public healthcare free of charge; others have to pay a fee or rely on the private healthcare sector.² Eligibility to free or discounted public healthcare depends on citizenship and socioeconomic criteria (number of children, income, employment, disability or chronic conditions). The package of services available to the different categories is defined by the Ministry of Health.³
- Medicines and devices funded by the state are procured centrally by the Ministry of Health via tender and supplied through the public sector.⁴,⁵ Other products are supplied by private actors, according to the Ministry of Health regulations (and the Ministry of Commerce regulation for medical devices), in line with EU regulation. A specialised agency and the Ministry of Health pharmaceutical services share responsibility for the application of those regulations.³,⁴
- A system is in place for reporting quality issues.⁵,⁶

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th>IDFAxis</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.1% of 20-79 year-olds</td>
<td>Official records: <strong>6.8%</strong> of the adult population</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are provided by GPs.⁶
- GPs represent the main points of diabetes information and advice.⁶
- Publicly provided diabetes products are dispensed at public hospitals; others are dispensed by private pharmacies.⁵,⁶

From the survey
- Based on collected responses and discussions with the Cyprus Diabetic Association, access to diabetes medicines and medical devices appears to have been protected from austerity measures so far.
- Some stock issues were reported but did not seem to interrupt treatment among people with diabetes.
- The current public financial coverage for diabetes products appears to liberate people with diabetes from having to make regular out-of-pocket expenditure for their medicines and most of their medical devices. However, this scheme has yet to be extended to the entire population and the list of covered products is limited.

Presence of products at national level
- At least one product from each of the categories surveyed was reported authorised for sale and effectively present in the country.¹,⁵,⁶

Guidelines and specific prescription criteria
- Cyprus has guidelines for diabetes care.¹,⁵
- The consumption and prescription of diabetes products are constrained by the list of publicly provided products and public tenders.⁵,⁶ No other specific criteria appear to be applied.⁶,⁶

Use
- Pens are the main insulin injection devices.¹
- Although a DPP4-inhibitor and a sulphonylurea were recently added to the list of publicly provided products,¹,⁶ their availability appears to be limited or awareness of their availability is low.¹
Although some accessibility issues were reported, they do not appear to have significant negative effects on people’s treatment.

- A few stock issues were reported but appeared to be resolved within a few days. Delays in order and supply as well as budgetary difficulties at the healthcare facility level have been mentioned as potential explanations for this situation.
- Some difficulties in getting to the point of dispensation have been reported but could not be confirmed by the Cyprus Diabetic Association.

### Financial coverage

Like most people with chronic diseases, people with diabetes are entitled to free, state-funded medical treatment delivered at public hospitals. The decision to include a given product on the list of publicly provided products is made by the Ministry of Health, according to the Council of Europe’s guidelines, or in response to a request made by public healthcare providers.

<table>
<thead>
<tr>
<th>Product Type</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>Free</td>
</tr>
<tr>
<td>Anti-diabetes medication</td>
<td>Mostly free — if included in the hospital formulary. If not included, 100% costs are paid for by the person with diabetes.</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free</td>
</tr>
<tr>
<td>Blood glucose test strips</td>
<td>Free</td>
</tr>
<tr>
<td>Glucometers</td>
<td>Not covered — 100% paid for by the person with diabetes. Associations may offer equipment at reduced prices.</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

### References

1. EURADA, FEND, IDF & PCDE. (2011)
2. Global health observatory data repository. (2013)
3. Theodorou, M., Charalambous, C., Petrou, C., Cylus, J. (2012)
4. PPRI & WHO (2011)
5. IDF-Europe Access survey (2013)
Healthcare expenditure profile (2011)\(^2\)

Total health expenditure per capita: **USD 2,864.20**

Proportion of government expenditure on health: **13.2%**

**Health system overview**

- The Greek population is covered by both the National Health Services and mandatory Health Insurance, administered by multiple health insurance funds.\(^3\)
- The Ministry of Health and Social Solidarity defines the services offered by the National Health Services\(^3\) while the services covered by health insurances have been harmonised over the last years.\(^6\)
- Most medicines and medical devices are supplied by private actors,\(^5,7\) according to the Ministry of Health and Social Solidarity regulations – in line with EU regulations. Different public organisations under the Ministry's authority ensure that these regulations are applied.\(^3\)
- A quality issues reporting system is in place.\(^5\)

**Diabetes prevalence\(^1\)**

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>7% of 20-79 year-olds (2011)</td>
<td>Official records: 10% of the population - An additional 20% of the population have impaired glucose tolerance (2008)</td>
</tr>
</tbody>
</table>

**Diabetes care procedure**

- Prescriptions are provided by diabetes clinicians or GPs depending on who made the initial diagnosis.\(^6\)
- Prescribers and, in the case of medical devices, manufacturers are the main points of diabetes information and advice.\(^6\)
- Diabetes products are mostly dispensed at pharmacies. Public hospitals are allowed to dispense diabetes products in some cases.\(^3,5,6\)

**Guidelines and specific prescription criteria**

- Greece has guidelines for diabetes care.\(^1\)
- The consumption and prescription of diabetes medicines and medical devices is closely related to reimbursement (see Affordability).\(^6\)
- The choice of diabetes product tends to be left to the judgement of the prescriber.\(^5\)
- However, the prescription of certain medical devices, such as insulin pumps or additional blood glucose test strips, requires the approval of a medical committee.\(^6\)

**Use**

- According to our survey responses, it seems that most of the people treated with insulin are using insulin analogues and insulin pens.\(^5\)
- The main treatment for people with other types of diabetes could not be assessed.
**Access to treatment**
- Access to prescribers has been hampered by the budget cuts affecting healthcare facilities, resources and personnel.
- Diabetes products have apparently not been as affected by out-of-stock issues to the same degree as other medicines and medical devices in Greece.
  - People with diabetes can easily switch from one brand to another if necessary and/or acquire emergency supplies from a diabetes association or specialist centres.
  - To avoid shortages due to parallel exports, these have to be reported quarterly to the Ministry of Health, and suppliers are required to ensure sufficient supply for national needs, plus a safety margin.
- Although coverage for diabetes products has been protected to date, the current economic crisis is directly affecting people’s capacity to afford their treatment.
  - People who are not covered by a health insurance fund can receive their medicines and medical devices free of charge at public hospitals.
  - Based on collected responses, it appears that many people with type 1 diabetes have their medicines and medical devices fully covered by health insurance. However, people with type 2 diabetes have to pay 25% of their medicines and face additional rationing of self-monitoring devices.
  - Many people with type 2 diabetes are encountering difficulties paying for their treatment. A 2013 survey from the pharmaceutical industry among people with type 2 diabetes found that 25% of them could not afford their medication and almost 30% could not afford their blood glucose-testing devices.
  - Additionally, certain medical devices (such as needles or insulin pumps) must be paid for in advance by people with diabetes before being reimbursed. Delays in receiving reimbursements from insurance funds is, in some cases, leading to financial difficulties and, consequently, some disruptions in treatment.
- It appears that mainly branded products are available on the market.
  - Survey respondents reported that their choice of brand was influenced largely by their doctor.
  - Responsibility for pricing was recently taken up by the Ministry of Health. The prices of all reimbursed diabetes products appear to be regulated. For medicines qualifying for reimbursement, the price is based on external reference pricing. Maximum mark-ups are applied to wholesalers and pharmacists while an additional rebate is granted on medicines purchased by hospitals. The current VAT rate applied to medicines is 6.5%.
  - With the economic crisis, Greece has been among the EU countries bringing the highest number of changes to its pharmaceutical policy: the price of medicines and the wholesalers’ margins have been cut; VAT rates have changed several times; a list of medicines explicitly excluded from reimbursement was reintroduced.
  - The prices of medicines in Greece in general are considered lower than in other EU countries.

**Financial coverage**
Any decision regarding reimbursement is made by the Ministry of Health. Co-payments vary according to the condition treated and the person’s income. For medicines, levels of reimbursement are based on a reference price (internal reference pricing). All reimbursements are carried out by health insurance funds.

<table>
<thead>
<tr>
<th>Medicine Type</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>Free</td>
</tr>
<tr>
<td>Anti-diabetes medication</td>
<td>Partially reimbursed</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free only to people treated with insulin Otherwise, not covered – 100% paid for by the person with diabetes</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Pens are donated by companies. Supplies are fully reimbursed</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Fully reimbursed</td>
</tr>
<tr>
<td>Blood glucose test strips</td>
<td>Free but the number of strips covered is limited according to the person’s type of diabetes</td>
</tr>
<tr>
<td>Glucometers</td>
<td>Not covered by the system but donated by companies</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free</td>
</tr>
</tbody>
</table>

Please note that the information provided above is not complete and may not apply to individual cases.

**Looking ahead**
The current status of diabetes care should not undergo any major changes in the immediate future. However, this will depend strongly on the evolution of Greece’s economy.

**References**
1. EURADA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
4. PPRI & WHO (2011)
5. IDF-Europe Access survey (2013)
10. One in three diabetics cuts insulin pump (2013, April 16)
From the survey
- Based on collected responses and discussions with the Italian Diabetes Association ANIAD, it appears that the impact of the economic crisis on individuals, institutions and wider society is a growing barrier to access to medicines and medical devices (see Affordability).
- Although a majority of surveyed people with diabetes reported having received education or information about treatment, this training is not yet universal and education is far less common among their relatives.

**Healthcare expenditure profile (2011)**

Total health expenditure per capita: **USD 3,435.6**

Proportion of government expenditure on health: **14.7%**

**Health system overview**

- Italy’s National Health Service is regionally based. Each region has responsibility for the provision of healthcare. The central government defines overarching objectives and principles of the Health Service, including the packages of benefits that the regions have, or are not permitted, to offer. A region can choose to offer additional benefits financed through its own budget. Thus, wide regional variations exist in terms of benefits and financial coverage.
- Medicines and medical devices are provided through a mixed system, which varies from one region to another. These supplies can be supplied by private actors only. They can be procured publicly (by regional authorities or healthcare facilities) through tenders or direct negotiations but supply to dispensing points is undertaken by private actors. Both sectors have to comply with the regulations of the Ministry of Health and the Ministry of Economics – in line with EU regulation. Specialised agencies ensure the application of those regulations.
- A quality issues reporting system is in place.

**Diabetes prevalence (2011)**

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.8% of 20-79 year-olds</td>
<td>Official records: 4.9%</td>
</tr>
<tr>
<td>Type 2 diabetes: 12% of people of over 56</td>
<td></td>
</tr>
</tbody>
</table>

**Diabetes care procedure**

- Prescriptions are mainly provided by GPs and diabetologists.
- Prescribers, as well as pharmacists, are the main points of diabetes information and advice.
- Diabetes products are dispensed largely at (public or private) community pharmacies and/or healthcare facility pharmacies, depending on the region.

**Presence of products at national level**

- At least one product from each of the categories surveyed appeared to be authorised for sale and effectively present in the country.

**Guidelines and specific prescription criteria**

- Italy has guidelines for diabetes care.
- It appears that the prescription of diabetes products is mainly left to each physician’s medical judgement.
- Regional differences in financial coverage (see Affordability) may also constrain consumption and prescription.
- In order to access medicines and medical devices, prescribers must complete a form describing a person’s condition and treatment. This form determines the Health Service entitlement – type and quantity of each product – of each person with diabetes.
- Although not officially enforced, some de facto specific criteria have been applied in certain regions (limiting the prescription of certain devices to certain people only, for instance).
- Associations report that people with diabetes have difficulties dealing with the complex, time-consuming procedure that is required to obtain diabetes medicines and medical devices.

**Use**

- People on insulin appear to be primarily using insulin analogues delivered with insulin pens.
- Oral medications seem to be prescribed mainly to people with type 2 diabetes – metformin is the most commonly used.
- Any person with diabetes is eligible for a blood glucose-monitoring device but the amount of strips covered by the National Health Service may vary according to each person’s condition.
**Accessibility**

- Most people with diabetes only have to pay a prescription fee of EUR 1 (USD 1.30), which was recently established on all medicines.
  - People with severe disability or those living on a very low income are exempted from this fee.
  - If shortages arise of a larger scale, professional association at the regional or national levels can become involved.

- It appears that mainly branded products are available on the market.
  - The price of all reimbursed products is regulated via a maximum price, which is set at the national level. This maximum price is negotiated with the manufacturers. However, additional rebates and discounts may be applied at the regional levels, depending on the way the product is supplied (see Key background information). Mark-ups are also regulated through a statutory maximum for wholesalers and a regressive scheme for pharmacists. Medicines benefit from reduced VAT rates (10% or below depending on the product).
  - It appears that presence of various networks and coalitions of patient and healthcare professional associations have allowed some barriers to access to be removed while limiting some of the differences related to Italy’s regionally structured health system.

- Decisions regarding the reimbursement of each product are made at the national and regional levels. At the national level, the specialised agencies responsible for regulating pharmaceuticals and medical devices also decide which products should be covered in all regions (up to a reference price). Such decisions are made based on cost-benefit and risk-benefit analyses, efficacy and budget impact. Based on the same criteria, regional or local authorities have the authority to cover additional products or quantities for all or some categories of people.

**Affordability**

- Occasional stock issues appear to be localised and have had a limited impact on people’s treatment. Most of them can have their doctors find an alternative to the unavailable product.

- If shortages arise of a larger scale, professional association at the regional or national levels can become involved.

- The available evidence suggests that accessibility is not the principal barrier to medicines and medical devices for people living with diabetes.
  - Reports of shortages of medicines and medical devices are rare, and when they occur, doctors are able to substitute the unavailable product.

- If shortages arise of a larger scale, professional association at the regional or national levels can become involved.

- With the economic crisis, Italy has brought many changes to its pharmaceutical policy: the above-mentioned fee on diabetes medicines has been imposed, the price of medicines have been cut, and wholesalers and retail margins have been changed.

**Financial coverage**

- Co-payments may be waived for people with diabetes once they are registered on the exempt list. However, this exemption does not apply to prescription fees, which has its own criteria for exemption (see Affordability).

- Decisions regarding the reimbursement of each product are made at the national and regional levels. At the national level, the specialised agencies responsible for regulating pharmaceuticals and medical devices also decide which products should be covered in all regions (up to a reference price). Such decisions are made based on cost-benefit and risk-benefit analyses, efficacy and budget impact. Based on the same criteria, regional or local authorities have the authority to cover additional products or quantities for all or some categories of people.

**References**

Healthcare Expenditure Profile (2011)²

Total health expenditure per capita: **USD 1,896.95**
Proportion of government expenditure on health: **13.3%**

Health system overview
- The Maltese government, through the Ministry for Health, the Elderly and Community Care (MHEC), guarantees a package of health services free of charge. People with chronic diseases, such as diabetes, and/or people with limited means are also entitled to additional benefits: certain outpatient medications free of charge, for instance.⁹,¹¹ The MHEC defines the list of subsidised medications.⁷,⁸,¹²
- Diabetes products included in that list are procured through public tenders by the MHEC and supplied to public healthcare facilities by private wholesalers.⁴,⁵,⁹ Other products are supplied by private actors, according to MHEC’s regulations, in line with EU regulation.⁴,⁷,⁹ A specialised agency ensures the application of all related regulations.¹⁰
- A quality issues reporting system is in place.⁵ The quality of products is also controlled during the tendering process.⁶

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.5% of 20-79 year-olds</td>
<td>No data</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are provided by hospital-based diabetes specialists (consultants) and GPs.⁶
- Consultants, diabetes nurse educators and GPs are the main points of diabetes information and advice.⁵
- Diabetes products are dispensed mostly at hospital pharmacies or community pharmacies.⁶

Presence of products at national level
- Products surveyed that are authorised for sale by the EU are authorised for sale in Malta, an EU Member State.¹¹
- However, the presence in the country of some of them, such as insulin pumps and DPP4 inhibitors, could not be confirmed.⁵

Guidelines and specific prescription criteria
- Malta has guidelines for diabetes care.¹⁵
- The prescription of diabetes supplies in the public sector is bound by the rules applied to all publicly procured medical products (see also Affordability):
  - Some insulin, especially insulin analogues, can only be delivered under certain conditions,⁷ such as: as a second-line treatment for people with type 1 diabetes; or to children or people with complications.⁸
  - Glucagon (medication for hypoglycaemia) can only be prescribed to people on insulin.⁵
  - People with type 2 diabetes are not entitled to self-monitoring devices via public procurement but these are on sale in the private sector.⁶,⁸

Use
- Pens are the main insulin injection devices (also see above for criteria on insulin).
- Only metformin and sulphonylureas are provided publicly⁵ – metformin being the most prescribed oral medication.¹
The available evidence suggests that accessibility is not the main barrier to medicines and medical devices for people living with diabetes.5,6

- Malta has developed a dispensation scheme called “Pharmacy of your Choice”,4 which enables people with diabetes to obtain publicly procured medicines and medical devices free of charge at the pharmacy closest to their home.1
  - The Maltese Association Against Diabetes called for initiatives to facilitate improved access to medicines and medical devices for elderly people with diabetes.1

Based on the available information, it would appear that medicines and medical devices are covered in the case of most people with type 1 diabetes.5,6 However, people with type 2 diabetes have to cover the entire cost of testing devices and, depending on their treatment regimen, for some of their medication out-of-pocket.6

- The Maltese Association Against Diabetes reported supporting members with type 1 diabetes and members with type 2 diabetes who face difficulties paying for their treatment, especially glucose test strips and oral medication.6
- Both branded and non-branded products appear to be available on the market.5
  - The brand to be used is determined by the prescriber.5
  - The choice of brand is also constrained by public tenders,3 which are obliged to choose the cheapest options for each tender. Tender contracts last for three years.6
  - Neither the diabetes associations nor the healthcare professional organisations are consulted in this process.6

- Diabetes products’ prices in the public sector are bound by public tenders.6 Reference pricing is used to evaluate proposals for public tendered diabetes supplies.2 Pricing in the private sector is unregulated.6

### Financial coverage

People with diabetes are eligible to certain free medication and devices as part of the Yellow Card (for chronic diseases) or Pink Card (for people on a low income) schemes. Participation on either scheme must be requested by the hospital consultant. This doctor also defines the specific list of medicines/medical devices each person’s Card should cover.3,6 The list of products covered under each scheme is defined by the MHEC, based on therapeutic and economic value, as well as international guidelines.9

<table>
<thead>
<tr>
<th></th>
<th>Free5,6 (see Availability for criteria)9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td></td>
</tr>
<tr>
<td>Anti-diabetes medication</td>
<td>Free if included in the national outpatient formulary list (metformin, sulphonylureas)1,5,8</td>
</tr>
<tr>
<td></td>
<td>Otherwise, not covered – 100% paid for by the person with diabetes 6</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Only people treated with insulin receive these free of charge</td>
</tr>
<tr>
<td></td>
<td>Otherwise, not covered – 100% paid for by the person with diabetes 6</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free5,6</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free5</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Blood glucose test strips</td>
<td>Only people with type 1 diabetes and pregnant women receive a free supply</td>
</tr>
<tr>
<td></td>
<td>Number of strips is limited to 50 strips/month (pregnant women may receive additional supplies)</td>
</tr>
<tr>
<td></td>
<td>Otherwise, not covered – 100% paid for by the person with diabetes 6</td>
</tr>
<tr>
<td>Glucometers</td>
<td>A person’s first device is not covered. Only people with type 1 diabetes have these replaced free of charge</td>
</tr>
<tr>
<td></td>
<td>Otherwise, not covered – 100% paid for by the person with diabetes 6</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Only people with type 1 diabetes receive these free of charge</td>
</tr>
<tr>
<td></td>
<td>Otherwise, not covered – 100% paid for by the person with diabetes 6</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

### References

1 EURADA, FEND, EIF, & PCDE. (2011).
2 Global health observatory data repository. (2013).
3 MHEC. (2012).
4 UPM & MHEC. (2010).
5 IDF-Europe Access survey (2013)
8 MHEC (2012).
10 Missions and Objectives (2013).
11 Malta Medicines Authority (2013).
12 Medicines Entitlement Unit (2013).
Healthcare expenditure profile (2011)²
Total health expenditure per capita: **USD 2,310.62**
Proportion of government expenditure on health: **13.4%**

Health system overview
- The National Health System (NHS) covers the majority of the population.³
- Overall regulation is carried out by the Ministry of Health but healthcare management is a regional responsibility.³
- Medicines and some consumables are supplied by private actors, according to Ministry of Health regulations — and in line with EU regulation.³,⁴ A specialised agency ensures the application of those regulations.³,⁴,⁷ Certain medical devices are procured through public tenders and supplied publicly.⁵,⁶
- A quality issues reporting system is in place.⁶

Diabetes prevalence¹
<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
</table>

Diabetes care procedure
- All doctors can prescribe diabetes medicines and medical devices.⁶ Prescribers are the main points of diabetes information and advice.⁶
- Diabetes medicines and some consumables (including strips and needles) are dispensed mostly at pharmacies. Other medical devices (including glucometers and pumps) are provided at consultations.⁶

Key diabetes data
Availability
- At least one product from each of the categories surveyed was reported authorised for sale and present in the country.⁵,⁶

Guidelines and specific prescription criteria
- Portugal has guidelines for diabetes care.¹
- Control over the consumption and prescription of medicines and medical devices is mainly achieved through reimbursement (see Affordability).⁵,⁶
- It appears that specific prescription criteria apply to oral medication and insulin.⁵,⁶
- Specific criteria also apply to publicly provided pumps:
  - Every year, a fixed number of pumps is provided free of charge: 100 for people with type 1 diabetes with difficulties managing their diabetes with conventional insulin therapy; 40 for children under 5; and 30 for women during pregnancy.
  - However, demand for pumps exceeds public quotas, leading to long waiting lists (up to two years). Negotiations are ongoing to have these quotas increased.⁶
- No criteria apply to blood glucose monitoring devices.

Use
- People treated with insulin mainly use insulin analogues.⁵
- Pens are the main insulin injection devices.⁵
- Pump use was lower among people living in rural areas than among people living in urban areas (see also Accessibility).⁵

From the survey
- Only few respondents reported having had any difficulties obtaining their diabetes supplies within the past two years. However, many healthcare professionals reported that dispensing points were having difficulties receiving supplies, especially insulin.
- Urban respondents and respondents living further from healthcare providers did not always report the same access issues. These differences may be a matter of physical access to treatment.
- Although collected responses show that access to education and information is generally good, a few gaps were found, especially among rural respondents.
- The very low number of respondents with diabetes other than type 1 diabetes makes it difficult to discuss access for these people.
### Accessibility

#### Access treatment
- Access to healthcare services has been impacted upon by recent austerity measures: staff and the number of healthcare facilities have been reduced, especially outside cities.\(^6\)
  - The collected evidence suggests that physical access to pump therapy is an issue (only available at hospitals; long waiting lists), especially for people living further away from a healthcare professional.\(^1,6\)
  - The survey findings also suggest some difficulties in accessing education and information, especially in rural areas.\(^5,6\)
  - Misinterpretations and misunderstandings of regulations — the application of certain fees to consultations and medical transport — are also creating further challenges to access to healthcare (see also Affordability)\(^6\)

#### Stock and shortages
- The small number of stock issues reported do not seem to have significant disruptive impact on people’s treatment.\(^5\) They appear to remain localised problems\(^5\) and people reportedly are able to find alternatives within a few days.\(^5\)
  - As mentioned above, stock issues are a problem at the dispensing level, which seems to have difficulties being supplied.\(^5\)
  - Delays in supply, costs-reduction measures leading to lower stock levels and parallel exports — especially for insulin — have been cited as potential explanations.\(^5,6\)

### Affordability

#### Financial coverage
The Ministry of Health decides on whether a product should be covered and at what rate.\(^3,4\) For medicines, the decision depends on the therapeutic value of the medicine and its price. People with diabetes, like people with other chronic conditions, are exempted from co-payment on certain medicines.\(^3\) Other medications are classified into categories with different rates of reimbursement according to their therapeutic value. Reimbursement rates are based on a reference price (the difference between the reference price and the retail price is paid out-of-pocket by people with diabetes).\(^3,4\) Medical devices apparently follow another scale.

