The Slovak healthcare system has undergone significant reform in recent years, and the new Government’s policies look set to continue this change.

SLOVAKIA AT A GLANCE

Area: 49,035 km²
Population: 5.5 million
Population growth: 0.14%
GDP: €63.2bn
GDP growth: -4.7%
Number of hospitals: 138
Number of hospital beds: approximately 36,000

Note: total healthcare expenditure: data for 2008, PPP
Source: PMR Publications, OECD 2010
INTRODUCTION

The Slovak Republic (Slovakia) has succeeded in turning its healthcare system from an integrated tax-based structure in which the state held a monopoly, into a decentralised social health insurance system populated by both public and private providers. This privatisation process has meant a migration of primary-care physicians to the private sector and the establishment of independent practices. Private out-of-pocket payments have increased but, until recently, remained relatively limited.

The reform process

Transformation of Slovak healthcare is still underway and as a result the industry is continuously changing. Following major policy shifts in the early 1990s, the government adopted a new set of healthcare reforms between 1998 and 2002, which defined the relationship between the Health Ministry, health insurance companies and healthcare providers. This period also led to the establishment of municipal and regional hospitals.

Private health insurance schemes were introduced in 2004 and a number of private companies were established to take advantage of this new market.

Unfortunately, the public tender process and financial management procedures in most Slovak hospitals remain poorly organised and insufficiently developed, which severely affects hospital budgets and opens the door to corruption.

Debt remains a key concern for the Slovak healthcare system. At the end of 2009, debt in the industry amounted to €193.5m, the bulk of which was owed to suppliers of drugs and healthcare devices. This represented a reduction of almost €80m in comparison with December 2008, according to figures from the Slovak Health Ministry. This reduction was the result of more than €130.7m in government aid provided to healthcare facilities at the end of 2009.

GOVERNMENT HEALTHCARE POLICY AND EXPENDITURE

With the exception of the Czech Republic, Slovakia has the highest per capita GDP figure (based on purchasing power parity) of all Central and Eastern European (CEE) countries. GDP per capita stood at almost €21,000 in 2009. Spending on healthcare is also one of the highest in the CEE region, reaching almost 8 per cent of GDP.

The Slovak healthcare system is still dominated by the public sector, with the state fund covering most medical services, including treatment by specialists, hospitalisation, prescriptions and pregnancy care. There is compulsory state-funded healthcare for all citizens and the Health Ministry oversees the National Health Service, which supervises the health insurance companies principally responsible for the funding of healthcare and reimbursements. Health insurance is mandatory for all citizens.

Private healthcare in Slovakia is, however, struggling, as a result of government legislation that restricts the competitiveness of private hospitals and health insurers. In October 2007, the Slovak Parliament banned Slovak insurers from using their profits for anything other than healthcare refunding; a policy that was to the detriment of these companies. Legal amendments in 2008, which required that private health insurers return profits to the healthcare system, further infuriated private operators. But the situation is changing. According to a recent programme declaration published by the new Slovak government its intention is to implement two kinds of insurance: compulsory and supplementary. This could stimulate the private healthcare market, provided that the basket of health services guaranteed within public insurance is specified and not too large in scope. Government has also outlined strictly-defined rules and profit limits, eg, if an insurer does not meet the time limits established for specific surgical procedures and patients have to wait longer, the cost of such surgery will be subtracted from the insurer’s profit.

eHealth

A new electronic healthcare system, known as eHealth, will be launched in Slovakia in early 2013 and, according to the Slovak Health Ministry, its implementation costs will reach €252m. The system will include a new electronic healthcare book and electronic prescriptions and will allow patients to book a doctor’s appointment electronically. Patients will be issued with a portable identity card, which – in addition to access to the National Healthcare Portal – will be a gateway to all of the services offered by the electronic healthcare system.

MARKET ACCESS

Increasing competitiveness

The number of drugs registered in Slovakia has increased gradually in the last few years. In 2005 some 4,300 new drug applications were submitted, in comparison with 8,800 in 2006 and 12,400 in 2008, according to the State Institute for Drug Control (SUKL). This, of course, increases competition on the Slovak pharmaceutical market.

Registration procedures

Slovak government has tried to make the registration process simpler and, in September 2009, the SUKL introduced a new system of e-application for the market authorisation of medicines in Slovakia.