<table>
<thead>
<tr>
<th>Product</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>Free(^5,6)</td>
</tr>
<tr>
<td>Anti-diabetes medication</td>
<td>Partially covered(^5)</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Depending on the type of medicines, partially or not covered(^5)</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free(^6)</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free(^5)</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free (see Availability for criteria)(^5,6)</td>
</tr>
<tr>
<td>Blood glucose test strips</td>
<td>Partially covered(^5)</td>
</tr>
<tr>
<td>Glucometers</td>
<td>Free(^5)</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Partially covered(^5)</td>
</tr>
</tbody>
</table>

*Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.*

### References
1. EURADA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
4. PPRI & WHO (2011)
5. IDF-Europe Access survey (2013)
6. APDP (personal communication) (2013)
Healthcare expenditure profile (2011)²
Total health expenditure per capita: **USD 2,218.50**
Proportion of government expenditure on health: **13%**

Health system overview
- The mandatory health insurance, administered by the Health Insurance Institute of Slovenia (HIIS), covers the entire population. The care package is defined by law.³
- The majority of people also subscribe to voluntary health insurance, which provides additional coverage (through reduced co-payments and/or additional services).³
- Medicines and medical devices are supplied mainly by private actors,⁵ following Ministry of Health rules — and in line with EU regulation.³,⁵ A specific agency ensures the application of these regulations.³,⁴,⁵
- A quality issues reporting system is in place.⁶

Diabetes prevalence (2011)¹
\[
\begin{array}{ll}
\text{IDF Atlas} & 10.3\% \text{ of 20-79 year-olds} \\
\text{National Data} & \text{Official records: 6.25\% of the total population} \\
\end{array}
\]

Diabetes care procedure
- Diabetologists prescribe for people with type 1 diabetes and people with complications; GPs prescribe for other people with diabetes.⁴
- Diabetes associations, pharmacists and the manufacturers of medical devices are the principal providers of diabetes information and advice about treatment.⁶
- Diabetes supplies are dispensed mostly at pharmacies.⁶ Some medical devices can be dispensed by the manufacturer or importer.¹

From the survey
- The low number of respondents with diabetes other than type 1 diabetes stymies any discussion of access for all people with diabetes.
- A minority of survey respondents reported having difficulties obtaining their diabetes products within the last two years — a pattern confirmed by healthcare professionals.
  - The small number of difficulties reported arose mostly due to occasional stock issues, which were resolved quickly and without causing disruption to treatment.
- No significant differences were reported between respondents in terms of access issues.
- Diabetes education and information about treatment was universal among the people surveyed but far less common among their relatives.
- The majority of respondents reported not having to pay for their diabetes medicines or devices.

Availability

Guidelines and specific prescription criteria
- Slovenia has national guidelines for diabetes care.⁵,⁶
- Control over the use of medicines and medical devices is maintained through reimbursement (see Affordability).³,⁴
  - It appears that the prescription of diabetes products is mainly left to each physician’s medical judgement; a small number of products have specific prescription criteria.
  - DPP4 inhibitors can be prescribed only to people with type 2 diabetes.⁵
  - Insulin pumps are to be primarily prescribed to people with type 1 diabetes, mainly children, pregnant women, and people with complications or poor blood glucose control with conventional insulin therapy.¹,⁵,⁶
  - Due to reimbursement constraints, blood glucose-monitoring devices are prescribed almost exclusively to people on insulin.¹,⁶

Use
- According to the Health Insurance Institute of Slovenia’s data, 42.4% of people with diabetes are on oral medication, 12.8% on insulin, and 8.4% on a combination of both.¹
- Pens are the most widely used insulin injection device.¹
• The available evidence suggests that accessibility is not the main barrier to medicines and devices for people living with diabetes.5,6
  - A small number of stock issues were reported, mostly involving blood glucose test strips, but which were resolved in a matter of days without causing serious disruptions to treatment.5
  - Some difficulties with physical access to treatment have been reported in rural or remote areas but this could not be confirmed by the Slovenian Diabetes Association.1,5

Accessibility

• People with type 1 diabetes and children do not appear to co-pay for their diabetes supplies.1,5 People with type 2 diabetes who are not on insulin receive most of their medication free of charge but pay for testing devices out-of-pocket.5
• It appears that most diabetes supplies on the market are branded products.4 In theory, the choice of brand is free5 and lower-priced products have to be offered at the dispensing point.1 However, the prescribers’ advice remains the strongest determinant in the choice of product.5
• The prices of medical devices and medicines are regulated. For medicines, external reference pricing is applied.4 Most diabetes products have to be imported from non-EU countries and are not exempted from taxes and tariffs.3 Wholesalers’ margins are regulated through fixed rates and maximum prices, while pharmacists’ payment (fee for service) are negotiated with the Health Insurance Institute of Slovenia.3 Reduced rates of VAT are applied to medicines and medical devices and medicines (reduced VAT of 9.5 % for the latter).4,5,6
  - Recently, the Health Insurance Institute of Slovenia negotiated a general price reduction on test strips.6

Affordability

• People with type 1 diabetes and children do not appear to co-pay for their diabetes supplies.1,5 People with type 2 diabetes who are not on insulin receive most of their medication free of charge but pay for testing devices out-of-pocket.5

Financial coverage

The HIIS decides whether a product is to be reimbursed. For a medicine, the decision is made according to a cost-benefit analysis and budget impact assessment. Reimbursement rates vary from 10% to 100%, depending on the medicine but most co-payments are covered by voluntary health insurance. Certain groups – children or people with diabetes who have developed complications – are exempt from having to make co-payments. The reimbursement rate for medicines is calculated according to the lowest price in its corresponding category.4,5

Most people appear to combine compulsory (Health Insurance Institute of Slovenia) and voluntary insurance. The table below represents the coverage available to most people through a combination of both insurances.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>Free1,5</td>
</tr>
<tr>
<td>Anti-diabetes medication</td>
<td>Free1,5</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free1,5</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free1,5</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free1,5</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free only to children with type 1 diabetes and certain adults with type 1 diabetes – limited 100 new pumps per year nationally Otherwise, not covered – 100% paid for by the person with diabetes 1,5,6</td>
</tr>
<tr>
<td>Blood glucose test strips</td>
<td>Free only to people on insulin1,5,6 up to 250 per month Otherwise, not covered – 100% paid for by the person with diabetes 1,5,6</td>
</tr>
<tr>
<td>Blood glucometers</td>
<td>Free only to people on insulin1,5,6 Otherwise, not covered – 100% paid for by the person with diabetes 1,5,6</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free or not covered6</td>
</tr>
</tbody>
</table>

Please note that the information provided above only presents a summary of the reimbursement system and may not apply to individual cases.

Looking ahead

The Diabetes Association of Slovenia worries that while health benefits for people with diabetes has been protected and maintained so far, the current financial situation may lead to cuts or rationing in the benefits package.4

References

1. EURADA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
4. PPR & WHO (2011)
5. IDF-Europe Access survey (2013)
Healthcare expenditure profile (2011)²
Total health expenditure per capita: **USD 3,026.65**
Proportion of government expenditure on health: **15.4%**

**Health system overview**
- In the Spanish **National Health System**, overall regulation of the health sector is carried out by the national authorities but healthcare provision and financing are the responsibility of the regions.³
- The care package is defined by a Royal decree, under the auspices of a committee of regional ministers.
- Medicines and devices are mainly supplied by private actors following Ministry of Health regulations — and in line with EU regulation.³ A specialised agency ensures the application of these regulations.³,⁴
- A quality issues reporting system is in place.³

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th></th>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IDF Atlas</strong></td>
<td>8.1% of 20-79 year-olds</td>
<td>National estimates: 13.8% of the adult population</td>
</tr>
</tbody>
</table>

**Diabetes care procedure**
- Prescriptions are provided by GPs and diabetes specialists.⁶
- GPs, specialists and pharmacists are the main points of diabetes information and advice.⁶
- Diabetes supplies are dispensed mostly at pharmacies. However, in some regions, glucose test strips are provided at a consultation or at primary care centres.⁶

**Key diabetes data**

**Key background information: country health system**

**Key diabetes data**

**Presence of products at national level**
- At least one product from each of the categories surveyed was reported authorised for sale and present in Spain.⁵,⁶

**Guidelines and specific prescription criteria**
- Spain has national guidelines for diabetes care.¹
- As well as national prescription criteria, each region may apply additional criteria.⁶
- Some medications can be prescribed only by specialists.¹
- Insulin pumps are prescribed primarily to people with type 1 diabetes who have completed an education programme; test their blood glucose at least four times a day; have been treated with multiple daily insulin injections for more than six months, yet fail to achieve good blood glucose control.⁶
- Prescription criteria for blood glucose test strips are developed at the regional level and thus vary across the country. Criteria have become stricter over recent years.⁶

**Use**
- Most people with type 1 diabetes use an insulin analogue.⁵,⁶
- Pens are the most widely used insulin injection device.⁵
- The first-line of drug treatment for people with type 2 diabetes is metformin.⁵
- Women with gestational diabetes are put on insulin if lifestyle changes fail to regulate their blood glucose.⁵
The available evidence suggests that accessibility is not the main barrier for people living with diabetes. However, it seems that access to diabetes education and information about treatment varies between the regions and levels of care (information is more widely available in specialised settings than general health centres).

- Like other health and disease areas, diabetes care has been affected by government cuts in health spending. Co-payments are applied to all medicines, although people with diabetes benefit from a reduced rate (see Table). A 2013 survey found that 40% cannot afford blood glucose test strips and 28% are unable to pay for the medication they need. People in low-income groups are suffering most. This assessment was shared by the healthcare providers surveyed.

- The prices of diabetes supplies are regulated at the national level. For medicines, prices are set through external reference pricing. The mark-ups applied by wholesalers and pharmacists are regulated through agressive scheme. A VAT of 4% is applied to medicines. As a result of the financial crisis, Spain has brought about many changes to its pharmaceutical pricing policy: the prices of medicines have been reduced; pharmacists’ margins have been increased on certain medicines; reference pricing methodology has been modified.

### Financial coverage

People with a chronic disease benefit from reduced co-payment rates on medicines (10%) as well as an expenditure ceiling per package (EUR 4.20 – USD 4.45). A decreasing number of people from other categories (elderly, unemployed, low-income) benefit from lower co-payment rates or exemptions. A number of categories were excluded from such benefits last year.

Decisions on financial coverage of diabetes products are made by the Ministry of Health, advised by committees representing regional health ministers and the Ministry of Economy and Industry. For medicines, decisions are based on therapeutic value, budget impact and internal reference prices.

**Table: Financial coverage**

<table>
<thead>
<tr>
<th>Item</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin and anti-diabetes medication</td>
<td>Partially covered</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Partially covered</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free or partially covered</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Partially covered</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Free for certain categories of people only (see availability for criteria). Otherwise, not covered – 100% paid for by the person with diabetes. Certain regions limit the number of strips.</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>People on insulin pumps may receive coverage for ketone test strips. For others, the situation is unclear.</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

**Looking ahead**

The Spanish Society of Diabetes reports that new medical devices and technologies are likely to be more restricted. However, as yet, this does not seem to have affected medication.

**References**

1. EURADA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
4. PPRI & WHO (2011)
5. IDF-Europe Access survey (2013)
CENTRAL AND EASTERN EUROPE
Healthcare expenditure profile (2011)²

Total health expenditure per capita: **USD 521.5**
Proportion of government expenditure on health: **11.3%**

**Health system overview**
- Bulgaria’s Health Insurance System, administered by the National Health Insurance Fund (NHIF), covers most of the population.³
- The Ministry of Health defines the care package³
- Medicines and medical devices are mainly supplied by private actors, according to the Ministry of Health’s regulations – in line with EU regulations.³,⁹ Specialised agencies ensure that these regulations are applied.³,⁴,⁹
- A quality-control system prior to distribution is in place but the existence of an issue-reporting system could not be confirmed.⁵

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.3% of 20-79 year-olds</td>
<td>Official records: <strong>8.3%</strong> of the adult population</td>
</tr>
<tr>
<td>Healthcare professionals estimates: <strong>7%</strong> of the adult population</td>
<td></td>
</tr>
</tbody>
</table>

**Diabetes care procedure**
- Prescription provided by GPs, based on a regimen defined by an endocrinologist (an additional procedure is required for people with type 1 diabetes and some people with type 2 diabetes — see below).⁶,⁹
- GPs and/or endocrinologists are also the main points of diabetes information and advice.⁶
- Diabetes products are dispensed mostly at pharmacies.⁵,⁶ Insulin can only be dispensed in specialised pharmacies.⁶

**Key diabetes data**

**From the survey**
- The very low number of respondents who were not being treated with insulin makes it difficult to evaluate access for these people.
- Many respondents reported encountering some kind of difficulty obtaining the medicines and medical devices they need — a pattern confirmed by healthcare professionals.
- Occasional stock issues (mainly for insulin analogues) and recurring affordability issues were the main causes of these difficulties, which left people without new supply for approximately one week in many cases.
- Although most of the people with diabetes reported having received education or information about treatment, the training is not yet universal and was far less common among their relatives.
- Monthly out-of-pocket expenditure for diabetes medicines and medical devices was higher among rural respondents than those who live in urban areas.

**Guidelines and specific prescription criteria**
- Bulgaria has national guidelines for diabetes care¹
  - People with type 1 diabetes and people with type 2 diabetes on new-medicines-based regimen (insulin analogues and incretin-based therapy) have to have their treatment regimen defined by an endocrinologist and then, approved by the NHIF.⁵,⁹
  - This approval procedure is about to be lightened—especially regarding approval from NHIF. Further responsibilities will be transferred to GPs.⁶
  - Specific prescription criteria seem to apply mainly to medicines — the prescription of medical devices left mainly to the prescriber’s assessment.⁵
  - Newer medications (like insulin analogues, DPP4 inhibitors and GLP-1 receptor agonists), depend on a person’s ability to follow treatment, and their not achieving good control with other therapies.⁵,⁶,⁷
- The consumption and prescription of diabetes medicines and medical devices is closely related to reimbursement (see Affordability).⁵

**Use**
- Pens remain the main insulin injection device² — pump therapy requiring 100% out-of-pocket payment by the user.⁴
- The use of the different types of medications reflects the criteria mentioned above.⁵
- The use blood glucose-monitoring devices appear to be quite widespread (at least among people using insulin).³
Accessibility

Affordability

Access to treatment
• People collect their diabetes products monthly on a given date.5
  • Physical access to endocrinologists (who must define the person’s treatment regimen) and specialised pharmacies dispensing insulin remains difficult for some people1 as these facilities are only located in major cities.5
  • Some specialist healthcare facilities located in more remote settings have been closed over the last years.4
  • Some gaps have been identified regarding the information and education received by people with diabetes about their treatment.1

Stock and shortages
• Occasional stock issues were reported, mainly affecting insulin analogues.5
  • According to the Bulgarian Diabetes Association, supply delays at the national level affected specific types of insulin analogues during 2012-2013, but this was an isolated incident and ad hoc solutions were found with healthcare professionals while negotiations were on-going with the manufacturers of the analogues.
  • Other shortages could not be confirmed by the Bulgarian Diabetes Association.5,6

Financial coverage

Special committee under the Council of Ministers and the Ministry of Health decide on reimbursement. For medicines, the decision is based on therapeutic, pharmacological, pharmaco-economic and socio-economic criteria.3,4,8 Levels of reimbursement depend on the person’s condition(s) and on NHIF annual budget.3,4,8 Type 1 diabetes is on the list of conditions that exempt people of co-payments on certain medicines.4

<table>
<thead>
<tr>
<th>Product</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>Free (see Availability for criteria on insulin analogues)1,5,6</td>
</tr>
<tr>
<td>Anti-diabetes medication</td>
<td>Depending on the medicines, fully or partially not covered at all1,5,6</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Only people treated with insulin receive these free of charge. Otherwise, not covered — 100% paid for by the person with diabetes5,6</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Pens are free5,6 but associated supplies are not covered — 100% paid for by the person with diabetes5,6</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Only syringes are free5,6 but associated supplies are not covered — 100% paid for by the person with diabetes5,6</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Not covered — 100% paid for by the person with diabetes5,6</td>
</tr>
<tr>
<td>Blood glucose test strips</td>
<td>Only people treated with insulin get them for free but limited to 1,100 strips per year for people under 18; 150 strips per year for others. Otherwise, not covered — 100% paid for by the person with diabetes5,6</td>
</tr>
<tr>
<td>Glucometers</td>
<td>Only people treated with insulin get one for free. Otherwise, not covered — 100% paid for by the person with diabetes5,6</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Not covered — 100% paid for by the person with diabetes5,6</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

References
1 EIRADA, FENI, IDF, & PCDE. (2011)
2 Global health observatory data repository. (2013)
4 PPR & WHO (2011)
5 IDF-Europe Access survey (2013)
6 Bulgarian Diabetes Association (personal communication) (2013)
7 Dončová, V., Brat, J., & Sorn, J. (2011)
9 Bulgarian Society of Endocrinology (personal communication) (2013)
Healthcare expenditure profile (2011)²
Total health expenditure per capita: **USD 1,506.90**
Proportion of government expenditure on health: **14.2%**

Health system overview
- The mandatory health insurance scheme, administered by more than ten health insurance funds, covers the entire population.³
- The list of benefits is defined by law but constrained by negotiations between health insurance funds and healthcare providers.³
- Medicines and medical devices are supplied principally by private actors, according to Ministry of Health regulations – in line with EU regulation.³,⁴ A specialised agency ensures the application of those regulations.³,⁴
- A quality issues reporting system is in place.⁶

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th></th>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.9% of 20-79 year-olds</td>
<td>Official records: 8% of the population</td>
<td></td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are mainly provided by diabetologists and to a lesser extent, GPs.⁴
- Prescribers also serve as the principal points of diabetes information and advice, along with pharmacists.⁶
- Diabetes products are dispensed mostly at pharmacies.⁵,⁶ Glucometers are usually obtained at consultations, along with education about self-monitoring.⁶

From the survey
- Based on collected responses and discussions with the Czech Diabetes Association, no significant access issues appear to affecting people with diabetes.
- Although many changes in the pricing and reimbursement policy have been implemented, they do not appear to have affected people with diabetes so far.

Key background information: country health system

Key diabetes data

Availability

Presence of products at national level
- At least one product from each of the categories surveyed was reported authorised for sale and effectively present in the country.⁵,⁶,⁹

Guidelines and specific prescription criteria
- The Czech Republic has guidelines for Diabetes care.¹
- Specific prescription criteria defined by health insurance funders are applied to:
  - Newer oral medicines, such as DDP-4 inhibitors, which can only be prescribed if metformin or sulphonylureas fail.⁶
  - Insulin analogues, which can only be used as a second-line treatment if treatment targets are not achieved with human insulin.⁶,⁹
  - Insulin pumps, which have to be recommended by a diabetes centre and can be prescribed to people with type 1 diabetes with poor glycaemic control or to people with complications.⁶,⁹
- Control over the consumption and prescription of medicines and medical devices is also maintained through reimbursement, especially for blood glucose-monitoring devices (see affordability).⁵,⁶

Use
- The use of insulin pump therapy appears to be quite developed,⁵,⁹ mostly among children and people with type 1 diabetes.⁶
- Metformin appears to be the most widely prescribed oral medication.⁵
Accessibility

The available evidence suggests that accessibility is not the principal barrier for people living with diabetes to obtaining medicines and medical devices: no particular difficulty was reported on this issue.5,6

Affordability

- Based on the information collected in our survey, most people with diabetes do not pay recurring expenses for their diabetes products.5,6
  - Additionally, co-payments are limited to EUR 200 per year for adults and EUR 100 per year for senior citizens.6
  - To date, changes in pricing and reimbursement (see below) have not affected people with diabetes.6
- Few non-branded products appear to be on the market.5
  - The brand that a person will use is determined by the prescriber. However, pharmacies are allowed to offer non-branded medical products if they are available.5,6
- The prices of all the diabetes products surveyed are regulated by the Ministry of Health.1 For medicines, prices are set through external reference pricing.5,6 Mark-ups are controlled at the retail level through a regressive scheme.4 A 15% VAT is applied to medicines.7
  - Over the last few years, the Czech Republic has reformed its pharmaceutical policy, mainly in order to contain costs. The price of medicines have been reduced; the list of reimbursed medicines has been reviewed; reference pricing methodology has been changed; mark-ups6,7 and the VAT rate have been changed.7,8

Financial coverage

The specialised agency regulating medicines and medical devices also decides their reimbursement. For medicines, this decision is based on efficacy, safety, quality, and cost-effectiveness in regard to their primary indication.3,4 Reimbursement levels are set by therapeutic groups and are based on a reference price that is fixed for each group.3,4 Additionally, a list of 300 fully covered substances has been established.1 Devices appear to follow another scale. Reimbursements are made by health insurance funders.5

<table>
<thead>
<tr>
<th>Item</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin and anti-diabetes medication</td>
<td>Free (see Availability for criteria)1,5</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free5</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free5</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Free5</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Pumps are free5,6,9</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Free5,6 but with limits on the number of strips:</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free5</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

References
1. EURADA, FENN, OIE, & PCEO. (2011)
2. Global health observatory data repository. (2013)
4. SUKL State institute for drug control. (2011)
5. IDF-Europe Access survey (2013)
7. SUKL State institute for drug control. (2013)
Healthcare expenditure profile (2011)²
Total health expenditure per capita: USD 986.90
Proportion of government expenditure on health: 12.3%

Health system overview
- The Health Insurance System, administered by the Estonian Health Insurance Fund covers most of the population.³
- The care package is defined jointly by the EHIF and the Ministry of Social Affairs.³
- Most medicines and medical devices are supplied by private actors, according to Ministry of Health standards – in line with EU regulation.³,⁶ A specialised agency ensures the application of those regulations.³,⁶
- A quality issues reporting system is in place.⁶

Diabetes prevalence¹

<table>
<thead>
<tr>
<th></th>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>9.1% of 20-79 year-olds (2011)</td>
<td>Official records: 3-4% (2009 estimate)</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- The main prescribers and points of diabetes information and advice could not be determined. Some evidence¹ suggests that both GPs and diabetes specialists are involved in diabetes care.
- Diabetes products are dispensed mostly at private pharmacies.¹⁷

Key diabetes data

About the data
We were not able to collect a large number of responses in this country. Thus, the information presented below is based mainly on a review of the literature.

Availability

Guidelines and specific prescription criteria
- Estonia has national guidelines for diabetes care.¹ However, control over the consumption of medicines and use of medical devices seems to be maintained through reimbursement (see Affordability).⁷,⁸

Use
- Patterns of use could not be assessed for this country.
Due to inadequate information, physical access and stock issues could not be assessed.

**Accessibility**

- An estimate of monthly out-of-pocket expenditure for diabetes products could not be obtained. However, it seems that most people with diabetes have to pay an out-of-pocket share of their treatment.
  - All medicines require a prescription fee, which varies according to the rate at which medicines are reimbursed.  
  - Only few categories of people – mostly young children – seem to be eligible to receive their medical devices free of charge.  
  - However, people who spend more than EUR 380 (USD 493) per year may receive further reimbursement from the Estonian Health Insurance Fund.
- These co-payments seem to be problematic especially among low-income groups. However, no specific data on diabetes could be found.
- A household survey showed that a quarter of the adults surveyed with a chronic condition did not take all their medicines because of affordability issues. This rate is even higher among low-income groups.
- Prices of reimbursed medicines are set either through internal reference pricing or through price agreements with the manufacturers, based on external reference pricing. Maximum regressive mark-ups are applied to both wholesalers and retailers. Medicines are charged a reduced VAT of 9%4 and import duties apply. Price components for medical devices could not be assessed.

**Affordability**

- Financial coverage

Reimbursement and pricing decisions are made by the Ministry of Social Affairs, following recommendations from the health insurance fund and the Medicines Agency. The criteria to decide whether a medicine is covered by the health insurance fund include an evaluation of its medical and therapeutic value, cost-effectiveness and budget impact, as well as the severity of the target condition. Criteria for medical devices could not be found but the assessment procedure may be less well-developed. Reimbursement levels are based on the reference price of a category of medicines; any differences between the reference price and the sale price have to be paid out-of-pocket. The reimbursement rates for medicines vary from 50% to 100% of the reference price, depending on the illness and the person's socioeconomic status. Medical devices follow a different reimbursement scale.

<table>
<thead>
<tr>
<th>Insulin</th>
<th>Free1,5,8</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-diabetes medication</td>
<td>Partially covered6</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Partially covered9</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Unclear – free1 or partially covered5,10</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Unknow</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Children under five and severe cases of children under 18 receive both free of charge.9 Other children between 5 and 18 receive supplies free of charge.9 In all other cases, pump therapy is not covered – 100% of expense paid for by the person with diabetes.10</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Partially covered5,6 with limits on the number of strips: - 600 strips per year for people with type 1 diabetes - 300 per year for people with type 2 diabetes using insulin - 100 per year for people with type 2 diabetes using oral medication - 1,200 per year for children and pregnant or breastfeeding women.1 Some glucometers may also be given out freely by companies</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Partially covered</td>
</tr>
</tbody>
</table>

References

1. EURADIA, FEND, IDF, & PCEO (2011)
2. Global health observatory data repository (2013)
4. PPRI & WHO (2011)
5. IFD–Europe Access survey (2013)
7. Rovimiet (2013)
8. Estonian Health Insurance Fund (2013a)
10. Estonian Health Insurance Fund (2013b)
Key background information: country health system

**Healthcare expenditure profile (2011)**
- Total health expenditure per capita: **USD 1,084.80**
- Proportion of government expenditure on health: **10.2%**

**Health system overview**
- The Health Insurance System, administered by the National Health Insurance Fund under government authority, covers the entire population.
- Central government defines the package of benefits covered by the National Health Insurance Fund while local governments are in charge of providing healthcare.
- Most medicines and medical devices are supplied by private actors, according to Ministry of Health standards and regulations — in line with EU regulation. Specialised agencies ensure the application of those regulations.
- A quality issues reporting system is in place.

**Diabetes prevalence (2011)**
- **IDF Atlas National Data**
- **7.6%** of 20-79 year-olds
- **Official records**: 7.6% of the population
- **Prevalence of type 2 diabetes**: 7.5% of the overall population

**Diabetes care procedure**
- Prescriptions are provided by specialists and GPs but prescription of certain diabetes medicines by GPs is restricted.
- Diabetologists and diabetes nurses are usually the main points of diabetes information and advice.
- Diabetes medicines are dispensed mostly at pharmacies while medical devices can be dispensed through a number of channels (such as at medical visits, through associations or at pharmacies).

**Key diabetes data**
- **About the data**
  We were not able to collect a large number of responses in this country. Thus, the information presented below is based mainly on a review of the literature and exchanges with the national diabetes association.
- **Presence of products at national level**
  - At least one product from each of the categories surveyed was reported authorised for sale and present in the country.
- **Guidelines and specific prescription criteria**
  - Hungary has national guidelines for diabetes care.
  - Other than metformin and sulphonylureas — which can be prescribed by a GP — all diabetes devices and medication have to prescribed by a specialist. However, the majority of people are treated by GPs.
  - Control over the consumption of medicines and medical devices is maintained through reimbursement (see Affordability).
  - Additional specific criteria apply for the prescription of insulin pumps. Only people with type 1 diabetes whose condition cannot be controlled by conventional insulin therapy after a given period of time, for instance, are eligible for a pump. People over 18 must also meet specific long-term blood glucose (HbA1c) targets to maintain their eligibility.
The available evidence suggests that accessibility is not a key barrier to obtaining diabetes medicines and medical devices.

**Accessibility**

**Access to treatment**
- Although the available diabetes outpatient clinics cannot cope with all people with diabetes, GPs are able to provide care for people with diabetes who are on a lifestyle regimen and are treated without medication, or on the oral medication listed above. 
- People with chronic conditions can receive three-month prescriptions. 

**Stock and shortages**
- Occasional short supply of certain types of insulin has occurred but people’s treatment has been modified accordingly without major difficulties. 
- People living with diabetes tend to retain small stocks of their products in preparation of these types of situations. 

**Affordability**

- Other than children with type 1 diabetes who are under 18, all other people with diabetes have to pay an out-of-pocket contribution to the cost of their treatment. A dispensation fee is also applied to all medicines and devices. 
  - According to collected responses in the capital city, the median out-of-pocket spending due to diabetes medicines and medical devices was HUF 10,000 (USD 44) per month, or HUF 120,000 (USD 533) per year. This makes up 4% of the 
    Household Net Adjusted Disposable Income, rising to as high as 8% for the poorest 20%.
  - Certain population groups with chronic diseases are eligible for subsidies to cover a share of their out-of-pocket health expenditure.
  - The imposition of treatment targets for people with type 2 diabetes as a condition for reimbursement of insulin analogues and pumps raised concerns in 2012. This measure was part of a general cut in the government budget for health and especially medicines. A year later, the National Health Insurance Fund revealed that 20% of people treated with analogues were affected by this measure; most of them were switched back to human insulin. 
  - The brand of the prescribed product is determined by the prescriber and a policy exists to favour lower-priced medicines. 
  - The price of reimbursed products is negotiated but constrained by the reference pricing used to set reimbursement. Mark-ups made by wholesalers and pharmacies are regulated through a system of regressive mark-ups. Medicines benefit from a reduced VAT of 5%. Mark-ups on medical devices have yet to be regulated. 

**Financial coverage**

Medicines for chronic conditions are eligible to higher reimbursement rates than others. Medical devices follow a different scale.

The National Health Insurance Fund Administration decides on reimbursements, based on the recommendations of the Technology Appraisal Committee. For medicines, reimbursement depends on the type of medicines, the severity of the treated condition, the medicine’s indication and the type of prescription. Internal and external reference pricing is also considered. Aside from the different rates applicable to different diabetes products, the National Health Insurance Fund’s reimbursement criteria varies also according to a person’s age, type of diabetes and in some cases, achievement of treatment targets. 

### Reimbursement Summary

<table>
<thead>
<tr>
<th>Insulin</th>
<th>Human insulin is free. Insulin analogues are free for people with type 1 diabetes and children. The reimbursement for people with type 2 diabetes (50% to 100%) depends on the number of injections per day, any complications, and achievement of treatment targets.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-diabetes medication</td>
<td>Partially reimbursed, with newer medication having the lowest rate of reimbursement.</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Partially reimbursed.</td>
</tr>
<tr>
<td>Pens, syringes and related supplies</td>
<td>Only children and people taking more than four injections per day receive free of charge. Others receive partial reimbursement.</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Free to children under 18. Partially reimbursed for adults (See criteria for Availability).</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Free for children under 18. Partially reimbursed for adults on insulin, with a limit on the number of reimbursed strips depending on the number of injections per day. Otherwise, not covered. 100% paid for by the person with diabetes.</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Free for children under 18. Partially reimbursed for adults.</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

**References**

1. EURADIA, FEND, IDF, & PCDE. (2011) 
2. Global health observatory data repository. (2013) 
5. IDF-Europe Access survey (2013) 
7. Disease is preceded by a tightening of insulin support. (2013) 
8. A fifth of patients were placed on a more expensive insulin. (2013) 
Healthcare expenditure profile (2011)²

Total health expenditure per capita: **USD 840.90**
Proportion of government expenditure on health: **9.3%**

Health system overview
- The National Health System is headed by an independent institution and covers the whole population.¹
- The package of benefits is defined by government ministers and the National Health System.³
- Most medicines and medical devices are supplied by private actors, according to Ministry of Health’s standards and regulations — and in line with EU regulation.¹,⁵ A Specialised agency ensures the application of those regulations.³
- A quality issues reporting system is in place.³

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.7% of 20-79 year-olds</td>
<td>Official records: 3.9% of the population including 20.6% on insulin</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are provided by GPs or diabetes specialists.¹
- The principal points of diabetes information and advice could not be determined.
- Diabetes medicines appear to be dispensed mostly at pharmacies, while medical devices appear to be dispensed through various channels — including healthcare centres, pharmacies, associations and specialised distributors...⁵

Availability

- At least one product from each of the categories surveyed appear to be authorised for sale and present in the country.¹,⁸

Guidelines and specific prescription criteria
- Although Latvia has national guidelines for the treatment of diabetes,¹ their implementation is not monitored.¹
- Latvia also has guidelines for rational use of medicines reimbursed by the National Health System.¹

Use
- Patterns of use and prescription could not be assessed.
**Access to treatment**
- Due to the lack of endocrinologists in some centres, access to diabetes specialists is limited. The capital city appears to be best served in this regard.¹
- In 2011, a programme was implemented to support family doctors in the prevention and care of chronic diseases.¹

**Stock and shortages**
- Although some stock issues may occasionally occur, they do not appear to provoke disruptions in treatment.¹

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**Insulin**
- Free¹,⁵

**Anti-diabetes medication**
- Free²,⁵,⁸

**Medication for hypoglycaemia**
- Free²,⁵,⁸

**Pens and related supplies**
- Not covered by the National Health System⁸ but may be obtained through donations¹

**Syringes and needles**
- Not covered by the National Health System⁸ but some people report being able to obtain supply free of charge⁵

**Pumps and related supplies**
- Not covered — 100% paid for by the person with diabetes⁵,⁸

**Blood glucose test strips**
- Only pregnant women receive 150 strips per month free of charge⁴
- Otherwise, partially covered³:
  - People on insulin receive 120 strips per month covered at 75%¹
  - People on oral medication receive 30 strips per month covered at 50%³

**Glucometers**
- Not covered by the National Health System⁹ but may be obtained through donations⁵

**Ketone test strips**
- Not covered by the National Health System⁹ but some people report being able to obtain a partially covered supply⁵

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Looking ahead
Latvia has been deeply affected by the financial crisis. As a result, the health budget has been significantly reduced while stronger controls are implemented on public spending.¹,³

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References
1. EURADIA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
4. PPRI & WHO, (2011)
5. DF-Europe Access survey (2013)
7. SIFFA. (2006)
**Healthcare expenditure profile (2011)**

- Total health expenditure per capita: **USD 875.38**
- Proportion of government expenditure on health: **12.6%**

**Health system overview**
- The mandatory health insurance, administered by the National Health Insurance Fund, covers the entire population.\(^6,4\)
- The package of benefits is defined by the Ministry of Health.\(^3,4\)
- Most medicines and medical devices are provided by private actors, according to Ministry of Health standards and regulations — and in line with EU regulation.\(^3\) A specialised agency ensures the application of those regulations.\(^3\)
- A quality issues reporting system is in place.\(^3\)

**Diabetes prevalence (2011)**

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.6% of 20-79 year-olds</td>
<td>National estimate: 2.3% of the population</td>
</tr>
</tbody>
</table>

**Diabetes care procedure**
- Prescriptions are provided mainly by endocrinologists and family doctors — the latter, particularly in the case of adults with type 2 diabetes.\(^6\)
- Doctors, nurses and pharmacists are the main points of diabetes information and advice, as well as diabetes products companies' representatives.\(^6\)
- Diabetes products covered by the National Health Insurance Fund are dispensed at public or private pharmacies. Other devices may be dispensed through multiple channels — healthcare professionals, pharmacies, associations, seminars.\(^5,6\)

**Presence of products at national level**
- At least one product from each of the categories surveyed was reported authorised for sale and present in the country.\(^5,6\)

**Guidelines and specific prescription criteria**
- Lithuania has national guidelines for the treatment of diabetes.\(^1\) It also has specific guidelines for the use of reimbursed medicines.\(^4,6\)

**Use**
- People treated with insulin tend to receive insulin analogues.\(^1\) Metformin is the most used of the oral medications and is among the most prescribed medicines. Metformin is also be prescribed for the treatment of type 1 diabetes in Lithuania.\(^1\) Never oral medications are only recommended as a second- or third-line treatments.\(^4\)
- Certain medicines — like glucagon, which is only given to people with type 1 diabetes — can only be prescribed by an endocrinologist.\(^6\)
- Pens remain the most widely used insulin injection devices.\(^1\) The prescription and use of insulin pumps is constrained by reimbursement criteria (see Affordability)\(^4\) and appear to be used mostly by people with type 1 diabetes.\(^1\)
Accessibility

- Accessibility does not seem to be an issue for most people with diabetes.
  - Although waiting lists may delay access to a prescriber in urban areas, alternatives exist if a person experiences difficulties. An exception is waiting lists for prescribers in rural areas, which may delay access for some.
  - Stock issues arise occasionally and in most cases, are resolved quickly, without causing disruption to treatment.
  - However, a small number of people appear to experience difficulties in both these respects.

Affordability

- Around half of the people with diabetes surveyed reported paying for part of their treatment out-of-pocket.
  - According to the Lithuanian Diabetes Associations, at least one brand in each of the categories of product reimbursed by National Health Insurance Fund can be obtained without co-payment.
  - However, few people experience financial difficulties.
  - According to the responses collected, median out-of-pocket spending on diabetes medicines and medical devices per month was LTL 57.50 (USD 22), or LTL 690 (USD 259) per year.
  - Median out-of-pocket expenditure per month for diabetes supplies was found to be higher among people with type 1 diabetes than among people with type 2 diabetes; and among people living in towns and cities compared to those living in rural areas. However, the reason for these differences is not clear.

Financial coverage

Diabetes is among the conditions that entitle those affected to reimbursed pharmaceuticals. People with type 1 diabetes, type 2 diabetes or gestational diabetes are entitled to 100% reimbursement for their medications. The Ministry of Health decides whether or not products are reimbursed and at which rates, following the recommendations of a joint committee representing the different state departments and agencies involved in health, and the Council of Mandatory Health Insurance. Whether a product is reimbursed depends on clinical and economic criteria for medicines; the degree of reimbursement depends on the target disease or whether it is prescribed for certain population groups. The amount covered by the National Health Insurance Fund is based on a reference price. Thus, people may be required to pay the difference between the retail and reference prices even on products that are covered 100%. The table below presents only an overview of National Health Insurance Fund coverage, without taking into account the potential differences between retail and reference prices.

<table>
<thead>
<tr>
<th>Item</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin and anti-diabetes medication</td>
<td>Free</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free (see also Availability for eligibility criteria)</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Not covered by National Health Insurance Fund; donated by companies</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Not covered — 100% paid for by the person with diabetes</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Supplies are partially covered by National Health Insurance Fund for children under 19 and pregnant women with type 1 diabetes. Pumps are donated or loaned by companies. Otherwise, pumps are not covered — 100% paid for by the person with diabetes</td>
</tr>
<tr>
<td>Blood glucose test strips</td>
<td>Free but limited according to person's type of diabetes, medication, age and whether pregnant</td>
</tr>
<tr>
<td>Glucometers</td>
<td>Not covered by National Health Insurance Fund but may be donated by companies</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Not covered — 100% paid for by the person with diabetes</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

Looking ahead

The Lithuanian Diabetes Association fears that access to medicines and medical devices may be affected by the new healthcare reform and budget reduction. Moreover, a number of patient organisations have been removed from different decision-making institutions of the Ministry of Health.

References

1. EURADA, FEND, IDF, & PODE. (2011)
2. Global health observatory data repository. (2013)
5. IDF-Europe Access survey (2013)
Healthcare expenditure profile (2011)²

Total health expenditure per capita: **USD 898.98**
Proportion of government expenditure on health: **11%**

Health system overview
- The mandatory health insurance, administered by the National Health Fund (NHF), covers almost the entire population.³
- The care package is defined by the Ministry of Health.³
- Medicines and medical devices are mainly supplied by private actors,³ according to Ministry of Health standards and regulations – and in line with EU regulation.³ A specialised body with regional branches, ensures the application of those regulations.³
- A quality issues reporting system is in place.³

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.6% of 20-79 year-olds</td>
<td>Diagnosed cases: <strong>3.4%</strong> of the population</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are provided by family doctors, with guidance from a diabetologist.¹
- GPs, diabetologists and pharmacists act as the main points of diabetes information and advice.⁶
- Diabetes supplies are dispensed mainly at pharmacies.⁵,⁶

From the survey
- Quite a few survey respondents reported having difficulties obtaining their diabetes supplies within the last two years.
  - Most of the respondents who faced problems reported stock issues as the primary cause, while many reported affordability issues.
  - Blood glucose test strips and insulin were worst affected.
  - Most of the people who faced these difficulties managed to find an alternative within a week (through diabetes associations or alternative dispensing points).
- Diabetes education and information about treatment was almost universal among respondents with diabetes but far less common among their relatives.
- All respondents reported having to make **out-of-pocket payments** for diabetes but strong differences exist between them as to the amount they usually had to pay.

Guidelines and specific prescription criteria
- Poland has national guidelines for the treatment of diabetes.¹

Use
- The use of medications and other supplies appears to be constrained by criteria for reimbursement.⁵,⁶
- Most people on insulin appear to use analogues, especially people with type 1 diabetes.⁵
- Use of the latest oral medications, such as DPP4 inhibitors, appears to be limited, apparently due to financial barriers (see Affordability).⁴,⁵,⁶
- The use of insulin pumps and self-monitoring devices seems to be wider among people with type 1 diabetes than among people with type 2 diabetes.⁵
The table below presents only an overview of the coverage enjoyed by the majority of people with diabetes.

### Affordability

- The affordability of outpatient treatment is a significant issue in Poland, and diabetes is no exception.3
- Even diabetes medicines under the 100% coverage rate require a lump sum to be paid by the person with diabetes.6 Since 2012, cuts have been made by the Ministry of Health negatively affecting reimbursed diabetes medicines and devices.5
- Most of the newest medications included in this study are not covered in any way by the NHF.3,9
- According to collected responses, median out-of-pocket payment for diabetes medicines and devices was PLN 150 (USD 47) per month, or PLN 1,800 (USD 560) per year.7 This makes up 4% of the Household Net Adjusted Disposable Income, or as much as 9% for the poorest 20%. Significant differences were found between respondents.

### Stock and shortages

- Coverage differs for different types of diabetes: reimbursement tends to be higher for type 1 diabetes than for type 2 diabetes.4 However, median out-of-pocket expenditure per month for diabetes supplies was found to be higher among people with type 1 diabetes than among people with type 2 diabetes.4 Based on the use patterns described earlier (see Availability) and according to what has been reported by the Polish Diabetes Association, this difference may be caused by the inability of many people with type 2 diabetes to access the medicines and devices they need, due to cost.
- Median out-of-pocket expenditure per month on diabetes supplies was found to be higher among people living in rural areas than among those living in towns and cities, although the reason for this difference is not clear.
- Large differences were also observed within these different categories of people with diabetes.
- People with a low income can apply for social benefits to help with co-payments.9
- Reimbursement reference prices encourage the use of the lowest-priced medicines and medical devices.4 However, the survey found that the advice of the prescriber is the key factor in the choice of brand.5
- The price of reimbursed medicines is derived through external reference pricing.9 Mark-ups applied by wholesalers and pharmacies are controlled through a mixed system (fixed and regressive mark-ups) and have been reduced over recent years.3,10 The pricing of reimbursed medical devices is also controlled but the mechanism could not be found.

### Financial coverage

The Ministry of Health decides whether a product is reimbursed and the reimbursement rates, based on the recommendations of a specialised agency. Eligibility for reimbursement is based on clinical and economic criteria for medicines.3 The rates of reimbursement depend on the types of medicine, the illness it treats and the characteristics of the patient (certain groups receive higher coverage).4 The reimbursement process is managed by the NHF. However, the amount covered by the NHF is based on a reference price. Thus, even supplies that are 100% covered may require the person with diabetes to pay the difference between the reference price and retail price.4 Additionally, reimbursement levels vary according to a person’s characteristics: age, disability, type and severity of diabetes.

The table below presents only an overview of the coverage enjoyed by the majority of people with diabetes.

<table>
<thead>
<tr>
<th>Item</th>
<th>Coverage Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>Human insulin is partially covered. Insulin analogues are either partially covered or not covered (100%)</td>
</tr>
<tr>
<td>Anti-diabetes medication</td>
<td>Partially covered or not covered — depending on the medicine</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Partially covered: only for people on insulin. Otherwise, not covered (100% paid for by the person with diabetes)</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Partially covered</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Pumps and supplies are free for children under 18 years. Otherwise, not free (100% paid for by the person with diabetes)</td>
</tr>
<tr>
<td>Blood glucose test strips</td>
<td>Partially covered</td>
</tr>
<tr>
<td>Glucometers</td>
<td>Only some people receive them for free. Otherwise, not covered (100% paid for by the person with diabetes)</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Partially covered</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

### References

1. EURADIA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
5. IDF-Europe Access survey (2013)

Looking ahead

Recent changes in reimbursement are raising concerns: access to newer medications is already limited and people with diabetes are reporting difficulties paying for their treatment.
Healthcare expenditure profile (2011)²

Total health expenditure per capita: USD 499.70
% of government expenditure spent on health: 11.9%

Health system overview
- The Health Insurance System, administered by the National Health Insurance Fund, covers the entire population.
- The National Health Insurance Fund, as the main purchaser of care, defines the care package covered jointly with the Ministry of Public Health.
- Most medicines and medical devices are supplied by private actors, according to Ministry of Public Health regulations – and in line with EU regulation.
- A quality issues reporting system is in place.