Pricing policy

Pricing policy is an important issue for companies trying to enter the market or launch a new drug. Since 2004 the prices of over the counter (OTC) drugs at manufacturer level have been freely set in Slovakia. The prices of Rx pharmaceuticals are regulated. In October 2010 the Slovak Ministry of Health re-introduced the degressive margin on medicine supplies to hospitals, which had applied previously between January 2008 and March 2009. The degressive margin means that drugs bought by hospitals will be split into different groups based on their price, and the supplier margins expressed in per cent will decrease as drug prices increase. Prior to its reimplementation, hospitals worked on a fixed rate and were buying medicines with a maximum 9 per cent margin. The ministry believes that re-introduction of the degressive margin will be an effective instrument for regulating drug consumption and decreasing the costs associated with drug policy, and anticipates cost savings of some €10m a year.

The Author

Content on this page was provided by Monika Stefanczyk, head pharmaceutical market analyst at PMR, a research company focused on Central and Eastern European countries.
COUNTERFEITING

Slovak legislation does not include a definition of counterfeit medicine. However, in a 2008 European Commission survey, Slovakia responded that, since 2000, four cases of counterfeit medicines have been reported in the country. These were anabolics and medicines for erectile dysfunction. Drugs identified as counterfeit by laboratory testing included Vega, Kamagra, Viagra and Somatohorm, samples of which were submitted by customs. It is believed these were put into circulation via internet sales. The authorities were not able to estimate, however, the extent of this phenomenon.

The Author

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REFORM INITIATIVES AND POLITICAL ISSUES

Since the parliamentary elections of June 2010, in which the centre-right coalition led by the SDKU ousted the left-wing SMER-SD government, there has been a steady flow of healthcare reform initiatives put forward for consideration in Slovakia. These range from plans which relate to both the wider sphere of healthcare, such as the transformation of hospitals into joint-stock companies, and the introduction of rules on payments to hospitals by health insurance funds, to a number of proposals directly relating to pharmaceuticals.

Under the stewardship of new health minister, Ivan Uhliarik, the Slovak Ministry of Health has prepared a package of reform proposals that it hopes to have implemented by 2011. This could have a significant effect on the Slovak pharmaceutical market. The package includes a measure to cap the expenditure on prescription drug co-payments of pensioners at €45 per quarter. Thereafter the state health insurance funds would cover all further co-payments. Similarly the expenditure on prescription drug co-payments of disabled people would be capped at €30 per quarter. But, according to former health minister Richard Rasi, quoted in the Slovak paper Pravda, these rules will mean that those pensioners or disabled people who choose to buy a prescribed medicine within a specified ATC group that is not the cheapest alternative in that group, will not have the co-payment reimbursed. The consequence of this could be that doctors will be inclined to prescribe cheaper generics. Uhliarik has stated, however, that in cases where the prescription of a generic is inappropriate for a patient for any reason, co-payments will be reimbursed.

Generic prescription is also a priority of the current reform package. While the previous Slovak government succeeded in making the international reference pricing system in Slovakia effective as a cost-containment instrument – bringing the proportion of total healthcare expenditure accounted for by pharmaceuticals down to 31 per cent in 2009 from 38 per cent in 2008 – the new government looks determined to bring this proportion down further. There is certainly a strong argument in favour of doing this as the current figure is still high in comparison with many comparable countries.

Other developments that could be significant from a pharmacos viewpoint include the continuing discussions and disputes concerning health insurance provision. While the left-wing SMER-SD government of Robert Fico had introduced controversial legislation banning health insurance providers from making a profit, the new Slovak government is now considering a plan to make it possible for health insurance providers to be profitable again. Health minister Ivan Uhliarik has focused on the possibility of health insurance providers making a profit from complementary, added-value services within the mandatory health insurance system, although initially, a basic benefits package would need to be agreed on. If it was implemented, this could mean that complementary health insurance packages feature more innovative, expensive drugs as part of a package of higher-value services.

However, considering the relative weakness of the governing coalition’s majority in parliament, it may be difficult for it to implement the reforms it is aiming for. The health reforms of the Slovak government preceding the SMER-SD administration voted out in June this year included fixed co-payments for doctors’ visits and prescriptions, but these were highly unpopular and were abolished by the next government as soon as it came into power. As in all central European countries, there is a high degree of sensitivity and scepticism concerning any involvement of the private sector in state healthcare provision, just as there is resistance to healthcare that is not free at the point of delivery. Therefore, continued political disagreements concerning further restrictions on patient access to more expensive prescription drugs through the tightening of regulations on generics prescription, and resistance to changes to the current ban on profits for health insurance providers should be expected.

Regional co-operation

Health reforms in Slovakia are informed and backed by regional and international organisations and groupings, in particular the European Union (EU) and the World Health Organisation (WHO). Since 1994 - the year after Slovakia’s amicable split with neighbouring Czech Republic - Slovakia has had its own WHO office in the capital, Bratislava. The latest biennial collaborative agreement between Slovakia and the WHO Europe includes a number of action plans to strengthen the country’s health system, including a particular focus on evidence-based policy guidance and on promotion of the scientifically-valid, cost-effective and safe use of medicines and other health technologies.