Diabetes prevalence (2011)¹

IDF Atlas
National Data

<table>
<thead>
<tr>
<th></th>
<th>9.2% of 20-79 year-olds</th>
<th>Official records: 6.5% of the population</th>
</tr>
</thead>
</table>
| Diabetes care procedure
- Prescriptions are provided by a diabetologist at a diabetes clinic.
- Diabetes clinics and diabetologists are the main points of diabetes information and advice.
- Diabetes supplies are dispensed mostly at community pharmacies or those located within public healthcare facilities. Some medical devices donated by companies may be also dispensed by healthcare teams.

Presence of products at national level
- At least one product from each of the categories surveyed was reported authorised for sale and present in the country.

Guidelines and specific prescription criteria
- Romania has national guidelines for diabetes care.
- The prescription of new diabetes medicines, such as insulin analogues or DPP-4 inhibitors, must be justified by the prescriber and reviewed by a medical commission.
- Control over the consumption of medical devices is achieved through reimbursement (see Affordability) – except in the case of insulin pumps:
  o For insulin pumps, priority is given to children and young people with type 1 diabetes; women planning a pregnancy or who are pregnant, adults with Down’s syndrome or having difficulties controlling their diabetes.
  o There is a yearly quota of subsidised pumps; all those eligible may not receive one.

From the survey
- Some of the survey respondents reported having experienced difficulties obtaining their diabetes supplies within the last two years – a pattern confirmed by healthcare professionals.
  o All respondents who faced problems reported stock issues as the primary cause for the difficulties. However, shortages of medical devices appear to have had a deeper impact on people’s treatment compared to medicines. This is because these shortages lasted longer and because there were no alternative supply options for medical devices.
  o Respondents living in rural areas reported treatment costs and financial difficulties as an added barrier to accessing diabetes supplies.
- Diabetes education and information about treatment was almost universal among people with diabetes but was far less common among their relatives.
- No significant differences in access issues were reported between people with different types of diabetes.
- Monthly out-of-pocket expenditure on diabetes was higher among rural respondents than those living in urban areas.
**Access to treatment**

- Physical access to diabetes care remains an issue, and difficulties arise mostly in rural areas.\(^5,6,8,9\)
  - In many regions, diabetologists and diabetes centres are found only in major cities, and the distribution of pharmacies remains unbalanced in favour of urban compared with rural areas.\(^6,8,9\)

**Stock and shortages**

- Of all the products surveyed, blood glucose test strips appear as the most likely to be affected by stock shortages.
  - Shortages often can be attributed to a breakdown in the supplier-pharmacy-health insurer chain. Delayed health insurance payments often mean pharmacies cannot afford to pay outstanding invoices; suppliers suspend future orders until previous invoices are settled.\(^5,6\)
  - Survey respondents reported that during periods of low or no stock, they lived without diabetes supplies until stocks were restored.\(^5\)

**Insulin and Anti-diabetes medication**

- Free\(^1,5,6,7\) *
  - Medication for hypoglycaemia: Not covered – 100% paid for by the person with diabetes\(^5,6\)
  - Pens and related supplies: Free on a quota basis for supplies\(^6,7\)
  - Syringes and needles: Free on a quotas basis\(^6\)
  - Pumps and related supplies: Free for certain types of diabetes and under certain conditions (see Availability)\(^5\)
  - Blood glucose test strips and meters: Free for people on insulin with a limit of 100 test strips every three months. Otherwise, not covered – 100% paid for by the person with diabetes\(^5,6\)
  - Ketone test strips: Not covered – 100% paid for by the person with diabetes\(^5,6\)

* Health insurance will only cover a drug up to the cost of the lowest priced brand. If a person chooses a more expensive brand, the price difference is paid out-of-pocket.

Please note that the information below presents only a summary of the reimbursement system and may not apply to individual cases.

**Looking ahead**

There is increasing debate over the reimbursement and the prescription criteria applied to new medicines and devices.\(^6\)

**References**

1. EURADA, FENI, IDE, & PCDE. (2011)
2. Global health observatory data repository. (2013)
4. PPRI & WHO (2011)
5. IDF-Europe Access survey (2013)
Healthcare expenditure profile (2011)

Total health expenditure per capita: USD 1,533.83
Proportion of government expenditure on health: 14.5%

Out-of-pocket expenditure represents 72% of private spending on health.

Proportion of government expenditure on health: 14.5%

Health system overview
- The mandatory health insurance system is administered by three different companies.
- The care package is defined by law.
- Medicines and medical devices are supplied principally by private actors, under Ministry of Health regulations and in line with EU regulation. A specialised agency ensures the application of these regulations.
- A quality issues reporting system is in place. However, the Slovakian Diabetes Association raised concerns over the capacity of the system to keep poor-quality devices out of the market.

Diabetes prevalence (2011)

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.7% of 20-79 year-olds</td>
<td>Official records: 7.5% of the population</td>
</tr>
<tr>
<td>Slovakian Diabetes Society estimate: 7% of the population</td>
<td></td>
</tr>
</tbody>
</table>

Diabetes care procedure
- People on insulin receive the prescriptions from a diabetologist, other people receive their prescription from a diabetologist or a GP.
- Prescribers and pharmacists are the main points of diabetes information and advice.
- Diabetes supplies are dispensed mostly at pharmacies. Some devices can also be dispensed by physicians or directly by companies.

Presence of products at national level
- At least one product from each of the categories surveyed was reported authorised for sale and present in the country.

Guidelines and specific prescription criteria
- Slovakia has national guidelines for diabetes care.
- New medicines appear to be prescribed as a second-line treatment.
- Pumps are prescribed to people with poor blood glucose control with conventional insulin therapy, or people with hypoglycaemia unawareness.
- Control over the consumption of medicines and medical devices is maintained through reimbursement.

Use
- Most people with type 1 diabetes are treated with insulin analogues. Pens are the most widely used insulin injection devices.
- Treatment for people with type 2 diabetes is determined by their physician.
- Women with gestational diabetes are managed for the most part via lifestyle changes and close blood glucose monitoring. Insulin is used only in a small number of cases.
SLOVAKIA

• The available evidence suggests that accessibility is not the main barrier to medicines and medical devices for people living with diabetes; no such difficulties were reported in the survey.5,6
• The provision of diabetes education and information about treatment has yet to be systematised. Currently, these depend on healthcare providers and associations and, thus, may not be equally available to all people with diabetes.6

Insulin is free1,7
Insulin analogues are free or partially reimbursed7
Anti-diabetes medication Free or partially reimbursed (depending on the medicine)7
Medication for hypoglycaemia Free or not covered (depending on the medicine)7
Pens and related supplies Free6
Syringes and needles Free5
Pumps and related supplies Fully reimbursed1,6
Blood glucose test strips and meters Free1 but with limits on the number of strips:6,7
- 100 per month for children and students
- up to 75 per month for adults on insulin
- 50 per quarter for adults on oral medications
Ketone test strips Free or partially reimbursed6

Financial coverage
Decisions regarding reimbursement are made by the Ministry of Health.1,4 Reimbursement criteria include calculations of comparative therapeutic value and medical value; a pharmacoeconomic evaluation (which includes cost-effectiveness and budget impact); as well as consideration of the social impact of the target disease.1,4 A maximum amount for reimbursement per medicine is set using internal reference pricing.1 Rates are updated every month.4

Looking ahead
The health insurances schemes may be merged into a single fund in the next few years, bringing changes to the health and reimbursement systems.6
A National Diabetes Programme is currently under discussion. Among various objectives, the Programme will enable the standardisation of diagnostic and therapeutic approaches; the establishment of a national register in order to improve monitoring of the epidemic and diabetes treatment results; and monitoring of healthcare expenditure for more efficient allocation of funds.4

References
1 EURADA, FEND, IDF, & PCDE. (2011)
2 Global health observatory data repository. (2013).
3 Szalay, T., et al. (2011)
4 PPRI & WHO (2011)
5 IDF-Europe Access survey (2013)
6 Association of Diabetic Patients of Slovakia (personal communication) (2013)
7 Doničová, V., Brož, J., & Sorin, I. (2011)
SOUTH-EAST EUROPE
About the data
We could not collect a large number of responses in this country. Thus the information presented below is based mainly on a review of the literature and exchanges with Albanian Diabetes Association and its healthcare professionals.

Healthcare expenditure profile (2011)
Total health expenditure per capita: **USD 254.60**
Proportion of government expenditure spent on health: **9.8%**

Health system overview
- The mandatory health insurance is administered by the Health Insurance Institute.
- Healthcare remains largely the responsibility of the Ministry of Health.
- Medicines and medical devices are supplied by private actors, according to Ministry of Health’s standards, while a specialised institution is responsible for registration of individual products in Albania. A reform of national regulation and standards on medicines and medical devices is underway in order to meet EU standards.
- Quality controls of products and suppliers are carried out mainly prior to distribution.

Diabetes prevalence

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0 % of 20-79 year-olds (2011)</td>
<td>Official Health Insurance Institute’s records: 2.45 % of the adult population (2012)</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescription are provided by endocrinologists and GPs, depending on a person’s treatment regimens.
- Prescribers are also the main points of diabetes information and advice.
- Most diabetes products are dispensed mostly at pharmacies. Meters are dispensed by the Albanian Diabetes Association.

Presence of products at national level
- Some medicines (like DPP4-inhibitors) or medical devices (like re-usable insulin pens) have only recently reached the market in Albania. Anti-hypoglycaemic medications and pumps remain unavailable in Albania.
- The small size of the Albanian market and the reduced list of reimbursed products have been cited as potential explanations for this situation.
- In order to encourage manufacturers to register their medicines in Albania, the registration procedure has been simplified for medicines already authorised by the EU or US agencies.

Guidelines and specific prescription criteria
- Albania has guidelines for diabetes treatment but these appear not to be implemented fully. The Albanian Diabetes Association is developing guidelines that will be disseminated in 2014.
- Insulin and second-line oral medications are primarily prescribed by endocrinologists.

Use
- People treated with insulin tend to receive human insulin — analogues being considered a second-line treatment.
- Pens are the main device for injecting insulin.
- People on oral medication are mainly treated with metformin or sulphonylureas. One DPP4 inhibitor was recently made available for the treatment of people with type 2 diabetes, but only as a second- or third-line treatment. The Health Insurance Institute estimates that about 20% of people with type 2 diabetes are being treated with insulin.
- Women with gestational diabetes who require medication are treated with insulin.
- The use of self-monitoring devices is limited by their cost — which has to be paid in full by people with diabetes.
Access to treatment
• Although improvements have been made, gaining physical access to diabetes care – mainly specialised care – can be problematic, especially in rural areas. Similar difficulties appear in terms of access to pharmacies.
  - As a result of these difficulties, people with diabetes living in rural areas may run out of some of the supplies they need because they cannot easily re-supply if problems arise.
  - These difficulties are made stronger by the organisation of the diabetes care pathway. People with diabetes have to refill their prescription every month. Their treatment regimen cannot be changed by any physicians until their next scheduled visit to their assigned prescriber.
• Information and education about treatment are mostly provided in the main cities and at the University Hospital Centre in Tirana. Hence, they appear to be difficult to access, especially for people not receiving treatment in a hospital, or for those living outside the capital city.

Stock and shortages
• Delays in the supply chain occasionally leave some points of dispensation out of stock. However, it would appear that many people with diabetes are able to adapt accordingly.

Insulin Free (see Availability for restriction on analogues)
Anti-diabetes medication Partially covered if included in the list of reimbursed medicines (metformin, glibenclamide, vildagliptin).
Otherwise, not covered – 100% paid for by the person with diabetes
Medication for hypoglycaemia Not available
Pens and related supplies
- Pre-filled pens are free
- Reusable pens are not covered by health insurance but donated by companies
The number of free needles is limited in both cases
Syringes and needles Unknown
Pumps and related supplies Not available
Blood glucose test strips and meters Not covered – 100% paid for by the person with diabetes
Some glucometers are donated by associations or manufacturers
Ketone test strips Not covered – 100% paid for by the person with diabetes

Financial coverage
Diabetes is among the health conditions that entitle people to have some diabetes medicines and medical devices covered. However, the number of reimbursed products is far smaller than the number of products on the market.
The Ministry of Health and the Health Insurance Institute decide on reimbursements. For medicines, reimbursement is defined according to therapeutic and economic criteria as well as internal reference pricing. Certain groups of people, such as children under 12 and people with a disability, also benefit from higher rates of reimbursement.

Looking ahead
Further to last June’s election, no change is anticipated until the new Ministry of Health is in place. However, it would appear to remain the case that, generally speaking, politicians’ awareness about diabetes does leave some room for improvement.
About the data

- Based on collected responses and discussions with the Israel Diabetes Association, it appears that the main barrier to access to medicines and medical devices is cost: most people have to pay a share of their treatment out-of-pocket.
- Some supply issues were reported by healthcare professionals, which do not seem to have affected people with diabetes.

### Healthcare expenditure profile (2011)²

Total health expenditure per capita: **USD 2,426.10**

Proportion of government expenditure spent on health: **10.7%**

#### Health system overview

- **Mandatory health insurance** is administered by five not-for-profit health groups (HMOs) and covers the whole population. The package of main covered benefit is defined by law.³,⁶ The majority of people have subscribed to additional coverage with their HMO or other voluntary health insurances.³,⁶
- Medicines and medical devices are mainly supplied by private actors, including the HMOs’ own networks. Regulation is set by the government, which delegates some of the implementation to a specialised agency.³ Although Israel is not a member of the EU, an agreement was signed in 2013 to facilitate mutual market access for the pharmaceutical industry. This led to some harmonisation of legislation regarding the pharmaceutical sector.⁷
- A **quality issues reporting system** is in place.⁵

### Diabetes Prevalence (2011)¹

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.5% of 20-79 year-olds</td>
<td>Official records: 6% of the population</td>
</tr>
</tbody>
</table>

#### Diabetes care procedure

- Prescriptions are provided by GPs or specialists.⁴
- GPs and specialists are the main points of diabetes information and advice.⁴
- Diabetes products are dispensed mostly at pharmacies.⁵,⁶

#### Presence of products at national level

- At least one product from each of the categories surveyed was reported authorised for sale and effectively present in the country.⁵,⁶

#### Guidelines and specific prescription criteria

- Israel has national guidelines for diabetes care.¹,⁵
- It seems that, aside from few medical devices, the choice of prescription of most diabetes products is left to the prescriber.¹
  - Ketone test strips appear to be primarily prescribed to people with type 1 diabetes.¹
  - Insulin pumps have to be prescribed by an endocrinologist or other diabetes specialist – principally to people with type 1 diabetes failing to achieve good glycaemic control with multiple daily insulin injections.⁵,⁶

#### Use

- The responses collected suggest that most people treated with insulin are using insulin analogues;¹ while metformin is one of the most prescribed oral medication.¹
- Pens are the main insulin injection devices.¹
• Available evidence suggests that accessibility is not the main barrier to medicines and medical devices for many people living with diabetes in Israel.\textsuperscript{5,6}
  \begin{itemize}
    \item A great variety of actors and channels provide information and education about diabetes and treatment (television, radio, schools, HMOs, hospitals, associations, support groups).\textsuperscript{5,6}
    \item Supply issues reported by healthcare professionals\textsuperscript{5} were not cited by people with diabetes as a problem,\textsuperscript{5,6} suggesting that although some healthcare facilities may have had difficulties replenishing their stock, they managed to ensure that people with diabetes received the products they needed.
    \item Some evidence suggest that physical access to a prescriber and/or dispensing points remain an issue for few specific population groups (disabled, people living in remote areas) but that some alternatives are offered by civil society.\textsuperscript{5,6}
  \end{itemize}

Insulin and anti-diabetes medication Partially reimbursed\textsuperscript{5,6}
Medication for hypoglycaemia Partially reimbursed\textsuperscript{5,6}
Pens and related supplies Partially reimbursed\textsuperscript{5,6}
Syringes and needles Partially reimbursed\textsuperscript{5,6}
Pumps and related supplies Free (see Availability for criteria)\textsuperscript{5,6}
Blood glucose test strips Partially reimbursed with limits on the number of strips\textsuperscript{5,6}
Glucometers Specific categories, like children, receive these for free Otherwise, they are partially reimbursed\textsuperscript{5,6}
Ketone test strips Only specific categories of people have them for free Otherwise, they are partially reimbursed\textsuperscript{5,6}

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

Looking ahead
The Israel Diabetes Association is optimistic: diabetes awareness is increasing in Israel, and a current positive attitude toward tackling the epidemic will lead to further progress regarding access to diabetes medicines and medical devices.\textsuperscript{6}

References
1 EURADIA, FEND, IDF, & PCDE. (2011)
2 Global health observatory data repository. (2013)
4 PPRI & WHO (2011)
5 IDF-Europe Access survey (2013)
6 Israel Diabetes Association (personal communication) (2013)
7 European Commission. (2013a)
From the survey

- All the people with diabetes who responded to the survey had type 1 diabetes. Thus, this stymies any discussion of access for all people with diabetes.
- With universal accessibility to diabetes medicines and devices having some way still to go, affordability is perceived as the main barrier.

Healthcare expenditure profile (2011)²

Total health expenditure per capita: **USD 333.77**

Proportion of government expenditure on health: **11.7%**

Health system overview

- The health insurance system, administered by the Health Insurance Fund, covers the entire population.³,⁷
- The package of benefits is defined by the Ministry of Health.³
- Certain diabetes products seem to be procured by the government.⁴ Others appear to be provided by the private sector,¹ regulated by a specialised agency, and according to Ministry of Health regulations.³,⁴,⁷
- A quality issues reporting system is in place.⁵

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.9% of 20-79 year-olds</td>
<td>No data</td>
</tr>
</tbody>
</table>

Diabetes care procedure

- Prescriptions are provided by GPs and diabetes specialists.¹
- Nurses, GPs and diabetes specialists all work in diabetes management.¹
- Diabetes products seem to be dispensed mostly at healthcare facilities and pharmacies.⁵

Presence of products at national level

- Most of the categories surveyed appear to include at least one product authorised for sale and present in Macedonia.¹,⁵,⁸
  - The presence of DPP-4 inhibitors on the Macedonian market could not be confirmed.⁵

Guidelines and specific prescription criteria

- Macedonia has adopted European and international guidelines for diabetes care and treatment.¹
  - It appears that medicines for hyperglycaemia and blood glucose-testing devices are prescribed only to people on insulin.
  - The choice of prescription for other medicines and medical devices depends apparently on the prescribers’ assessment of the condition and health status of the person with diabetes.⁵
Access to treatment

- Physical access to dispensing points appears to remain an issue for some people with diabetes.
  - The uneven (geographical) distribution of healthcare facilities might go some way to explaining this.
- Collected responses suggest that the provision of diabetes education and information about treatment is not universal yet.

Stock and shortages

- A small number of stock issues were reported, affecting mostly medical devices.
  - Delays in the supply chain were cited as provoking the problem.

Insulin Free

Anti-diabetes medication Only certain medicines are fully or partially covered

Medication for hypoglycaemia Free (see Availability for criteria)

Pens and related supplies Free

Syringes and needles Free

Pumps and related supplies Free

Blood glucose test strips and meters Only people treated with insulin receive these free of charge and the number of strips is limited:
  - 125 per month for people with type 1 diabetes
  - 4 per month for people with type 2 diabetes

Ketone test strips Not covered — 100% paid for by the person with diabetes

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

Financial coverage

People with diabetes appear to be entitled to receive certain products free of charge through the national diabetes programme.

The Ministry of Health decides on the eligibility of medicines for reimbursement. Medicines have to be included on the Health Insurance Fund’s list to be reimbursed. This list is designed according to therapeutic guidelines and risk/benefit analyses. A maximum amount for reimbursement per medicine is set using reference pricing.

A cap on reimbursement also appears to be applied to medical devices.

References

1. EURADIA, FEND, IDF, & PCDE. (2011)
4. WHOCC PPRI, (2011)
5. IDF-Europe Access survey (2013)
Healthcare expenditure profile (2011)²

Total health expenditure per capita: **USD 622.05**
Proportion of government expenditure on health: **14.1%**

Out-of-pocket expenditure represents 96% of private spending on health.

Proportion of government expenditure on health: 14.1%

Diabetes prevalence (2011)³

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.4% of 20-79 year-olds</td>
<td>Official records: 8.2% of the population</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are provided by GPs, informed by endocrinologists’ reports. Both sets of professionals are the main points of diabetes information and advice; counselling centres have been closed.⁶,⁸
- Diabetes products are dispensed mostly at public pharmacies.⁶,⁸

Guidelines and specific prescription criteria
- Serbia has national guidelines for diabetes care.¹
- Endocrinologists define treatment but only GPs are authorised to write prescriptions.⁶,⁸
- Control over prescription and the use of medicines and medical devices is mainly achieved through RHIF’s coverage (see Affordability)⁶.
- The list of reimbursed medicines includes both human insulin and insulin analogues, metformin, sulphonylureas and glucagon.⁶,⁷

Use
- Pens are the most widely used insulin injection devices. Pumps are used almost exclusively by people with type 1 diabetes.⁵,⁶
- Metformin, first-line treatment for people with type 2 diabetes,¹ is the most widely prescribed oral medication.⁵
- Blood glucose-monitoring devices are prescribed mainly to people on insulin.⁵,⁶

From the survey
- Some of survey respondents reported having experienced difficulties obtaining their diabetes supplies within the last two years — a pattern confirmed by healthcare professionals.
  - The majority of the respondents who faced problems obtaining their supplies reported stock issues as the primary cause, while affordability was also a key issue.
  - Blood glucose-monitoring devices and insulin were most affected.
  - These difficulties took from a few days to a few weeks to be resolved.
  - A small number of respondents mentioned additional challenges to access for people living in remote areas; their cause was not clear.
- Diabetes education and information about treatment was almost universal among the people with diabetes surveyed but far less common among their relatives.
- Monthly out-of-pocket expenditure for diabetes medicines and devices was higher among rural respondents than those living in urban areas; and among people with type 2 diabetes compared with their peers with type 1 diabetes.
Access to treatment

- Some evidence suggests that access to healthcare professionals and treatment may be an issue in some remote areas. 1 The roots of this problem could not be clearly identified.
- Access to diabetes education and information about treatment may become an issue in the future as public funding for counselling centres has ceased. Moreover, there will be no additional training for GPs, who are now responsible for providing health information to people with diabetes. 6

Stock and shortages

- Stock issues in public pharmacies are a recurring problem for people needing insulin and self-monitoring devices. 5
  - Delays at various stages along the supply chain and in the payment of suppliers, as well as administrative issues at national level, have been cited as potential catalysts for this situation. 4, 5, 6
  - The reluctance of certain stakeholders to engage in the creation and implementation of the new centralised procurement system 4 have also created problems over the past year. They seem resolved by now. 6
- Additionally, due to budget constraints, the prescription of insulin is closely scrutinised by the RHIF — leading to rationing of the amount of insulin prescribed to people, especially in the case of insulin analogues. 6
- Although people with diabetes seem to be able to find alternatives — mostly through the private sector and/or diabetes associations 5, 6 — this rationing and the various disruptions have become an important source of stress. 6

Insulin* Free 6, 7
Anti-diabetes medication* Metformin and sulphonylureas are free or partially covered
Others are not covered — 100% paid for by the person with diabetes 6, 7
Medication for hypoglycaemia* Only people on insulin are eligible for one of these medicines free of charge
Otherwise, not covered — 100% paid for by the person with diabetes 5, 6, 7
Pens* and related supplies Free 5, 6
Syringes and needles Free 5, 6
Pumps and related supplies Free of charge to the following only: people with type 1 diabetes; children under 15 years-old; pregnant women; adults with complications
Otherwise, not covered — 100% paid for by the person with diabetes 5, 6, 7
Blood glucose test strips and meters Free of charge only to people with type 1 diabetes and with a limit of:
- 150 test strips per month for children and pregnant women
- 50 test strips per month for adults
Otherwise, not covered — 100% paid for by the person with diabetes 5, 6, 7
Ketone test strips People under 26 on insulin receive strips free of charge
Otherwise, not covered — 100% paid for by the person with diabetes 6

*All medicines require the person with diabetes to pay a prescription fee of RSD 50 (USD 0.64).

Please note that the information provided above only presents a summary of the reimbursement system and may not apply to individual cases.

References
1 EURADA, FEND, IDF, & Pcede. (2011)
2 Global health observatory data repository. (2013)
4 Ihs. (2012, November 28)
5 IDF-Europe Access survey (2013)
6 Diabetes Association of Serbia (personal communication) (2013)
8 Serbian Association for the Study of Diabetes (personal communication) (2013)
Healthcare expenditure profile (2011)²

Total health expenditure per capita: USD 696.23
Proportion of government expenditure on health: 12.8%

Health system overview
- The General Health Insurance Scheme has unified the former health insurance schemes and covers most of the population. It is administered by the Social Insurance Organisation (SIO), which also defines the care package.⁷
- Most medicines and medical devices are supplied by private actors,³ according to Ministry of Health regulations, which are implemented by specialised agencies.⁷,⁸ As a candidate country for EU membership, Turkey is in the process of amending its legislation on pharmaceuticals and medical devices in line with EU standards.³,⁹
- Although a quality control system is in place,³,⁸ diabetes associations have raised concerns over the reliability and transparency of the procedure.⁶ Reporting of quality issues is undertaken largely by the associations.⁴

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th>IDF Atlas National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.4% of 20-79 year-olds</td>
</tr>
<tr>
<td>Official records: 13.7% of the population</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are provided by GPs or specialists — after the appropriate certificate has been obtained at a hospital (see Availability).⁶
- Prescribers are the main points of diabetes information and advice.⁶
- Diabetes supplies are dispensed mostly at pharmacies. Some insulin pens may also be dispensed at hospitals.⁶

About the date
We could not collect many responses in this country. Thus, the information presented below is based mainly on a review of the literature and exchanges with the national diabetes association.

Presence of products at national level
- At least one product from each of the categories surveyed was reported authorised for sale and effectively present in Turkey.¹⁵,¹⁶,¹⁸

Guidelines and specific prescription criteria
- Turkey has national guidelines for diabetes care.¹
- Once diagnosed, people with diabetes must then obtain a certificate describing their condition and outlining their treatment.
  - The certificate has to be requested by their physician, and is granted by a diabetes-specific medical board at university or government hospitals. Besides medical file, this procedure requires people with diabetes to go to the hospital for an evaluation (see also Accessibility).
  - Each certificate is valid for two years, making the procedure above one that is regularly repeated. The government is trying to reduce this period of validity to only one year; diabetes associations would like to increase it to five years.⁶
- Certain medicines, such as DPP4 inhibitors and analogues, can only be prescribed by certain specialists (Endocrinologists or hospital internists for the former, internists, paediatricians, endocrinologists and cardiologists for the latter).³
- Control over prescription and the use of other medicines and medical devices is maintained through the SIO's financial coverage (see Affordability).³,⁹

Use
- Pre-mixed insulin seems to be the principal line of treatment for people on insulin, while some long-acting analogues are used as a second- or third-line treatment.⁶
- Oral medications can only be prescribed for type 2 diabetes.⁶
- The use of medical devices seem to be constrained by factors relating to reimbursement (and co-payment) — except for ketone test strips, which, despite full coverage, are not widely used by people with diabetes.⁶
**Accessibility**

**Access to treatment**
- Although disparities in access to specialists and hospitals have been reduced with the current health reform, this inequality is still an issue for many people: certain procedures can be carried out only by a specialist or at a hospital.
- **Diabetes education** and information about treatment for people not treated with insulin remain out of reach of many people living in rural or remote areas.
  - A number of association-driven programmes targeting people with diabetes and future trainers were launched recently to address these gaps.

**Stock and shortages**
- No supply issues were reported.

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**Affordability**

**An estimate of monthly out-of-pocket spending on diabetes supplies could not be obtained.**
- Although the care package was unified by the current health reform, implementation of the reform is incomplete, leaving in place financial barriers to diabetes medicines and devices.
  - Access to free or partially covered medicines and devices depends on a certificate from the medical board (see sections above) and enrolment in the General Health Insurance Scheme.
    - Registration with the General Health Insurance Scheme costs around TL 40 (USD 20 per month), paid either by the individual or by their employer. A number of people have been unable to pay their contribution and, consequently, are unable to register.
    - Not only the implementation of the reform but the way this is interpreted, vary across regions — creating difference in the coverage of medicines and medical devices.
  - Former government schemes and independent programmes to support people in low-income groups or people without insurance have been discontinued since the inception of the single health insurance scheme.
  - All children receive free treatment, regardless of whether their guardian(s) has registered for the scheme.
  - Many non-branded products appear to be on the market and public coverage encourage lower-priced brands (see Table).
  - The choice of brand of diabetes product is made by the prescriber but is also constrained by reimbursement.
  - The price of all medicines is set through **external reference pricing**. Discounts can be negotiated for reimbursed medicines. The mark-ups applied by pharmacists and wholesalers are regulated through a **regressive scheme** and 8% VAT is applied.

**Financial coverage**

Provided that they are registered with the SIO, people with diabetes are exempt from co-payments on medicines. They must present the certificate described above describing their disease and listing the supplies they will need.

Decisions concerning reimbursement are made by the SIO, informed by a joint committee which includes members of the SIO, Ministry of Health, Ministry of Finance, academics, and representatives of the pharmaceutical industry.

For each medicine, the SIO covers an amount based on the lowest-priced products in its category. For devices, the SIO covers fully a list of brands; other devices are covered by a set amount.

Diabetes groups have expressed concerns that inclusion on the fully reimbursed list depends on price and budget concerns, rather than on the quality of the product.

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<table>
<thead>
<tr>
<th>Insulin and Anti-diabetes medication</th>
<th>Free</th>
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</thead>
<tbody>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free</td>
</tr>
<tr>
<td>Syringes and needles</td>
<td>Partially covered</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Partially covered</td>
</tr>
</tbody>
</table>
| Blood glucose test strips and meters | Free or partially covered (see above) with a limit of:
  - 100 test strips per 3 months for people with type 2 on oral medication
  - 150 test strips per month for people on insulin
    The number of test strips for children with type 1 diabetes and pregnant women is defined on their certificates. |
| Ketone test strips                   | Free |

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

---

**References**

1. EURADIA, FEND, IDF, & PCEO. (2011)
2. Global health observatory data repository. (2013)
3. Tatx M. et al. (2011)
4. PPR WHO (2011)
5. IDF-Europe Access survey (2013)
7. Rian, R. et al. (2013)
10. Andriciu, C. (2008b)
EASTERN EUROPE
Healthcare expenditure profile (2011)\(^2\)

Total health expenditure per capita: **USD 141.5**
Proportion of government expenditure on health: **5.8%**

Health system overview
- The government guarantees a basic package of services free of charge or at subsidised rates to all citizens, and additional benefits to specific groups (including people with diabetes).\(^3,6\) The creation of a State Insurance System has been announced\(^4\) but its future implementation remains undefined.
- Medicines provided through public facilities and included in the list of essential medicines are procured centrally via tenders, and managed by a specialised government agency. Other medicines or devices are provided by private actors, according to the Ministry of Health’s regulations.\(^5\) However, as of 2010, national legislation was not fully compliant with international standards of good practice.\(^5\)
- A quality issues reporting system is in place.\(^5\)

Diabetes prevalence (2011)\(^1\)

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.0% of 20-79 year-olds</td>
<td>Healthcare professionals estimate 2.15% of the adult population</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are provided at the primary healthcare level, mostly by endocrinologists and, to a lesser extent, by GPs or family doctors.\(^6\)
- Healthcare professionals appear function as the principal point of information and advice for diabetes care.\(^6\)
- Diabetes medicines are dispensed mainly at public primary healthcare facilities – by pharmacists or nurses. Medical devices tend to be dispensed at private pharmacies.\(^6\)

Availability
- All surveyed categories of medicine are present in Armenia\(^6\) but only human insulin, metformin, glibenclamide and gliclazide are contained in the list of essential medicines.\(^9\) Some other medicines may be present through private actors or imported from the Armenian diaspora.\(^6\)
- Blood glucose monitoring devices, insulin pens and insulin syringes seem to be present in the country.\(^4\)

Guidelines and specific prescription criteria
- The development of guidelines for the treatment of diabetes is part of a National Strategy on Diabetes adopted in 2011.\(^6\)
- The quantity of oral medication per prescription is limited, so two monthly visits to a doctor are required to top-up medication.\(^6\)
- Some policy-makers and doctors have expressed their concerns over state procurement allegedly giving priority to lower-priced products over higher-quality ones.\(^1\) This information could not be confirmed by other sources.

Use
- Syringes are the most common insulin injection device.\(^6\)
- Pattern of use for other diabetes products could not be assessed for this country.
Access to treatment

- Physical access to, and coverage of, primary care facilities — which provide care and certain medications — has improved. However, most endocrinologists remain concentrated in the capital city.

Stock and shortages

- Overall, the supply of publicly procured medicines has improved. Insulin coverage appears to be universal, although occasional shortages are reported due to inaccurate forecasting of future needs. The supply of oral medication remains underfunded, provoking recurring shortages: in 2012, as little as 30% of the country's needs were covered by State supply.
- For publicly procured medicines, people often have to switch from one type or brand of medication to another.
- Information on stocks in the private sector was unavailable.

Insulin and Anti-diabetes medication

- Human insulin and the oral agents on the list of essential medicines are free.
- Other medicines are not covered — 100% of expense paid for by the person with diabetes.

Other medicines

- Not covered — 100% of expense paid for by the person with diabetes.

Syringes, pens and related supplies

- Not covered — 100% of expense paid for by the person with diabetes.
- Free provisions are occasionally made by certain health facilities or through international or private donations.

Pumps and related supplies

- Not covered — 100% of expense paid for by the person with diabetes.

Blood glucose test strips and meters

- Not covered — 100% of expense paid for by the person with diabetes.
- Children may occasionally receive these products for free through international or private donations.

Ketone test strips

- Unknown

Financial coverage

The list of medicines covered by the State is based on the list of essential medicines. Certain groups (people with a disability, children under seven, elderly people...) or people with certain health conditions (including diabetes) are entitled to free or subsidised medicines.

Affordability

- In general, the affordability of healthcare and treatment remains an issue in Armenia and people requiring treatment for their diabetes are no exception.
- According to a 2012 survey, people with diabetes spend between USD 26 and USD 128 per month for their medication.
- These expenditures relate to medical devices and medications that are not covered by the State. However, expenditures also occur when there are shortages of medicines in the public sector and individuals are forced to purchase privately.
- There is currently no control over the pricing of diabetes products (including mark-ups by distributors) but this situation may change with ongoing legislative reform.
- While Armenia has one of the lowest GDP in the European region, it seems that the prices of many medicines in the country are similar to those found in OECD countries.

Looking ahead

The implementation of the National Strategy on Diabetes was scheduled to start in 2012. National legislation on pharmaceuticals is being revised.

References

7. HITT-CISS. (2013d).
Healthcare expenditure profile (2011)²

Total health expenditure per capita: **USD 356.9**

% of government expenditure spent on health: **3.7%**

Health system overview

- The State defines a care package (including diabetes care and treatment) that is provided free of charge but its boundaries are unclear and implementation uneven throughout the country.¹ A law creating a mandatory health insurance was adopted in 1999 but has yet to be implemented.⁴
- Medicines and medical devices included in the care package are procured through public tenders.¹,³,⁶ Health facilities are allowed to purchase additional supplies.⁶ Further products are supplied by private actors.³,⁶
- The regulation and quality-control of the pharmaceutical and medical devices sectors are the responsibility of the Ministry of Health, together with a specialised agency.³,⁴ However, it would appear that no quality issues reporting system is operational.⁶

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.6% of 20-79 year-olds</td>
<td>Official records; <strong>1.52%</strong> of the population</td>
</tr>
</tbody>
</table>

Diabetes care procedure

- Prescriptions are provided by endocrinologists at local polyclinics.⁶
- Endocrinologists are also the main points of information and advice.⁶
- Diabetes products are dispensed mainly at polyclinics or community pharmacies.⁵,⁶

Key background information: country health system

From the survey

- Almost all survey respondents reported having difficulties obtaining their diabetes products within the last two years — a pattern confirmed by healthcare professionals.
  - Stock and affordability issues were the two main reasons behind these difficulties
  - Insulin, insulin pens and glucose test strips were most affected.
  - While the majority of respondents who faced problems obtaining their supplies were able to find alternative solutions — especially through the diabetes association — many remained without supplies for more than two weeks.
- These difficulties affected people regardless of their type of diabetes or whether they were living in a rural or urban area.
- Education or information about treatment was almost universal among the people with diabetes involved in the survey and their relatives.

Key diabetes data

<table>
<thead>
<tr>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Presence of products at national level</td>
</tr>
<tr>
<td>• At least one product from each of the categories surveyed was reported as authorised for sale and present in the country.³,⁵,⁶</td>
</tr>
<tr>
<td>• However, only medications that are included in the list of essential medicines,¹ and the medical devices covered by the national diabetes programme are provided for free.¹,⁵,⁶ The exact content of both lists is not publicly available and could not be obtained.</td>
</tr>
<tr>
<td>• The national diabetes association has expressed concern that local authorities may prioritise low price over quality in the procurement of publicly provided diabetes products.⁶</td>
</tr>
<tr>
<td>Guidelines and specific prescription criteria</td>
</tr>
<tr>
<td>• Azerbaijan has guidelines for diabetes care,¹ which are being progressively implemented.⁶</td>
</tr>
<tr>
<td>Use</td>
</tr>
<tr>
<td>• According to national statistics, 24% of registered people with diabetes are treated with insulin⁵</td>
</tr>
<tr>
<td>• Human insulin and syringes remain the most used insulin treatment.¹,⁶ Insulin analogues and insulin pens are prescribed as a priority to children or to adults who were started on those products as children.¹,⁶</td>
</tr>
<tr>
<td>• Metformin and sulphonylureas are the most commonly used oral medications.⁵,⁶</td>
</tr>
</tbody>
</table>
AZERBAIJAN

Access to treatment

• Physical access to care has improved, as all districts have now at least one polyclinic. Physical access to pharmacies may remain an issue in certain rural areas but this could not be confirmed by local actors.

• In order to benefit from publicly provided products, people need to be registered on the national diabetes register — the lengthy registration process may delay access to free treatment.

Stock and shortages

• In terms of access to medicines and medical devices, stock and inadequate supply issues are reported as the main barriers for people living with diabetes.

  o Annual needs forecasts on which procurement and distribution only take into account current numbers and do not cover the needs of those who will be diagnosed in the forthcoming year.

  o Although the national diabetes programme’s budget has tripled since 2012, available funds seem to remain insufficient to cover therapeutic needs.

  o Inefficiencies at the administrative level and throughout the supply chain may also contribute to these shortages.

• Recurrent shortages may have contributed to the development of an illegal market for diabetes products in certain areas.

Insulin and anti-diabetes medication

Free if included in the list of essential medicines.
Otherwise, not covered — 100% paid for by the person with diabetes.

Medication for hypoglycaemia

Free.

Pens and related supplies

Only children receive them for free; otherwise, not covered — 100% paid for by the person with diabetes.

Syringes and needles

Not covered — 100% paid for by the person with diabetes.

Pumps and related supplies

Not covered — 100% paid for by the person with diabetes.

Blood glucose test strips and meters

Free but with a limit of two boxes of test strips per year per person.

Ketone test strips

Not covered — 100% paid for by the person with diabetes.

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

References


Looking ahead

The Presidential elections held in October 2013 may bring some changes in health and diabetes policies.

Gaps remain between official entitlements and real-world provision of treatment. Therefore, constant monitoring of the national diabetes programme is required.
Healthcare expenditure profile (2011)

Total health expenditure per capita: **USD 307.1**
Proportion of government expenditure on health: **13%**

Out-of-pocket expenditure represents 91% of private spending on health.

Health system overview

- The **national health system** is decentralised: the Ministry of Health assumes overall responsibility but local authorities manage and fund primary and secondary healthcare.
- Most healthcare services are free to all citizens at the point of care. Additionally, people with diabetes (like those with certain other conditions) are entitled free-of-charge to pharmaceuticals that are included in the list of essential medicines.
- Medicines for major diseases included in the list are procured through central or regional tenders and then distributed, based on local-authority orders, through a state distribution system.
- Specialised agencies are in charge of quality control and a quality issues reporting system is in place.

Diabetes prevalence (2011)

<table>
<thead>
<tr>
<th>Source</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDF Atlas</td>
<td>9.4% of 20-79 year-olds</td>
</tr>
<tr>
<td>Official records</td>
<td>2.1% of the population including type 1 diabetes: 7.2%; type 2 diabetes: 92.5%; other diabetes: &lt;0.01% (2008 figures)</td>
</tr>
</tbody>
</table>

Diabetes care procedure

- Prescriptions are mainly provided by endocrinologists who also function as a key point of information and advice for diabetes care, alongside associations and some private educational initiatives.
- For the most part, diabetes products are dispensed at pharmacies but some medical devices may also be provided during medical visits. Certain insulins can be dispensed only by state-owned pharmacies.

Guidelines and specific prescription criteria

- Belarus has guidelines for the treatment of diabetes.
- Only endocrinologists can prescribe insulins.
- Prescription of medicines and medical devices is constrained by financial coverage and public provision (see affordability).

Use

- As of 2011, all people with type 1 diabetes and less than 10% of people with type 2 diabetes were on insulin.
- For people on insulin therapy, human insulin remains the main line of treatment.
- Most people on insulin rely on syringes; only 11% use pens.
- Metformin is usually the first line of treatment for people on oral medication.

Key background information: country health system

From the survey

We were unable to collect a large number of responses in this country. Thus, the information presented below is based mainly on a review of the literature and exchanges with the national diabetes association.

Key diabetes data

Availability

Presence of products at national level

- At least one product from each of the categories surveyed was reported as authorised for sale and effectively present in the country:
  - However, public procurement for medicines is limited to the list of essential medicines, which includes human insulin and insulin analogues; metformin, sulphonylureas, thiazolidinediones (gliptazones) and glucagon.
  - Some evidence suggests public procurement gives priority to domestically produced products.
  - Some stakeholders are concerned about the quality of certain diabetes products currently on the market and that public procurement may favour lower prices over quality.
BELARUS

Access to treatment

- Access to diabetes care is hampered by the lack of doctors in general\(^6\) and of physicians trained in diabetes care in particular.\(^1,4,7\)
- Although improvements have been made regarding access to specialised diabetes healthcare, many people with diabetes living in rural areas face difficulties to see an endocrinologist, most of whom work in hospitals.\(^6\)
- Regarding prescriptions, people with diabetes can receive three-monthly prescriptions, which reduces the number of required visits to their physician.\(^4\)

Stock and shortages

- There have been some reports of occasional shortages,\(^1\) especially for oral medication.\(^1\) However, this could not be confirmed by the national associations.
- Tenders are awarded annually. Consequently, publicly supplied brands may change from one year to another or the supply of a given brand may be interrupted for some time if the procurement process is delayed.\(^7\)
  - There have been a number of reports about people on insulin who have encountered difficulties adapting to this regular change of medication.\(^7\) Additionally, intolerance to a given brand of insulin may not be a sufficient grounds to receive a publicly procured alternative.\(^7\)

Insulin Human insulin is free.

Depending on the regional budget,\(^4\) analogue insulin is free for children, students and people with complications or co-morbidity/ies 6

Anti-diabetes medication Only those included in the essential medicines list are free. Otherwise, not covered – 100% paid for by the person with diabetes\(^6,9\)

Medication for hypoglycaemia Free\(^6\)

Pens and related supplies Free for children under 18 years-old, students, pregnant women and people with complications. Otherwise, not covered – 100% paid for by the person with diabetes\(^1,6\)

Syringes and related supplies Free\(^4\)

Blood glucose test strips and meters Glucometers are subsidised for children, pregnant women and certain adults with disability status\(^1,4,6\)

These categories of people receive one test strip/day for free. Otherwise, not covered – 100% paid for by the person with diabetes\(^1,4,6\)

Ketone test strips Not covered – 100% of expense paid for by person with diabetes\(^1\)

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

Affordability

- The majority of people with diabetes pay a share of their treatment (especially medical devices)\(^7\) out of pocket.\(^1,4,6\) However, the financial burden due to diabetes treatment varies between regions, depending on local-authority coverage.\(^4\)
  - Disability benefits may provide financial support to cover these costs. People registered as "disabled" are also entitled to further free supplies (see Table). While all registered children with diabetes are eligible for these benefits, only adults with certain complications or co-morbidity/ies can benefit.\(^6,9\)
  - An estimate of monthly out-of-pocket expenditure for diabetes products could not be obtained. However, the Belarusian Humanitarian Organisation considers that restrictions on free medicines and medical devices (especially anti-diabetes medication, insulin analogues and glucose test strips) remain the principal barrier for people with diabetes.\(^6\)
- Unless products are purchased privately, the choice of brands is constrained by public tenders.\(^5,6,7\) There is an active policy to promote non-branded products.\(^6\)
- Publicly provided products are under strict price control by the government; no mark-up is authorised.\(^3\) In the private sector, limits are applied to the overheads that can be charged by importers, distributors and retailers.\(^4\) Other price components in the private sector could not be determined.

Financial coverage

Diabetes (like certain other conditions) entitles those affected to free medications\(^6\) that are included in the essential medicines list.\(^8\)

The provision of medicines and medical devices is financed through both federal and regional government budgets. Consequently, certain regions offer wider benefits than others.\(^7\) As a result, the table below provide only an overview of the benefits enjoyed by a majority, not all, of people with diabetes.