The biennial agreement also calls for an increased focus on evidence-based public health programmes promoting healthy lifestyles, as part of a bid to improve preventative measures and responses to the causes of premature, avoidable disease and death. These priorities, which imply a more preventative cost-effective approach to healthcare, are reflected in some of the policy initiatives implemented by the previous government. These include the shake-up of the international reference pricing system in April 2009, and the creation of a website on which Slovaks insured under the public health insurance system are able to find cheap generic substitutes of prescription drugs, empowering them in their own efforts to make savings.

Judging by the reform proposals of the current government, the same priorities are reflected.

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Pricing and reimbursement of pharmaceutical products in Slovakia has undergone significant changes in the past year, as the country has sought to shift its unwanted status as the OECD country which spends the largest proportion of its healthcare budget on medicines. Still, however, the basic elements of the system remain the same. In Slovakia, the reimbursement of pharmaceuticals is based on a combination of different reimbursement categories and a reference price system. Within the Slovak reimbursement system, there are four main categories. Category A applies to drugs with no patient co-payment, which can be prescribed by both general practitioners and specialists; category I applies to drugs with no co-payment, but that are subject only to prescription by a specialist; category V refers to vaccines for which no patient co-payment is required and category S refers to drugs for which patients need to make a co-payment. Levels of co-payments are set according to bands: up to €1; between €1 and €2; between €2 and €3.5; between €3.5 and €5, and above €5.

A new international reference pricing (IRP) system for drugs reimbursed in full or in part was implemented in April 2009, whereby maximum prices are set in accordance with the arithmetic mean of the six lowest manufacturer drug prices existing in those EU member states where the drug is distributed. As such, drug manufacturers who want their drugs placed on the reimbursement list are obliged to provide information about the prices of their products in all EU countries where the drug is distributed and sold. Any medicine with a maximum manufacturer price higher than the arithmetic mean of the six lowest manufacturer prices in the EU cannot be placed on the list. This requirement does not, however, apply to generic medicines or those medicines distributed and sold in fewer than six EU member states. The first generic drug in a particular ATC category to enter the reimbursement list has to have a price that is 20 per cent lower than that of the reference product already on the list.

Prior to this system, it was generally agreed that the IRP system Slovakia had in place was not properly applied and, as such, the categorisation system was unable to ensure the kinds of savings it was intended to. Although the new system’s lower drug prices have been beneficial for patients, it impacts companies’ revenues on the Slovak market.

There is a list of documents that should be submitted in order to apply for the inclusion of a medicine in the reimbursement system. During the application the drug manufacturer, or its legal representative, is required to submit basic information about the pharmaceutical (such as its name, form, strength, defined daily dose, packet size, composition and authorisation number as provided by the Slovak Institute for Drug Control). The applicant must also include the provision of information about drug prices in the country of origin of the manufacturer and in all EU member states in which the drug is distributed, along with data pertaining to a pharmacoeconomic analysis of the drug in question (eg the prevalence of the disease which the drug is alleged to address in the Slovak Republic, the estimated number of patients treated for the disease in a calendar year and other data). The applicant should also provide proposed reimbursement and co-payment levels in addition to a proposed retail price for the drug in question. The full list of criteria requirements has been provided for in Act 577/2004, with later amendments.

The submitted applications are analysed by the Categorisation Committee, the advisory body that makes recommendations to the Health Ministry. The final decision on the inclusion of the drug on the reimbursement list, however, lies with the Health Ministry. The decision is issued within 180 days from the time the application is submitted to the Ministry. If data is missing from the application, the Ministry will ask the applicant to provide the missing details within 30 days and will issue its decision within 180 days from the date on which the missing information is provided.

In the case of an application for the inclusion of a medicine on the reimbursement list where the maximum retail price for the daily-defined dose proposed by the applicant is at least 10 per cent lower than the cheapest maximum retail price for the daily-defined dose of an equivalent medicine containing the same active substance and prescribed for the same symptoms currently on the reimbursement list, the decision will be issued within 90 days.

The Categorisation Committee consists of 11 members, three of whom are proposed by the Health Ministry, three by the Chamber of Physicians and five by health insurance companies.