<table>
<thead>
<tr>
<th>Insulin</th>
<th>Human insulin is free. Depending on the regional budget,(^4) analogue insulin is free for children, students and people with complications or co-morbidity/ies Otherwise, not covered – 100% paid for by the person with diabetes(^1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-diabetes medication</td>
<td>Only those included in the essential medicines list are free. Otherwise, not covered – 100% paid for by the person with diabetes(^6,9)</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Free(^6)</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free for children under 18 years-old, students, pregnant women and people with complications. Otherwise, not covered – 100% paid for by the person with diabetes(^1,6)</td>
</tr>
<tr>
<td>Syringes and related supplies</td>
<td>Free(^4)</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Glucometers are subsidised for children, pregnant women and certain adults with disability status(^1,4,6) These categories of people receive one test strip/day for free. Otherwise, not covered – 100% paid for by the person with diabetes(^1,4,6)</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Not covered – 100% of expense paid for by person with diabetes(^1)</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

References
7. HITT-CISS. (2013a).
Healthcare expenditure profile (2011)²

- Total health expenditure per capita: **USD 328.30**
- Proportion of government expenditure on health: **6.9%**

Health system overview
- **Mandatory private health insurance** has existed since 1995. The government provides health vouchers for households judged to be under the poverty line in order to purchase health insurance, and offers certain services for free or at a subsidised price to specific groups.¹³
- Most medicines and medical devices are procured and provided by private actors.³,⁹
- Quality control is carried out prior to distribution by a specialised agency under the authority of the Ministry of Health.¹,⁵ However, some evidence⁵,⁴ suggests that this agency may lack the resources it requires to perform its duty systematically.

Diabetes prevalence (2011)¹

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>3.3% of 20-79 year-olds</strong></td>
<td>Official records: <strong>5 – 7%</strong> of the population</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescriptions are provided by endocrinologists but also by GPs.⁷
- The prescription of diabetes medicines by GPs is restricted.⁷
- The prescriber functions also as the main point of diabetes information and advice on treatment.¹,⁷
- Diabetes products are dispensed mainly at local pharmacies.⁷,⁹

- **Presence of products at national level**
  - At least one product from each of the surveyed categories was reported authorised for sale.¹,² However, the high costs of certain technologies (and consequent low demand for them), as well as delays in maintaining proper registration, may make certain products occasionally unavailable.¹,²

- **Guidelines and specific prescription criteria**
  - Guidelines by the American Diabetes Association and European Association for the Study Diabetes are reported being used.¹ However, responses from healthcare professionals⁵,⁷ suggest their interpretation and implementation may vary from one area to another.
  - While GPs’ prescriptions of diabetes medicines are restricted, those of endocrinologists are not.¹
  - Most people with diabetes seem to be treated with oral medication¹ (especially metformin⁵).
  - Insulin analogues seem to be mainly prescribed as a second-line treatment.¹,⁷

About the data
We were unable to collect a large number of responses in this country. Thus, the information presented below is based mainly on a review of the literature and exchanges with the national diabetes association.
Access to treatment

• Physical access to pharmacies in rural areas has improved. However, accessing (and supplying) pharmacies in remote, mountainous areas can be problematic.6,9
• Access to endocrinologists seems to represent a greater barrier.1 Potential explanations for this difficulty include the fact that they tend to be concentrated in urban areas (university clinics or hospitals7), and that there has been a lack of investment in specialised care training8 in the last few years.

Stock and shortages

• According to responses from healthcare professionals,5 supply does not seem to be a major problem in Georgia.

Insulin Human insulin and a basal analogue (glargine) are free9,1,5,6 Other insulins are not covered and must be paid for by the person with diabetes5,6

Anti-diabetes medication Not covered — 100% paid for by the person with diabetes

Medication for hypoglycaemia Unclear — reported as being free for children in some of the literature1,9 but denied by healthcare professionals5,7

Pens and related supplies Unclear — reported as being free by some of the literature1,9 but denied by healthcare professionals5,7

Syringes and related supplies Not covered — 100% paid for by the person with diabetes

Pumps and related supplies Not covered — 100% paid for by the person with diabetes

Blood glucose test strips and meters Unclear — reported free for children by some of the literature1,9 but denied by healthcare professionals5,7

Ketone test strips Not covered — 100% paid for by person with diabetes

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

Looking ahead

Although some steps have been taken to improve access to healthcare in Georgia, low awareness about diabetes among the general public and politicians, and a lack of political will on this issue, make further improvements difficult.6,7

Accessibility

Affordability

• Generally, affordability is a major barrier to access to healthcare and medicines in Georgia,6 and diabetes is no exception.6,7,9
  o Medical visits and treatment require out-of-pocket payments from most people.6,7,9 Some diabetes associations provide certain services free of charge.9
  o According to responses collected in the capital city,5 median out-of-pocket spending on diabetes medicines and medical devices per month was GEL 35 (USD 21), or GEL 420 (USD 256) per year.

• Available information suggests that prices and mark-ups in the pharmaceutical sector are not regulated and rely on market competition and fluctuations.4 Regulation for medical devices is unknown.
  o The mark-ups on medicines in Georgia are reported as being higher than in other European countries.6
  o The pharmaceutical market is described as an oligopoly (limited to a small number of sellers), which limits competition.4
  • Based on the response of healthcare professionals, it seems that very few non-branded products are available in Georgia. The brand of the target product is determined by the prescriber.5,7

Financial coverage

Products provided under state’s programmes are dispensed free of charge.1 However, the complete list of these benefits and its implementation is unclear (see table below).
Healthcare expenditure profile (2011)^2

Total health expenditure per capita: **USD 454.9**
Proportion of government expenditure on health: **10.5%**

**Health system overview**
- The government guarantees a free package of services to all citizens and additional benefits to specific groups, and for “socially significant” diseases, such as diabetes. ^1^ The provision of diabetes services has been delegated to regional authorities. ^1^
- Medicines and medical devices for diabetes covered by the government are procured through yearly public tenders, which are managed by a public purchasing agency at the national and regional levels. ^1,^ ^4,^ ^5,^ ^6,^ ^7,^ ^11^ Since 2009, the distribution system has been under reform in order to align it with international standards — through a public-private partnership. ^3^
- Public procurement includes quality specification; ^4^ a number of reporting mechanisms for quality issues are in place. ^6^

**Diabetes prevalence (2011)^1**

<table>
<thead>
<tr>
<th></th>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7.5% of 20-79 year-olds</strong></td>
<td></td>
<td><strong>Official records: 1.3% of the population</strong></td>
</tr>
</tbody>
</table>

**Diabetes care procedure**
- Prescriptions are provided mainly by endocrinologists, who also are the main point of diabetes information and advice. ^1,^ ^6^ Since 2012, care for people with type 2 diabetes is undertaken by GPs. ^6^
- Diabetes products are dispensed at pharmacies. ^1,^ ^6^

**Key diabetes data**

- At least one product from each of the categories surveyed was reported authorised for sale ^5^ and present in the country. ^5^

**Guidelines and specific prescription criteria**
- Kazakhstan has guidelines for the treatment of diabetes. ^1^
- Prescription has to take into account the list of medicines and medical devices covered by the nationwide care package for diabetes. ^1^
  - New medicines were recently added to this list, while the volume of publicly procured medicines has increased. ^6,^ ^9^
  - Diabetes prescriptions are renewed monthly. ^9^
- A 2012 study showed that 70% of people with diabetes were on oral medications (mostly sulphonylureas and metformin) while 42% were on insulin. ^9^
Access to treatment

- Access to care has been reported as an issue. However, it is not clear whether this is due to a lack of healthcare professionals or the requirement that prescriptions be renewed monthly.\(^6,7\)
  - Task shifting for type 2 diabetes care was adopted in 2012 and diabetes training programmes for GPs are being implemented.\(^6\)
- Some inequalities remain between regions in terms of the number of endocrinologists and pharmacies.\(^1\)

Stock and shortages

- Supply has improved but occasional shortages persist due to delays in distribution or insufficient supplies.\(^5,6\)

Affordability

Most people living with diabetes in Kazakhstan pay an out-of-pocket contribution to the cost of their treatment to complete the state’s care package (additional consumables, the oral medications that are not covered).

An estimate for annual out-of-pocket diabetes expenditure could not be obtained. However, the 2012 study mentioned above puts average annual out-of-pocket expenditure for diabetes medicines and medical devices at KZT 26,515 (USD 176).\(^9\)

The available information suggests that the price of medicines is high, including those paid at procurement.\(^4,7\) Furthermore, prices are not regulated.\(^4\) There is no promotion of non-branded products. As a result, the more expensive branded products are most often prescribed.\(^4,11\)

Financial coverage

Diabetes is considered a socially significant disease; people with the disease are entitled to free healthcare and outpatient medications.\(^5,4\)

Insulin and medical devices for people on insulin are funded by the central government, oral medications are funded through regional budgets. Thus the coverage for oral medicines may vary between regions.\(^1,7\) A new reimbursement model began implementation in 2012 aimed at increasing the list of oral medications and the share of their costs covered by public budgets.\(^8\)

<table>
<thead>
<tr>
<th>Item</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>Free(^1,5,7,9)</td>
</tr>
<tr>
<td>Anti-diabetes medication</td>
<td>Free/partially covered/not covered at all — depending on the medication (^5)</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Only people on insulin receive these for free Otherwise, not covered — 100% paid for by the person with diabetes (^4)</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Free(^1,5,7,9) — with a limit of one new pen every 50-75 cartridges and 100 needles per year(^9)</td>
</tr>
<tr>
<td>Syringes and related supplies</td>
<td>Free(^1,5,7,9)</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Only children under 15 receive these free Otherwise, not covered — 100% paid for by the person with diabetes (^4)</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Only people on insulin receive these for free — with a limit of 300 test strips per year Otherwise, not covered — 100% paid for by the person with diabetes (^5,7,9)</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Only people on insulin receive these for free Otherwise, not covered — 100% paid for by the person with diabetes (^5,6)</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

Looking ahead

Multiple reforms are underway regarding the benefit package for diabetes medicines and medication and their supply.\(^5,6,8,10\)

References

1. EURADIA, FEND, IDF, & PCEO. (2011)
2. Global health observatory data repository. (2013)
4. HAI Global. (2005a)
5. IDF-Europe Access survey (2013)
Healthcare expenditure profile (2011)\(^2\)

Total health expenditure per capita: **USD 71.3**

Proportion of government expenditure on health: **11.6%**

Health system overview

- The government defines and guarantees a package of services: primary healthcare is free to all citizens, other services require co-payments. Exemptions exist for specific groups or certain conditions. The mandatory health insurance system also covers a share of co-payments for people with insurance. The provision of services is the responsibility of regional authorities.\(^3\)
  - Since 2006, people with diabetes are entitled by law to a list of benefits, including free treatment.\(^5,3\)
- Diabetes medicines included on the national list of essential medicines and the medical devices covered by the national program are purchased centrally through public tenders. Individual health facilities can procure additional stock on their own budget. Other products are provided by private actors,\(^1,3,5,6,7\) which is subjected to the Ministry of Health’s regulation\(^3\). However, as of 2011, legislation did not comply fully with international standards of good practice.\(^3,7\)
- Quality control is carried out prior to distribution but no system exists to report quality issues.\(^6,7\)

Diabetes prevalence (2011)\(^1\)

\begin{tabular}{|c|c|}
\hline
\textbf{IDF Atlas} & \textbf{National Data} \\
\hline
4.9 % of 20-79 year-olds & \textbf{Official registry: below 1%} \textbf{(comprising 93% type 2 diabetes, 7% type 1 diabetes)} \\
\hline
\end{tabular}

Diabetes care procedure

- Prescriptions are provided by endocrinologists and family practitioners.\(^5,6\)
- Doctors and, in rural areas, nurses are the main points of diabetes information and advice on treatment.\(^6\)
- Diabetes products are dispensed at either healthcare centres or pharmacies, depending on the product.\(^6\)

Guidelines and specific prescription criteria

- Guidelines for diabetes treatment exist, based on European and US standards but their implementation is constrained by lack of resources, medicines and medical devices.\(^5\)
- Prescription and use are conditioned by the criteria for financial coverage (see below).
- In 2008, about 8% of people with diabetes registered with the Ministry of Health were on insulin.\(^1\)

**About the data**

We could not collect many responses in this country. Thus, the information presented below is based mainly on a review of the literature and exchanges with the national diabetes association.
**Access to treatment**

- Lack of education and diabetes knowledge about their condition seem to remain a major issue.
- The supply of medicines and medical devices has improved: nowadays, most areas receive insulin, syringes and at least one type of oral medication.
  - Gaps may remain between people’s needs and the quantity supplied.
  - The treatment regimen has to be adapted to supply rather than the other way around.

**Affordability**

- Financial access to treatment remains a major issue throughout the country; diabetes care is no exception.
  - Elderly people (who represent 70-80% of people with type 2 diabetes) and people living in rural areas are particularly affected.
  - This is due to poverty but also high prices.

<table>
<thead>
<tr>
<th>Medication Type</th>
<th>Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>Free</td>
</tr>
<tr>
<td>Anti-diabetes medication</td>
<td>Two types of oral medication are free. Others are paid for entirely by the person with diabetes.</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Unknown</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Only children get these for free. Otherwise, not covered — 100% of expense paid for by the person with diabetes.</td>
</tr>
<tr>
<td>Syringes and related supplies</td>
<td>Free</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>N/A</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Not covered — 100% of expense paid for by the person with diabetes. Some people receive donations through associations.</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Unknown</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

**References**

1. EURADA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
6. Dr. Satarov N. (personal communication) (2013)
Healthcare expenditure profile (2011)²

Total health expenditure per capita: **USD 333.8**

Proportion of government expenditure on health: **13.3%**

Proportion of out-of-pocket expenditure represents 83% of private spending on health.

Health system overview

- Moldova introduced mandatory health insurance in 2004,⁷ which acts as a single purchaser of care. However, universal coverage has not been achieved: in 2011, 20% of the population remained uninsured, many among low-income groups.¹
- The Ministry of Health defines the care package covered by national insurance. It includes a list of conditions for which healthcare is covered and a list of subsidised medicines.³ Medicines (including insulin) covered by national programmes are provided free of charge.
- Insulin is procured through centralised tenders but distributed by the winning tenderer.⁶ All other outpatient medicines and devices for diabetes are directly procured by pharmacies.⁶ The Medicines & Medical devices Agency ensures the application of national regulations regarding supply and distribution systems.³,⁴ However, as of 2011, national legislation was not fully compliant with international quality standards.³,⁴ Regulation for medical devices is also much more recent and less developed than the one for medicines.⁵

Diabetes prevalence¹

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
</table>

Diabetes care procedure

- Prescriptions are provided by endocrinologists and GPs.¹
- The main points of diabetes information and advice could not be determined.
- Some medications are dispensed at healthcare facilities while others are dispensed at pharmacies.¹

Availability

- Although at least one product from each of the categories surveyed appear to be authorised for sale,⁵ their presence in the country could not be confirmed.⁵
- The national list of essential medicines includes human insulin and insulin analogues, metformin, repaglinide and glibenclamide.⁶
- The regulatory agency’s capacity to control the quality of medicines has been disputed.⁶

Guidelines and specific prescription criteria

- Moldova has guidelines for the treatment of diabetes¹ but the degree of implementation of these recommendations could not be assessed.
- In 2011, pumps were primarily prescribed to children.¹

Use

- Human insulin, metformin and medication for hypoglycaemia are reported to be the most widely prescribed diabetes medications.¹

About the data

We were unable to collect a large number of responses in this country. Thus, the information presented below is based mainly on a review of the literature.
### Access to treatment
- Against a backdrop of significant shortages of healthcare professionals, ensuring a sufficient number with training in diabetes care remains an issue.
- Physical access to pharmacies in rural areas is also an issue, especially in the south of the country.
- The diabetes education and information provided for people living with diabetes remains insufficient.

### Stock and shortages
- Shortages of publicly procured medicines are common.
  - Delays in the procurement procedure may contribute to this problem.
- Shortages are also found in the private sector, and are not limited to diabetes.

### Insulin free
- Anti-diabetes medication
  - Unclear: reported to be free or partially reimbursed in some literature but denied by respondents

### Financial coverage
Like other people in Moldova with a chronic disease, people with diabetes are entitled to certain medication free of charge.

<table>
<thead>
<tr>
<th>Item</th>
<th>Reimbursement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>Free</td>
</tr>
<tr>
<td>Anti-diabetes medication</td>
<td>Unclear</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Unclear</td>
</tr>
<tr>
<td>Pens and related supplies</td>
<td>Unclear</td>
</tr>
<tr>
<td>Syringes and related supplies</td>
<td>Unknown</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Unclear</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Not covered</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Not covered</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

### References
1. EURADIA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
5. IDF-Europe Access survey (2013)
8. WHO. (2009)
10. HITT-CISS. (2013b)
Healthcare expenditure profile (2011)²

Total health expenditure per capita: USD 806.70

Proportion of government expenditure on health: 10.1%

Health system overview
- Russia introduced mandatory health insurance in 1993, which relies on public collection and pooling of contributions at the federal level, and on private health insurers for the purchasing of care.³,⁶ A care package, defined by the government, is provided free of charge but its implementation is uneven across the country.³ Certain groups or people with chronic or severe conditions, such as diabetes, are also entitled to additional benefits, including free or discounted outpatient drugs.⁷
- Medicines and medical devices covered by national health programmes are procured through tenders at the federal and regional levels.³ Other products are procured and supplied by private actors.³ Specialised public agencies and their regional centres are responsible for the regulation and quality control of the pharmaceutical and medical devices sectors, in line with federal government’s legislation.³ The Ministry of Health has also established a system for healthcare providers to highlight any adverse quality issues.¹¹ The forthcoming reform of pharmaceutical care includes regulatory changes and the strengthening of control capacities.¹⁰

Diabetes Prevalence¹

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.5% of 20-79 year-olds (2011)</td>
<td>Official records: 2.55% of the population (2011)</td>
</tr>
<tr>
<td>90% type 2 diabetes; 10% type 1 diabetes (2008)³</td>
<td></td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Prescription are provided by endocrinologists and by GPs (GPs especially in rural areas).³,⁸
- Endocrinologists are the main contact point for diabetes information and advice.¹¹
- Diabetes supplies are dispensed mostly at healthcare facilities and pharmacies.⁵,¹¹

Guidelines and specific prescription criteria
- Russia has national guidelines for Diabetes care.¹
- Medication cannot be prescribed for more than one month at a time.⁹
- Insulin analogue is primarily prescribed to children and pregnant women or people at high risk of developing complications.⁵,¹¹
- Insulin pumps are primarily prescribed to children.¹¹
- All types of diabetes are eligible for the prescription blood glucose test strips, but quantities of strips are limited by the type of diabetes and local interpretation of federal standards.¹¹

From the survey
- Almost all survey respondents reported having difficulties obtaining their diabetes products within the last two years — a pattern confirmed by healthcare professionals.
  - Most of the respondents who faced problems obtaining their products reported stock issues as the primary cause, while some reported affordability issues.
  - All of the products surveyed were affected, in particular glucose test strips and insulin.
  - Quite a few of the respondents who faced problems obtaining their products (whatever the cause) reported remaining without supply for more than two weeks. This proportion is even higher among people with type 2 diabetes.
- Although the majority of people with diabetes reported having received diabetes education and information about treatment, this provision is not yet universal and was far less common among their relatives.
- Monthly out-of-pocket expenditure for diabetes medicines and medical devices was higher among rural respondents than those who live in urban areas; and among people with type 2 diabetes than people with type 1 diabetes.

Presence of products at national level
- At least one product from each of the categories surveyed was reported authorised for sale and present in the country.¹⁰ At least one drug from each of the categories of medication surveyed are included in the list of essential drugs.⁵
RUSSIAN FEDERATION

Access to treatment

• While efforts have been made since 2006 to double the number of endocrinologists, their number remains insufficient and they are primarily concentrated in urban areas.7
  o Mobile diabetes clinics have been established to provide care in remote areas.7
• Additionally, as healthcare provision is the responsibility of local governments, disparities arise between regions.3
• The available evidence suggests that obtaining medicines and medical devices is quite time consuming for people with diabetes.
• The obligation to renew each medical prescription every month impacts the physicians’ workload and complicates access to essential medication for people with diabetes.8

Stock and shortages

• Stock issues are reported as the primary cause for difficulties in obtaining diabetes supplies.5
  o Inadequate public supply may explain these findings.
  o According to the Russian Diabetes Federation, when insulin shortages occur, people with diabetes are usually offered alternative types or brands of insulin. However, some people with diabetes have refused to use the other products and so, have experienced disruptions in treatment.11

Financial coverage

Diabetes medicines and medical devices enjoy specific coverage. For pharmaceuticals, public procurement is based on the federal list of essential medicines.8 However, as the provision of medicines and medical devices is financed through both federal and regional government budgets, certain regions offer wider benefits than others.5 As a result, the table below can only provide an overview of the benefits enjoyed by the majority of, but not all, people with diabetes.

<table>
<thead>
<tr>
<th>Medicine/Device</th>
<th>Coverage/Expense</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin</td>
<td>Free5,7,8 but specific criteria apply to analogue insulin (see Availability)</td>
</tr>
<tr>
<td>Anti-diabetes medication</td>
<td>Free5,7,8 – regional differences in the list of molecules covered7,8</td>
</tr>
<tr>
<td>Medication for hypoglycaemia</td>
<td>Not covered — 100% paid for by the person with diabetes</td>
</tr>
<tr>
<td>Pencs and related supplies</td>
<td>Free11, although some people reported paying for these supplies</td>
</tr>
<tr>
<td>Syringes and related supplies</td>
<td>Not covered — 100% paid for by the person with diabetes</td>
</tr>
<tr>
<td>Pumps and related supplies</td>
<td>Only children receive them free of charge. Otherwise, not covered — 100% paid for by the person with diabetes</td>
</tr>
<tr>
<td>Blood glucose test strips and meters</td>
<td>Free for children1</td>
</tr>
<tr>
<td>Ketone test strips</td>
<td>Not covered — 100% paid for by the person with diabetes</td>
</tr>
</tbody>
</table>

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

Accessibility

Affordability

• Most people living with diabetes in Russia pay an out-of-pocket contribution to the cost of their treatment, either to cover shortages in public supply or to complement shortfalls in public coverage.5,7,8
  o According to collected responses, median out-of-pocket payment for diabetes medicines and medical devices per month was RUB 4,237 (USD 112), or RUB 50,844 (USD 1,340) per year. This constitutes 9% of the Household Net Adjusted Disposable Income, rising to 32% for the poorest 20%. Significant differences were found between respondents:
  • Median out-of-pocket expenditure per month for diabetes supplies was found to be higher among people with type 2 diabetes than among people with type 1 diabetes. Higher median monthly out-of-pocket expenditure on diabetes supplies was also found among people living in rural areas compared to those living in towns and cities, although the reason for this difference is not clear.
  • According to collected responses, the choice of brand for a given product was strongly influenced by the advice of their physician, and to a lesser extent, constrained by the availability of supplies from the national programme.
  o New legislation was passed recently instructing physicians not to use brand names when prescribing medicines. However, certain specific types of medicines such as insulin are exempt from this obligation.11
• For medicines that have to be purchased and that are included in the list of essential medicines, a maximum selling price is set by the Ministry of Health upon registration, through external reference pricing. Mark-ups are also set by federal law.11 The pricing of medical devices could not be assessed.

Looking ahead

A new strategy to reform pharmaceutical care has been adopted and will be implemented in 2014. Its main objectives include the creation of a new reimbursement system for pharmaceuticals, the modification of price regulation and the strengthening of the supply system.4,10,11 Additionally, the Russian Diabetes Federation is discussing new federal standards for diabetes care with the Ministry of Health.11

References

1 EURADIA, FEND, IDF, & PCE. (2011)
2 Global health observatory data repository. (2013)
3 Popovich, L. et al. (2011)
4 Skonieczna, A. (2013)
5 IDF-Europe Access survey (2013)
7 Doničová, V., Brož, J., & Sorin, I. (2011)
8 HITT-CISS. (2013c)
10 Ministry of Health of the Russian Federation (2012, December 17)
11 Russian Diabetes Federation (personal communication) (2013)
From the survey
- A majority of survey respondents reported having difficulties obtaining their diabetes products within the last two years — a pattern confirmed by healthcare professionals.
  - Most of the respondents who faced problems obtaining their products reported stock issues as the primary cause.
  - Few alternatives are available when no stock is present; while associations may offer some products, many people have to do without their products until the problem has been resolved.
- According to healthcare professionals and diabetes associations, affordability and limited public resources constitute major constraints to the treatment of diabetes.
- Diabetes education and information about treatment was almost universal among the people with diabetes but was far less common among their relatives.
- No significant differences in access issues were reported between urban respondents and respondents living further from healthcare providers. However, differences between administrative regions could not be assessed through this survey.

Healthcare expenditure profile (2011)
Total health expenditure per capita: **USD 263**
Proportion of government expenditure on health: **11.7%**

Diabetes prevalence (2011)

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5% of 20-79 year-olds</td>
<td>No data</td>
</tr>
</tbody>
</table>

Diabetes care procedure
- Any physicians can prescribe diabetes supplies.
- Prescribers are also the main points of diabetes information and advice on treatment.
- The products provided by the national programme or regional budgets are dispensed by healthcare facilities during medical visits or at local pharmacies. Additional supplies are dispensed at pharmacies. Some medical devices can also be obtained through diabetes associations or aid organisations.

Guidelines and specific prescription criteria
- Ukraine has national guidelines for diabetes care.
  - Prescribing is constrained by tight resources and limited stock at health facilities.
  - Certain doctors prefer to prescribe certain brands.
  - The authorities appear to support the use of domestically produced supplies, especially for insulin.
  - Adults on insulin receive primarily human insulin. As a priority, analogues are prescribed to children and pregnant women. Metformin, gliclazide and glibenclamide are reported to be the most widely used oral medications.
UKRAINE

Access to treatment
- The answers from the survey suggest that diabetes education and information about treatment is almost universally provided to people with diabetes but is far less common for their relatives.5

Stock and shortages
- Stock issues have been widely reported by people living with diabetes, associations and healthcare professionals.
  - Delays in payment for publicly procured supplies, delays throughout the supply chain, as well as inadequate funding and supply compared to people's needs, have been cited as possible explanations for this situation.5,6,8 Similar problems are found in the case of other chronic diseases.6,8
  - However, the supply of insulin has improved since the previous national diabetes programme.6,8
  - The available evidence also suggests that the quality of insulin supply in certain regions may be affected by supply chain disruptions.5,6,8

Insulin
- Human insulin is free.1,5,6,8
- Insulin analogues are mainly provided for free to children and pregnant women.5,6,8

Anti-diabetes medication
- Not covered — 100% paid for by the person with diabetes.1,5,6,8
- Some regions offer partial coverage.5,6,8

Medication for hypoglycaemia
- Unclear — certain categories of people may receive it for free.5,8

Pens and related supplies
- Free only for children and pregnant women.
- Other specific groups seem to receive partial coverage.
- The rest receive no coverage and have to pay full cost.5

Syringes and needles
- Not covered — 100% of expense paid for by the person with diabetes.5

Pumps and related supplies
- Not covered — 100% of expense paid for by the person with diabetes.5,6,8

Blood glucose test strips and meters
- Free only for children and pregnant with a limit of 550 strips per year.
- Otherwise, not covered — 100% of expense paid for by the person with diabetes.5,6,8

Ketone test strips
- Not covered — 100% of expense paid for by the person with diabetes.5,6,8

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

Accessibility

Affordability
- Most people living with diabetes in Ukraine pay an out-of-pocket contribution to the cost of their treatment, either to cover shortages in public supply (buying supplies from alternative sources) or to complement public coverage.5,6,8
  - Based on collected responses, median out-of-pocket spending per person on diabetes medicines and other supplies was estimated at UAH 500 (USD 63) per month — UAH 6,000 (USD 751) per year.5

Financial coverage
The financial burden of publicly provided treatment for diabetes is shared by national and regional governments:
- Although its procurement has been decentralised,6,8 insulin supply is mostly financed by national budget (regional authorities only providing a small share of the funds).1,4,6,8
- Oral medications’ coverage has been the responsibility of regional authorities, as a result, it may differ from one region to another.1,4,6,8 However, a new reimbursement system for this type of medication is to be implemented in 2014.6
- Some medical devices receive partial coverage from national or local budgets but most of them have to be purchased at full cost by people with diabetes.1,4,6,8

Looking ahead
As mentioned above, a new reimbursement system for oral medication as well as a reference pricing system for insulin are about to be created.6

Improvements in the field of access to diabetes care and treatment is hampered by frequent changes at the Ministry of Health, and constrained by the current political and economic situation of the country.6

References
1. EURADIA, FEND, IDF, & PCDE. (2011)
2. Global health observatory data repository. (2013)
5. IDF-Europe Access survey (2013)
7. Stefanyshyna O. (personal communication (2013)
Healthcare expenditure profile (2011)

Total health expenditure per capita: **USD 88.40**
% of government expenditure spent on health: **8.5%**

Out-of-pocket expenditure represents 90% of private spending on health.

Health system overview

- The government guarantees a basic package of services for free or at subsidised rates to all citizens, and additional benefits to specific groups. Provision of care is the local authorities’ responsibility.
- Medications for the public sector are mainly procured centrally by the Ministry of Health and distributed by public companies. Private distributors primarily supply the private sector but may also supply the public sector following individual negotiations.
- Quality control is the responsibility of the Ministry of Health.

Diabetes prevalence (2011)

<table>
<thead>
<tr>
<th>IDF Atlas</th>
<th>National Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>5% of 20–79 year-olds</td>
<td>Official records: &lt;0.5% (including 16% with type 1 diabetes) of the population</td>
</tr>
<tr>
<td></td>
<td>Healthcare professionals’ estimates (2007-2009): 5% – 6% of the population</td>
</tr>
</tbody>
</table>

Diabetes care procedure

- Prescriptions are mostly provided by endocrinologists, who are also the main points of diabetes information and advice about treatment.
- Diabetes products are dispensed mostly at pharmacies. However, supplies provided through international programmes or associations can be dispensed in other settings.

Presence of products at national level

- Not all the surveyed products seem to be present in Uzbekistan:
  - Glucagon was not registered and was not authorised for sale; while DPP4-inhibitors were undergoing registration at the time of the survey.
  - The status and presence of ketone test strips could not be confirmed. Pumps have recently been registered.

Guidelines and specific prescription criteria

- Uzbekistan has national guidelines for diabetes care.
- Only specialist doctors can prescribe insulin.

Use

- Prescribing and use of supplies are constrained by supplies available through public provision or international programmes:
  - Human insulin is the principal medicine for people on insulin. Some insulin analogues are distributed through public provision or international programmes but otherwise, they have to be purchased in the private sector. Syringes remain the most common insulin injection device, except among children, who have access to pens.
  - Trends in the use of oral medications appear to be in line with what is included in the national list of essential medicines: mainly, metformin and sulphonylureas.
**Access to treatment**
- Local endocrinology services have been created in rural areas to facilitate physical access to care and prescribers.6
- Access to diabetes education and information about diabetes and treatment remains an issue in outpatient settings, especially for people living outside the metropolitan area. With the support of the authorities, the Association of Endocrinologists of the Republic of Uzbekistan is developing regional diabetes education and information sessions for people living outside the capital city.6

**Stock and shortages**
- Supplies to the different regions seem to have improved and are reported as being regular.6
- It appears that, due to financial constraints, free, publicly-provided supplies cannot cover the needs of all people with diabetes.1,6 Thus, supplies have to be rationed and prioritised:6 (see Affordability).
- Public supply seems also to be subject to changes, depending on the companies that win national tenders.6

**Insulin**
- Only people with type 1 diabetes and some people with type 2 diabetes get it for free5,6
- Otherwise, not covered — 100% of expense paid for by the person with diabetes1,5,6

**Anti-diabetes medication**
- Depending on the medication, some supplies are free5,6
- Mostly not covered — 100% paid for by the person with diabetes5,6

**Medication for hypoglycaemia**
- N/A

**Pens and related supplies**
- Free for children5,6
- Otherwise, not covered — 100% of expense paid for by the person with diabetes5,6,8

**Syringes and needles**
- Not covered — 100% of expense paid for by the person with diabetes5,6,8

**Pumps and related supplies**
- Not covered — 100% of expense paid for by the person with diabetes6

**Blood glucose test strips and meters**
- Children and teenagers receive these free of charge5,6
- Otherwise, not covered — 100% of expense paid for by the person with diabetes5,6,8

**Ketone test strips**
- Unknown

Please note that the information provided above only present a summary of the reimbursement system and may not apply to individual cases.

**Looking ahead**
The Association of Endocrinologists of the Republic of Uzbekistan is working closely with the State and is about to hold a workshop at the Legislative Chamber of the Supreme Council (Oliy Mejlis) to support the creation of legal framework for diabetes.6

**References**
1 EURADIA, FEND, IDF, & PCDE. (2011)
2 Global health observatory data repository. (2013)
5 IDF Europe Access survey (2013)
6 Association of Endocrinologists of the Republic of Uzbekistan (personal communication) (2013)
7 Rechel, B., et al. (2013)
CONCLUSION
This publication highlights disparities in access to quality medicines and medical devices for diabetes care across 47 countries of the European region. This study presents evidence to policy makers and stakeholders on the difficulties faced currently by people living with diabetes in terms of access to the treatment they need throughout the IDF Europe Region, in order to help resolve some of the challenges raised by the diabetes epidemic. The variety of circumstances encountered during this study reflects the diversity that characterises the Region. Fundamentally, the 47 countries surveyed here have indeed highly diverse healthcare capacities and resources. While the European Region includes some of the oldest, well-established models of health systems, which have achieved universal coverage for their populations, it also includes health systems and health coverage schemes in transition and development. Total spending on health per capita varies from more than USD 9,000 in Switzerland to less than USD 100 in Kyrgyzstan and Uzbekistan; public payers take on more than 85% of total health spending per capita in the Netherlands, but only about 22% in Georgia.

These factors inevitably have an impact on access to the medicines and devices people need to control their diabetes. Meanwhile, between countries in the Region, there are wide disparities between diabetes prevalence, hence, the burden the disease represents, and the level of priority it has on the political agenda.

These differences among countries should therefore be considered carefully when assessing each country’s performance and potential to act.

Sources of information

Although the different phases were carried out systematically, the amount and quality of the collected data differed greatly across and within surveyed countries. First of all, almost no questionnaires were collected from national health authorities. Consequently, information on national policies and guidelines was gathered almost entirely through desk research and thanks to other stakeholders – healthcare professionals, diabetes associations, industry, professional associations. Language barriers and a tight deadline certainly were challenges in order to collect the requested information. Importantly also, certain types of data were not available because they are not publicly disclosed.

Secondly, our questionnaires were made available online – through IDF Europe’s communication channels and sent to IDF Europe’s Members – and rely on self-reported information. As a result, although every effort was made to obtain unbiased, representative information, the survey team had no control over the respondent sample or the way they chose to answer questions. The different target groups and sources of information were chosen to try to pre-empt potential biases, while the size of the responding group was beneficial in addressing this challenge. However, this project has encountered some difficulties that were well known in diabetes. Information about type 1 diabetes was for instance much more widely available than information on other types of diabetes. This difficulty in reaching out and obtaining information from and about people with other types of diabetes was raised by a number of associations and interviewees during the survey and is a problem worth looking at in future work. Collecting information from healthcare professionals or people with diabetes in rural areas was an additional challenge. Crossing the different sources of information allowed to correct for these inequalities and to make the collected information as comparable as possible.

Scope

This survey focused only on a selection of medicines and medical devices for diabetes; it does not cover the full range of currently available products for diabetes care or products to treat diabetes-related complications. The survey did reveal, however, that while access to medicines is a well-developed field of research, only a very limited number of resources were actually available to the public regarding access to medical devices.

Certain fields of research could not be integrated in this project and could be a field for future work. These include the impact of the behaviour and practices of people with diabetes and diabetes care professionals towards diabetes products, on access to these products. Additionally, although efforts were made to integrate broad healthcare issues into the analysis, access to diabetes care in its totality and a comprehensive study of related issues were beyond the scope of this study.

a IDF European Region is based on WHO’s regional distribution
Key findings and discussion

Availability under constraint

This study highlighted differences in the availability of diabetes treatment options Region-wide. The majority of the 47 European countries studied appear to have the full list of product categories surveyed, authorised and present on their national markets. Yet a number of countries have not secured the availability of all the different types of products. Additionally, the collected information suggests that the range of products marketed within each category also vary. However, this element could not be fully investigated in this study and would require to be researched further.

Market authorisation and registration procedures have a role to play in these differences. But other factors, such as national manufacturing capacities, the size of a national market and potential coverage by public payers, are also significant. The differences found within the European Economic Area despite centralised or harmonised procedures provide a good example of this. The availability of diabetes products depends on the interaction between market features and public policies on health and trade.

European countries and citizens do not have the same range of choices to treat diabetes. The availability of treatment options is first of all affected by the unequal number of products and types of products marketed in each country.

We found that the treatment options actually available to people with diabetes and healthcare providers are affected further by the product selection made by health systems and their classification within prescription guidelines. Indeed, all 47 countries have, or are developing, guidelines for the treatment of diabetes, which establish circumstances for prescribing individual products: who can prescribe them, where they can be prescribed, and to whom they should be prescribed. Wide-ranging differences in the content and power of these guidelines to influence care exist across Europe. Newer products appear more likely to be subject to specific criteria. This reflects not only the ongoing scientific debates over the optimal use of different products; it also highlights the dual role of prescription guidelines – as a guarantee of good clinical practice, but also as a tool for containing costs. Notably, the influence of the cost-containment factor may not always reflect the level of pressure on public health financing; it may relate more to the overall organisation and regulation of the health system.

The range of treatment choices available to individual people with diabetes and healthcare providers is affected further by the assessments made by health institutions of each product’s clinical role, and by controls over health spending both resulting in prescription guidelines and criteria.

Ensuring continuous accessibility

The biggest differences were found, both across and within the 47 European countries, in the field of accessibility. Accessibility is intrinsic to the organisation of all health systems and diabetes care in particular. Hence, accessibility can be seen as a reflection of their respective performance.

In the current study, the biggest differences in access to diabetes medicines and medical devices, both across and within the 47 European countries, were found in the field of accessibility. However, the diversity in this Region appears to have given rise to different solutions and initiatives at the local and national levels, creating opportunities for the exchange of good practice.

Such diversity makes it difficult to draw general conclusions. However, we can flag up some trends. Physical access issues, when these exist, affect mainly access to specialised care or specific types of products that are submitted to specific control. Hence, many countries in the Region have chosen to bring prescribing and dispensing closer to the patient, i.e. into primary care, reducing the need for frequent access to specialised care. A number of published evidence suggests that most of diabetes care can be transferred to primary care. However, while such initiatives may make physical access easier, they must come with proper continuous training for healthcare professionals working in primary care. Transferring responsibility for care also entails primary healthcare professionals becoming the main point of treatment information and advice for people with diabetes, as well as their primary contact with healthcare.
new technologies are introduced into diabetes care, training for healthcare professionals in the use of these new therapies will be an essential component in their successful uptake.

Considerable differences exist in terms of physical access to care and diabetes products across the Region. This issue is a major challenge in some countries. The role of the different healthcare professionals at different levels of care, and their respective capacity to contribute to overcoming this obstacle, should be considered carefully.

From the results of the study, it became clear that almost all countries in the European Region will need to make adjustments in order to ensure universal access to continuous education and information. Our survey determined only whether or not people with diabetes and their family had had access to education and information about medication on at least one occasion. Nevertheless, this study uncovered gaps and inequalities in almost 47 countries. These findings may apply to diabetes education as a whole, which takes a holistic approach to diabetes self-management, and education about treatment. The chronic nature of diabetes and its implications for lifestyle and treatment require people with diabetes to play a central role in managing their condition. People with diabetes need to gain the capacity to maintain autonomous control, making education an essential element of diabetes care. Education should be life-long and tailored to each socio-cultural and socioeconomic setting.

As well as inequalities and gaps in access to treatment, our study revealed a paradox in the accessibility of diabetes products. Stock and supply issues of varying importance appear to occur across the Region. However, in the majority of countries, it would appear that the healthcare professionals are worst affected, as it is often their responsibility to find alternatives and prevent any disruptions in treatment. The actual impact of such difficulties on their daily practice could not be fully investigated in this study but deserves further research. While in most cases, these shortages appear to be addressed locally through ad hoc, one-off solutions, our study also identified a number of robust initiatives to address or prevent such shortages. Professional associations and government agencies have developed systems to identify products affected by shortages and inform healthcare professionals and suppliers about alternatives. A number of countries have placed legal requirements at some or all levels of the supply chain in order to guarantee sufficient supply of products at all times. The diversity of actors involved in the supply of diabetes products and the difficult balance between guaranteeing continuous supply without jeopardising the viability of the supply chain make this a delicate challenge. However, a transparent, participative process may be key to ensuring the uninterrupted provision of medicines and medical devices to people with diabetes.

Some of the challenges highlighted in this publication regarding local constraints on accessibility to diabetes products also suggest that such an inclusive, transparent process would be beneficial at the local level. That is to say, a process that would involve both people with diabetes and the local health authorities; and entail interaction between neighbouring local health authorities. Such a process would help to ensure that the quantity and types of diabetes products supplied locally meet the needs of each community, and avoid in-country inequalities. Transparency and exchange of information might improve understanding among all stakeholders of the different constraints that affect healthcare at the local level.

An uninterrupted, adequate supply of diabetes supplies has yet to be secured. The impact of difficulties relating to supply on healthcare professionals should be further investigated.
Affordability – balancing individual protection with health system sustainability

All countries in the Region face a complex challenge: balancing the affordability of the diabetes products necessary for proper management with the provision of care in other disease areas, while ensuring the sustainability of the health system. Maintaining such a balance has been made increasingly difficult by the current economic crisis. This publication highlights different approaches being taken across the Region to surmount this challenge and underscores some of the undesirable side effects triggered by certain decisions.

The wide differences between and within countries in terms of the costs covered for diabetes supplies make it difficult to draw conclusions that are applicable to the whole Region. However, this study found that all 47 countries offer some coverage for diabetes products, even where a general public system to pay for medicines and medical devices does not exist. Predictably though, the financial protection that is actually offered to different categories of people with diabetes differs greatly. Some of these differences appear inevitable due to the constraints on capacity and resources mentioned above. Moreover, the methods used to select products subject to public financing vary a great deal from one country to another – beyond the scientific debates that exist in the Region on the different products. In some cases, the same terminology may refer to very different situations. We also found considerable differences between the assessment of medicines compared with medical devices in most countries – with sometimes a significant capacity gap between the two.

Furthermore, affordability from the point of view of the system and affordability for individuals appear to be accounted for in different ways. There are concerns that, in some cases, the system’s interests may disproportionately outweigh the needs of the individual. Such worries and suspicions are exacerbated because those primarily affected are excluded from the decision-making process. The complexity and, in some cases, lack of transparency of some of these decision-making processes appear to be a source of much frustration and apprehension. As well as the valuable information that could be obtained through an inclusive, open process, such an approach would provide an opportunity to explain decisions and reassure people with diabetes and healthcare providers about the guarantees offered by the decision-making process. Such information would help to address some of the gaps in implementation that have been identified in a number of countries.

Whether a diabetes product is affordable or not to a person with diabetes depends primarily on how it is supported financially by the health system. The transparency of any criteria for supporting products is crucial. The involvement of people with diabetes and healthcare professionals in related decision-making processes would improve understanding of the differences between countries, and contribute to the implementation of these decisions.

This study confirmed that most of the 47 countries attempt via price controls to limit the impact of diabetes products’ cost on healthcare budgets. However, the scope and impact of such controls vary across countries and between products. The role of pricing policies in keeping diabetes-related expenditure down for both the health system and people with diabetes should be acknowledged. However, price controls have yet to be implemented throughout the Region, and have not been extended to all diabetes products, reducing potentially positive impact of price containment regulation on affordability.

The complexity of such controls needs to be taken into account. Indeed, these have to balance cost-containment with the financial viability of the different stakeholders, and in some cases, other industrial policy objectives, without hindering innovation. The structure of the market of diabetes products – only a few brands available for most products – might be also limiting the impact of policies aimed at reducing the cost of diabetes treatment, such as policies promoting non-branded, lower-priced alternatives. The impact of such factors on affordability requires further investigation.

Data on the prices of different diabetes products were particularly difficult to obtain. The complexity of the different health financing schemes may partially explain this. Moreover, certain price components, such as those negotiated at the national level prior to distribution, are simply not publicly available. The information collected during this study also suggests that the increasing use of international price comparisons (reference pricing) has not resulted in a harmonisation of prices across the Region; and that significant differences remain between and sometimes within countries. Different approaches to implementing
the same price control methods may partially explain this. Major differences were also found regarding the pricing policy applied to medicines and those applied to medical devices. There is a lack of publicly available information on the pricing of diabetes devices. Some evidence suggests that this is because regulations and policies for medical devices are relatively new. Also, the regulatory implications of the distinction between medicines and medical devices may go some way to explaining these differences.

The affordability of diabetes products for people with diabetes and for health systems can be supported by adequate price regulation policies. However, such a policy tool has yet to be rolled out systematically throughout the Region or to include all products. Unfortunately, publicly available information on these aspects is scarce.

Finally, our findings highlighted the differences in financial support available to different categories of people with diabetes. Differentiated schemes may provide additional support to vulnerable groups or for treatment that very few people could afford on a regular basis. However, such mechanisms remain partial and selective in certain countries and may create new, or widen existing, inequities. So although the creation of safety nets in many European countries has to be a widely acknowledged social advancement, careful consideration should be given to their implications for the categories excluded from these schemes. Furthermore, the difficult economic situation in many European countries is likely to have impoverished some people with diabetes, making it more difficult for them to pay for the expenditure they were previously able to afford for the treatment of their condition. The efforts of some countries to maintain public financing of diabetes products despite constraints on their budgets are not to be underestimated. However, it appears that the new reality faced by a number of people with diabetes may require new safety nets to be created in order to ensure that all people with this condition are able to afford the treatment they need.