Every quarter, the Categorisation Committee meets to review the prices of reimbursed drugs in Slovakia, and either moves them into new co-payment bands or keeps them in the same ones, depending on international reference pricing (IRP) data. During the next session of the Categorisation Committee in October, for instance, 19 oncology drugs are due to change categories and their resulting method of reimbursement. As a result, these drugs – mostly highly-expensive, targeted oncology drugs – will now be available from hospitals exclusively, and not pharmacies. While it is unusual for such drugs (many of which are intravenously injected) to be accessed by patients directly at pharmacies, the reason for this change is thought to be the fact that the Ministry of Health will save on the margins charged by pharmacies and wholesalers.

Slovakia has been a fairly favourable market for the reimbursement of innovative pharmaceutical products, and recent updates to the country’s list of reimbursed drugs have included a number of highly-expensive, innovative oncology drugs. However, some major obstacles to patient access have also been imposed, such as time-restricted reimbursement introduced by the Slovak Ministry of Health for sanofi-aventis’ cardiovascular drug Plavix (clopidogrel). Reimbursement was restricted to one year in June 2009. Although this decision was reversed in April 2010, similar time restrictions have been imposed on a number of other expensive drugs.

Most recently, the Slovak Ministry of Health has come up with a proposal to change the international reference pricing system so that the price of drugs in Slovakia is set with reference to the second-cheapest market for a given drug in the EU. The Ministry estimates that this change will amount to a €50m annual saving. Government is also considering allowing the process of drug registration and categorisation for generics to take place at the same time, allowing it to make savings from the generic faster than if it were to undergo these processes separately. These latest two planned initiatives – announced by the Slovak Ministry of Health in late September – have highlighted its determination to go even further than its predecessor in achieving cost-containment in pharmaceutical reimbursement. This could imply price erosion in other countries where drug prices are connected to Slovakia’s through international price referencing.

The Authors

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FOCUS ON SLOVAKIA

GENERICS AND INNOVATIVE DRUGS

Policies
As much as 98 per cent of R&D spending in Slovakia’s pharmaceutical industry emanates from private entities (pharmaceutical and biotechnology companies), with the remaining 2 per cent coming from government and academia, according to data from the Slovak Association of Research-Based Pharmaceutical Companies (SAFS).

In October 2009 the Slovak Health Ministry initiated a public campaign aimed at encouraging the country’s citizens to buy cheaper generic medicines. On the Health Ministry’s website patients now can check how much they have to pay or contribute towards a reimbursed medicine (the patient co-payment amount is displayed), as well as check whether a cheaper equivalent is available on the market. Patients can also browse the medicines database by selecting a relevant ATC group.

Slovakia’s SUKL established a new subcommittee in September 2009 to increase the quality of services provided for generic drugs manufacturers. Known as the Subcommittee for Generic Medicinal Products, this body operates within the framework of the SUKL’s Committee for Medicines and is responsible for the assessment of documentation submitted by manufacturers during the authorisation process of generic medicines.

Market share and value
According to PMR estimates, in 2008 generic drugs accounted for about 27 per cent of the Slovak pharmaceutical market in terms of value. The generic drug market in Slovakia was worth SKK9.9bn (£300m) in 2008, which represented a increase of 22 per cent in Slovak koruna terms. The original drug market grew by around 21 per cent, from SKK22.5bn (£666m) in 2007 to SKK27.4bn (£827m) in 2008.

In 2009, Slovak patients purchased 29 million or 33 per cent more packets of drugs than in 2005, according to the Slovak Health Ministry data. Cancer and haematological conditions seem to occupy the top positions on the drug consumption list, but in some cases, such as antibiotics, the increased amount consumed could also be a sign of unnecessary drug prescription. The Slovak Health Policy Institute claims that the increase in drugs’ consumption has resulted from a combination of factors such as the ageing Slovak society, earlier diagnosis of disease and the marketing activities of pharmaceutical companies.

PMR estimates show that after growth in excess of 20 per cent in 2007 and 2008, the rate pertaining to the Slovak generic drug market slowed down in 2009. This reflects a general pharmaceutical market slowdown, resulting from the economic crisis and changes in the reimbursement lists, which reduced the prices of pharmaceuticals (although in most cases this applied to innovative pharmaceuticals). On the flipside, interest in cheaper drug equivalents should increase in Slovakia as a result of the difficult financial situation, meaning the economic downturn and price reductions will have a far greater effect on innovative medicines than generics.

Additionally, the results of several actions pertaining to the generic drug market are being seen eg, a social campaign encouraging the country’s citizens to buy cheaper, generic medicines.

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SHARE OF GENERIC AND INNOVATIVE DRUGS

Source: report “Generics and innovative drugs in Central and Eastern Europe”, PMR 2009

ESTIMATED MARKET VALUE OF GENERIC AND INNOVATIVE MEDICINES

Source: report “Generics and innovative drugs in Central and Eastern Europe”, PMR 2009

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