Differentiated treatment benefits may be a strong tool to ensure equity. However, the impact of such schemes beyond the target groups should also be carefully considered.

Facing the cost of inaction

Ensuring access to diabetes medicines and devices is certainly a costly, complex and resource-consuming challenge and it is only one element in high-quality, comprehensive diabetes care. This study by no means aimed to minimise the difficulty it represents for countries and other stakeholders; it has tried to identify bottlenecks in access and inequalities, while offering a regional perspective that may inspire new solutions based on the experiences of other countries.

Improving access to diabetes medicines and medical devices may appear too complicated and costly for European countries in a time of economic crisis. However, the prospect of short-term savings should not hide the long-term consequences of inadequate access to diabetes medicines and devices. Access to supplies is an essential element of diabetes care. Unmanaged or poorly treated diabetes can lead to disabling and life-threatening complications.

Studies in various Western European countries have demonstrated that the costs of managing diabetes-related complications are far greater than the cost of care for controlled and well-managed diabetes. Research on type 2 diabetes has revealed that managing diabetes complications such as cardiovascular or kidney diseases is much more expensive, mainly due to hospitalisation costs. In addition, the cost of inpatient care for people with diabetes is higher than outpatient diabetes care. A recent OECD report estimated that the EU average number of hospital admissions due to uncontrolled diabetes with diabetes-related complications was more than double the EU average for uncontrolled diabetes hospital admissions without complications. Moreover, drugs to treat complications make up the largest proportion of diabetes-related pharmaceutical costs.

The cost of untreated or poorly treated diabetes also represents an enormous financial burden on the economy and wider society due to loss of productivity, absence from work, disability and the challenges created for care providers.

This study proves that access to diabetes care is an investment in a healthier and more productive society, as well as a contributor to long-term economic growth.
Ensuring people with diabetes have access to the treatment they need will enable them manage their condition properly. This will in turn allow them to avoid developing costly complications and premature death, and lead a productive and healthy life. **Strong political commitment and investment in diabetes research, informed prevention strategies, and equal access to high-quality care need to be at the heart of Europe’s response to the growing diabetes epidemic. Safeguarding the Region’s economic future and the sustainability of its healthcare model depend on this.**

**References**

2. WHO, 2002
3. Willaing, I. et al., 2013a
4. Willaing I. et al., 2013b
12. UN Human Rights Council, 2013a
15. OECD, 2012
ANNEXES
Annex 1: Survey and interview

Survey
The three questionnaires developed for national health institutions; healthcare professionals; and people with diabetes are available upon request.

Interviews
Diabetes care professionals
Albania – Prof. Florian Toti
Georgia – Dr Lika Tsutskiridze
Kyrgyzstan – Dr Nurdin Satarov
Romania – Adina Sanpetreanu (diabetes nurse)
Switzerland – Claudia Huber (diabetes nurse)
United Kingdom – Healthcare professional specialised in diabetes care

Member Association of IDF Europe
Albania – Shoqata E Diabetit Në Shqipëri
Austria – Österreichische Diabetes Gesellschaft
Azerbaijan – Azerbaijan Diabetes Society
Belarus – Belarusian Humanitarian Organisation
Belgium – Vlaamse Diabetes Vereniging
Belgium – Association Belge du Diabète
Bulgaria – Bulgarian Diabetes Association (BAD)
Croatia – Hrvatski savez dijabetickih udruga
Cyprus – Cyprus Diabetic Association
Czech Republic – Czech Diabetes Society / Ceska Diabetologicka Spolecnost
Denmark – Diabetesforeningen
Faroe Islands – Diabetesfelag Føroya – Faroes Diabetes Organization
Finland – Finnish Diabetes Association
France – Association Française des Diabétiques (AFD)
Georgia – Georgian Union of Diabetes and Endocrine Associations
Germany – diabetessE
Greece – Hellenic Diabetes Federation/Ελληνική Ομοσπονδία Διαβήτη
g Hungary – Magyar Diabetes Tarsasag
Iceland – Samtak Sykurshuka/Icelandic Diabetes Association
Ireland – Diabetes Federation of Ireland
Israel – Israel Diabetes Association

Experts and Stakeholders
Supply chain and procurement in Eastern Europe – International expert regularly working in the CIS sub-region
Pharmaceutical policies in Europe – Researcher, UK
Supply chain and procurement in Eastern Europe – Olga Stefanyszyna, executive director of Ukrainian Community Advisory Board (UCAB), Ukraine
EU Community pharmacists – Pharmaceutical Group of the European Union (PGEU), professional association
Full-line wholesalers – The European Association of Pharmaceutical Wholesalers (GIRP), professional association
European medical technology industry – EUCOMED, professional association
European pharmaceutical industry – European Federation of Pharmaceutical Industries and Associations (EFPIA), professional association

Italy – ANIAD – Associazione Nazionale Italiani Atleti Diabetici
Kazakhstan – Diabetes Association of the Republic of Kazakhstan
Lithuania – Lithuanian Diabetes Association
Luxembourg – Association Luxembourgeoise du Diabète ALD asbl.
Malta – Għaqda Maltija Kontra D – diajbetè
Netherlands – Diabetes Vereniging Nederland
Norway – Norges Diabetesforbund
Poland – Polskie Stowarzyszenie Diabetyków
Portugal – Associação Protectora dos Diabéticos de Portugal
Romania – Societatea Romana de Diabet, Nutritie si Boli Metabolice
Russian Federation – Russian Diabetes Federation
Serbia – Diabetes Association of Serbia
Slovakia – ZVAZ Diabetikov Slovenska
Slovenia – Zveza Drustev Diabetikov Slovenije
Spain – Sociedad Española de Diabetes
Sweden – Svenska Diabetesförbundet
Switzerland – Schweizerische Diabetes Gesellschaft
Turkey – Türkiye diyabet Vakfı
Ukraine – International Diabetes Association of Ukraine (IDAU)
United Kingdom – Diabetes UK
Uzbekistan – Association of Endocrinologists of the Republic of Uzbekistan
Annex 2: Reported median annual out-of-pocket expenditure on diabetes medicines and medical devices

<table>
<thead>
<tr>
<th>Sub-regional groups</th>
<th>Country#</th>
<th>Annual median out-of-pocket spending on diabetes medicines and devices (USD)</th>
<th>Share of Household Net Adjusted Disposable Income spent on diabetes products (%)</th>
<th>Share of Household Net Adjusted Disposable Income spent on diabetes products for the poorest 20% (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>North-West Europe</strong></td>
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<td>2.1</td>
<td>4.6</td>
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<td></td>
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<td>311.5</td>
<td>1.2</td>
<td>2.6</td>
</tr>
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<td></td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Germany*</td>
<td>1,792</td>
<td>0.6</td>
<td>1.4</td>
</tr>
<tr>
<td></td>
<td>Ireland</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Luxembourg*</td>
<td>233.6</td>
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<td>1</td>
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<td></td>
<td>Netherlands*</td>
<td>77.8</td>
<td>0.3</td>
<td>0.7</td>
</tr>
<tr>
<td></td>
<td>Sweden</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Switzerland</td>
<td>757.9</td>
<td>2.5</td>
<td>6.0</td>
</tr>
<tr>
<td></td>
<td>UK</td>
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<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>South-West Europe</strong></td>
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<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Cyprus</td>
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<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Greece*</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Italy</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Portugal</td>
<td>352.7</td>
<td>1.8</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Slovenia*</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Spain*</td>
<td>428.4</td>
<td>1.9</td>
<td>6.1</td>
</tr>
<tr>
<td><strong>Central and Eastern Europe</strong></td>
<td>Bulgaria</td>
<td>1,589.5</td>
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<td>1</td>
</tr>
<tr>
<td></td>
<td>Czech Republic</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Hungary*</td>
<td>532.6</td>
<td>3.8</td>
<td>8.5</td>
</tr>
<tr>
<td></td>
<td>Latvia</td>
<td>208</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Lithuania</td>
<td>259</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Poland</td>
<td>559.9</td>
<td>3.6</td>
<td>9.1</td>
</tr>
<tr>
<td></td>
<td>Romania*</td>
<td>538.4</td>
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<td>1</td>
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<tr>
<td></td>
<td>Slovakia*</td>
<td>273.6</td>
<td>1.6</td>
<td>3.6</td>
</tr>
<tr>
<td></td>
<td>Israel</td>
<td>155.8</td>
<td>0.8</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>FYR Macedonia*</td>
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<td>1</td>
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<tr>
<td></td>
<td>Serbia</td>
<td>70.1</td>
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<tr>
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<td></td>
<td>Georgia</td>
<td>255.8</td>
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<td>1</td>
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<tr>
<td></td>
<td>Russian Federation</td>
<td>1,340.2</td>
<td>8.8</td>
<td>32.3</td>
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<tr>
<td></td>
<td>Ukraine</td>
<td>751</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

* The samples of respondents in these countries were limited to people with type 1 diabetes or people treated with insulin. Thus the annual out-of-pocket expenditure that was reported may not be representative for people with another type of diabetes and/or treatment.

# This information could not be obtained in the following countries: Denmark, the Faroe Islands, Finland, Iceland, Norway, Malta, Estonia, Albania, Turkey, Armenia, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Uzbekistan.

† The corresponding OECD data on Household Net Adjusted Disposable Income was not available for this country. Therefore, this percentage could not be calculated.
## Annex 3: Reported median prices for a selection of diabetes products

Individual country data are available upon request.

<table>
<thead>
<tr>
<th>Human Insulin</th>
<th>10ml vial; U100</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sub-region</strong></td>
<td><strong>Retail price (USD)</strong></td>
</tr>
<tr>
<td><strong>Countries with data</strong></td>
<td><strong>Sub-regional median [Range]</strong></td>
</tr>
<tr>
<td>Western EU and EFTA Member States</td>
<td>France; UK</td>
</tr>
<tr>
<td>Mediterranean EU Member States</td>
<td>Italy</td>
</tr>
<tr>
<td>Central EU Member States</td>
<td></td>
</tr>
<tr>
<td>South-East Mediterranean States</td>
<td></td>
</tr>
<tr>
<td>Member States of the Commonwealth of Independent States</td>
<td>Azerbaijan; Georgia; Russian Federation; Ukraine</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Metformin</th>
<th>1 tablet; 500 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sub-region</strong></td>
<td><strong>Retail price (USD)</strong></td>
</tr>
<tr>
<td><strong>Countries with data</strong></td>
<td><strong>Sub-regional median [Range]</strong></td>
</tr>
<tr>
<td>Western EU and EFTA Member States</td>
<td>France; Switzerland; UK</td>
</tr>
<tr>
<td>Central EU Member States</td>
<td>Bulgaria; Czech Republic; Lithuania; Poland, Romania</td>
</tr>
<tr>
<td>South-East Mediterranean States</td>
<td>Albania; FYR Macedonia; Serbia</td>
</tr>
<tr>
<td>Member States of the Commonwealth of Independent States</td>
<td>Azerbaijan; Georgia; Ukraine</td>
</tr>
</tbody>
</table>

This information could not be provided for Mediterranean EU Member States.

<table>
<thead>
<tr>
<th>Sitagliptin</th>
<th>1 tablet; 100 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sub-region</strong></td>
<td><strong>Retail price (USD)</strong></td>
</tr>
<tr>
<td><strong>Countries with data</strong></td>
<td><strong>Sub-regional median [Range]</strong></td>
</tr>
<tr>
<td>Western EU and EFTA Member States</td>
<td>France; Switzerland; UK</td>
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<tr>
<td>Central EU Member States</td>
<td>Czech Republic</td>
</tr>
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</table>

This information could not be provided for Mediterranean EU Member States, South-East Mediterranean States and Member States of the Commonwealth of Independent States.
### Insulin pen
1 reusable device

<table>
<thead>
<tr>
<th>Sub-region</th>
<th>Countries with data</th>
<th>Retail price (USD)</th>
<th>Cost to individual (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Western EU and EFTA Member States</strong></td>
<td>France; Germany; Switzerland; UK</td>
<td>59.23 [33.00 – 148.61]</td>
<td>Austria; Belgium; France; Germany; Ireland; Luxembourg; Netherlands; Sweden; UK</td>
</tr>
<tr>
<td><strong>Mediterranean EU Member States</strong></td>
<td>Italy</td>
<td>69.77 [-]</td>
<td>Croatia, Italy, Portugal</td>
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<tr>
<td><strong>Central EU Member States</strong></td>
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<td>14.86 [-]</td>
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</tr>
<tr>
<td><strong>South-East Mediterranean States</strong></td>
<td>Albania</td>
<td>19.47 [-]</td>
<td>Serbia</td>
</tr>
<tr>
<td><strong>Member States of the Commonwealth of Independent States</strong></td>
<td>Russian Federation; Ukraine</td>
<td>61.56 [57.43 – 65.68]</td>
<td>Russian Federation; Ukraine</td>
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</tbody>
</table>

### Insulin pump
1 conventional device

<table>
<thead>
<tr>
<th>Sub-region</th>
<th>Countries with data</th>
<th>Retail price (USD)</th>
<th>Cost to individual (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Western EU and EFTA Member States</strong></td>
<td>Germany</td>
<td>4 718.96 [-]</td>
<td>Austria; Belgium; France; Germany; Luxembourg; Netherlands; Sweden; UK</td>
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<td><strong>Mediterranean EU Member States</strong></td>
<td>Greece; Slovenia;</td>
<td>3 213.06 [3 050.77 – 3 375.35]</td>
<td>Greece; Italy; Portugal; Slovenia</td>
</tr>
<tr>
<td><strong>Central EU Member States</strong></td>
<td>Bulgaria; Lithuania; Poland</td>
<td>4 505.35 [3 732.62 – 5 298.32]</td>
<td>Bulgaria; Poland</td>
</tr>
<tr>
<td><strong>South-East Mediterranean States</strong></td>
<td>Serbia</td>
<td>4 534.72 [-]</td>
<td>Israel; TFYR Macedonia; Serbia</td>
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<tr>
<td><strong>Member States of the Commonwealth of Independent States</strong></td>
<td>Azerbaijan; Russian Federation</td>
<td>3 315.24 [3 312.10 – 3 318.38]</td>
<td>Azerbaijan; Russian Federation</td>
</tr>
</tbody>
</table>

### Blood glucose test strips
1 box of 50 strips

<table>
<thead>
<tr>
<th>Sub-region</th>
<th>Countries with data</th>
<th>Retail price (USD)</th>
<th>Cost to individual (USD)</th>
</tr>
</thead>
<tbody>
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<td><strong>Western EU and EFTA Member States</strong></td>
<td>Belgium; France; Germany; Luxembourg; Switzerland; UK</td>
<td>37.31 [24.00 – 48.51]</td>
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<tr>
<td><strong>Mediterranean EU Member States</strong></td>
<td>Greece; Italy; Slovenia</td>
<td>42.84 [38.95 – 71.66]</td>
<td>Croatia; Greece; Italy; Portugal; Slovenia; Spain</td>
</tr>
<tr>
<td><strong>Central EU Member States</strong></td>
<td>Czech Republic; Latvia; Lithuania; Poland; Romania</td>
<td>20.50 [8.13 – 31.79]</td>
<td>Bulgaria; Czech Republic; Latvia; Lithuania; Poland; Romania</td>
</tr>
<tr>
<td><strong>South-East Mediterranean States</strong></td>
<td>Albania; TFYR Macedonia; Serbia</td>
<td>25.71 [19.47 – 33.57]</td>
<td>Albania; Israel; TFYR Macedonia; Serbia</td>
</tr>
<tr>
<td><strong>Member States of the Commonwealth of Independent States</strong></td>
<td>Azerbaijan; Georgia; Russian Federation; Ukraine</td>
<td>27.19 [25.02 – 32.46]</td>
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Chronic disease
Chronic diseases are health conditions of long duration and generally slow progression, such as diabetes, cardio-vascular and respiratory diseases or cancer. They are the leading cause of mortality worldwide.

Co-payment
Type of cost-containment mechanism where the cost of healthcare is shared between the health system and the patient. The co-payment amount is set by the insurance or health system and is paid by the patient each time a medical service is accessed. It can be defined either as a fixed amount or as a proportion of the cost per service. Apart from its financial implications, the implementation of co-payment has a regulatory effect on demand for healthcare.

Coverage
Coverage refers to the financial protection offered by the health system to the population through the financing of certain health services or products.

Diabetes education
An inclusive process involving people with diabetes, their carers and families, that aims to provide the tools, skills and knowledge they need to adapt behaviour and effectively self-manage their condition(s). Good self-management improves people with diabetes’ health status and quality of life - reducing the need for healthcare interventions.

EU laws on medical devices
Medical devices, like all other goods, are subject to EU competition and trade rules under the single market. The EU has set harmonised standards for intellectual protection of medical device innovation. In order to bring a medical device onto the EU internal market, a set of rules and standards must be followed, which are defined at the EU level, regarding the quality and safety of the device. These standards and rules vary according to the risk classification of the device. However, the implementation of these rules and the certification of individual devices depend on Member States – through designated national institutions in charge of monitoring compliance and enforcing these rules - and to a lesser extent, on manufacturers themselves. This has resulted in uneven implementation of EU standards and rules. To improve safety and surveillance, and level the implementation of EU norms, the EU legislative texts which regulate the standards and certification of safety, quality and efficiency of medical devices (i.e. Medical Devices Directives and Regulation) are currently being revised.


EU laws on medicines
Although healthcare remains the competence of EU Member States, a number of aspects of pharmaceutical policies depend on EU laws. The EU has set harmonised standards for intellectual protection of innovations in all sectors including pharmaceuticals; and discussions are on-going to foster cooperation in this field. Marketing authorisation for specific categories of medicines – such as diabetes drugs – is centralised in the hands of the European Medicines Agency; which assesses the safety, efficacy and quality of medicines. The Agency is also responsible for a number of safety-monitoring activities on marketed medicines. Although pricing and reimbursement policy is a national competence, national legislation and procedures have to comply with the EU Transparency Directive, which aims to ensure transparent national decision-making in this field to prevent disruptions in the single market. The supply of medicines must comply with the regulatory, quality and control criteria defined in the EU Directive on medicinal products for human use.

Sources: “Central authorization of medicines”, 2013; Vogler, S. et al., 2011, Southern Med Review; Personal communication with professional organisations: EFPIA (European Federation of Pharmaceutical Industries and Associations), 2013; GIRP (European Association of Pharmaceutical Wholesalers), 2013
European Economic Area (EEA) Agreement
This agreement brings together the EU Member States and three countries of the European Free Trade Association (Iceland, Norway and Liechtenstein) in a single market, referred to as the 'internal market'. All EU legislation relating to medicines and medical devices is covered under the EEA Agreement. As such, all Member States of the European Economic Area have harmonised their regulatory frameworks and authorisation procedure for medicines and medical devices.

Health Technology Assessment (HTA)
This process evaluates the medical, social, economic and ethical issues related to the use of a health technology, to provide objective evidence to health policy-making.

Household Net Adjusted Disposable Income
This indicator developed by the OECD represents the amount of money a household earns - and can spend on goods and services - per year minus taxes. For further information about this indicator, visit the OECD Better Life Index, http://www.oecdbetterlifeindex.org/

Mandatory Health Insurance
This is a type of health system where healthcare costs are covered by health insurance schemes. Enrolment and contribution to such a scheme or schemes is compulsory for the population. Mandatory health insurance systems are generally characterised by the separation of healthcare provision and healthcare financing functions: health insurance schemes act as purchasers of health services from public and/or private providers.

Mutual recognition agreements
Bilateral agreements between the EU and a third country that aim at facilitating market access through preferential access to conformity assessment and certification.

National Health System/Services
This type of health system is generally characterised by public provision of health services to the whole population, mostly free-of-charge at the point of care and financed by government general revenue (mainly taxes).

Non-branded products
In this publication, non-branded products refer to products that share similar characteristics with a product already on the market (the original or branded product) and so, may be to some extent, substitute it. It includes generics, biosimilars or ‘me-too’ products.

Out-of-Pocket Expenditure
Health-related payment made by a person on its own resources - i.e. an expenditure which is not covered or reimbursed by a third party payer like a health insurance.

Parallel Trade
Form of trade where goods and products are traded from one market to another without the consent of the original manufacturer or supplier. It is lawful in the EU under the principle of free movement of goods in the single market. Barriers or restrictions on such a trade are prohibited by EU treaties. However, some restrictions may be justified and authorised under EU law to protect health and life.

Pharmacoeconomic Analysis or Pharmacoeconomics
The description and comparative analysis of the value of a health product based on its cost versus its effects or benefits to healthcare systems and society.
Prevalence (national/comparative)
This is the proportion of people affected by a certain condition at a given time in a population. In this publication we make a distinction between national diabetes prevalence (also called current prevalence) and comparative diabetes prevalence (or age-standardised prevalence). National diabetes prevalence represents the share of the population that has diabetes in each country. Comparative diabetes prevalence assumes that all countries in the region share the same age profile for a better comparability of the data. All national and comparative prevalence estimates were retrieved from *IDF Diabetes Atlas, 5th Ed.*

Private Health Expenditure
This type of expenditure covers all health spending from private entities, such as private voluntary insurance corporations, the voluntary sector or households (i.e. out-of-pocket payments).

Procurement
The process of acquiring or purchasing services or goods from an external source. In the current publication, it concerns the purchasing of medical products from manufacturers or suppliers. Public procurement is the procurement of goods and services on behalf of a public authority, such as a government agency. To prevent fraud, the law of most countries regulates government procurement more or less closely.

Public Health Expenditure / Government Health expenditure
This type of expenditure covers all health spending from public bodies, i.e. government, regional or local authorities, national health insurance funds or social security schemes.

Quality Issues Reporting System
The structure, frameworks, procedures and resources that aims at identifying, reporting and addressing medical products that fail to meet national and/or regional standards.

Reference pricing (external/internal)
Reference pricing is a price setting tool mostly applied to medicines. Two types of reference pricing can be distinguished. External reference pricing consists in setting the price of a specific medical product according to the price of that same product in other countries. Internal reference pricing sets the price or maximum reimbursement level of a medical product according to those applied to products classified in the same category or considered similar. Both types of reference pricing may be combined or used separately. Additionally, they can be both implemented using a range of different methodologies (including median, average, or lowest price...).

Regressive mark-up scheme
Regressive mark-up schemes are a way to regulate the charges, costs and profits suppliers and retailers add to the price of medical products. Under such a scheme, mark-ups are capped according to a regressive scale: the higher the price, the lower the mark-up.

Rural
In the context of this publication, rural is defined according to the distance to a healthcare professional; any person with diabetes living over 5 km from a practicing doctor and/or pharmacy is considered here as rural.

Substitution
Replacement of a product by another one classified as equivalent. However, equivalence criteria used in such a classification may vary from one health authority to another.

Tender
Tenders are a type of procurement procedure where suppliers are selected based on the quotations they submitted to the competent authority, further to its call for bids. Supply contracts are awarded to the applicant or applicants who submitted the offer that respond best to the criteria set by the authority.
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