DELSA/HEA/WD/HWP(2008)1

OECD OCDE

PHARMACEUTICAL PRICING AND REIMBURSEMENT POLICIES IN SLOVAKIA

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31

OECD HEALTH WORKING PAPERS

Unclassified **DELSA/HEA/WD/HWP(2008)1**

Organisation de Coopération et de Développement Economiques
Organisation for Economic Co-operation and Development

25-Feb-2008

English - Or. English

DIRECTORATE FOR EMPLOYMENT, LABOUR AND SOCIAL AFFAIRS
HEALTH COMMITTEE

DELSA/HEA/WD/HWP(2008)1
Unclassified

Cancels & replaces the same document of 22 February 2008

Health Working Papers

OECD HEALTH WORKING PAPER N0. 31

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JEL Classification: I18, I11

JT03241090

English - Or. English

DIRECTORATE FOR EMPLOYMENT, LABOUR AND SOCIAL AFFAIRS

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ACKNOWLEDGEMENTS

This paper was prepared by Zoltán Kaló, Associate Professor and Programme Director, Health Economics Research Centre, Eotvos Lorand University, Budapest; and Elizabeth Docteur and Pierre Moïse of the OECD Health Division, Directorate for Employment, Labour and Social Affairs. Mr. Moïse is on secondment to the OECD from Health Canada.

The authors wish to thank the Ministry of Health of the Slovak Republic (MoH) and the State Institute for Drug Control (SUKL) for helping to arrange the mission during which much of the information used in this report was collected. Special thanks go to Ján Mazag for commenting on a draft version of this report.

Thanks are due also to the experts and stakeholders interviewed in the course of preparing this report, many of whom furnished data or publications referenced in the work: MUDr. Daniel Klačko (Secretary of State, Ministry of Health (MoH)), Ing.Mgr. Dagmar Hrmová (GlaxoSmithKline), Doc. PharmDr. Juraj Sýkora, CSc (Medicine Policy Department, MoH), Ing. Miriam Stanková (Coordinator of the Health Sector for the OECD, MoH), MUDr. J. Masaryk (Adviser of the General Director, Common Insurance Company, Inc.), MUDr. Eliška Marušáková (Head of Department of Health Programs, Union Insurance Company, Inc.(UnionZP)), MUDr. I. Strnisko (Department of Health Programs, (UnionZP)), PharmDr. T.Tesaŕa (Department of the Pharmaceutical Care, European Insurance Company, Inc.(EIC)), PharmDr. J.Bachletová, (Manager of the Pharmaceutical Care, (EIC)), MUDr. Etela Janeková (Director of the Division of Health Care Activities, Dôvera Insurance Company, Inc.), MUDr. B. Koreň (Deputy Director for the Purchase of the Health Care, Apollo Insurance Company, Inc. (AIC)), PharmDr. A. Árviová (Deputy Director for Monitoring of the Health Care, (AIC)), MUDr. J. Kochan (General Insurance Company, Inc. (GIC)), MUDr. B. Haveleková (GIC), Ing. Darina Kyliánová (Chairman of the Institute, Institute for Intelectual Property Rights (UPV)), Ing. L. Marčoková (Director of the Patent Department, (UPV)), PharmDr. D. Stará, CSc. (Head of the Section of Registration, (SUKL)), Ing. Sína Niku (Association of Wholesalers, Producers and Pharmacists), PharmDr. Š. Krchňák (Member of the Presidium of the Chamber, Chamber of Slovak Pharmacists (SLeK)), RNDr. J. Šipeky (SLeK), MUDr. K. Šimovičová (Slovak Medical Chamber), MUDr. K. Sedláková (Slovak Medical Chamber), MVDr. S. Strachotová, MBA (Chief Executive, Slovak Association of Original Producers (SAFS)), MUDr. P. Trnovec (Deputy Chairman of the Board of Directors, SAFS), Ing. V. Marko, CSs. (Member of the Board of Directors, SAFS), Christian Wieser (Chairman of the Slovak Generic Association (GENAS)), MUDr. A. Svoreňová (Deputy Chairman of GENAS), PharmDr. M. Palagyi (Member of GENAS Regulatory Affairs Subgroup), Ing. Yvonna Žittňanová (Procuratrix of the SARAP, Slovak Association of Companies in the area of Medicine Regulation (SARAP)), Ing. A. Lukačovičová (SARAP), MUDr. K. Krizanová (National Oncological Institute), Ing. Mongi Msolly, MBA (General Director, National Institute for Cardio-vascular Diseases, Inc. (NICVD)), MUDr. I. Gašparovič (Deputy Director, NICVD.) and MUDr. D. Kučerová (Pharmacologist of the Institute, NICVD).

The authors thank Lihan Wei for assistance in the production of tables and figures included in this report; Valérie Paris and Peter Scherer, for their comments and suggestions; and Gabrielle Luthy and Marie-Christine Charlemagne for secretarial support.

ABSTRACT

This paper examines aspects of the policy environment and market characteristics of Slovakia's pharmaceutical sector, and assesses the degree to which Slovakia has achieved certain policy goals.

Pharmaceutical expenditure in Slovakia accounts for a higher share of total health expenditure than it does in any other OECD country, and the share of national income going to pharmaceuticals is exceeded only in Hungary. Although its relatively low national income is a partial explanation for Slovakia's status in this respect, this review finds that Slovakia has scope to reduce its expenditures and the rapid rate of growth in its pharmaceutical spending.

Financing of pharmaceutical expenditure in Slovakia rests more heavily on the public sector than is typical in the OECD, with out-of-pocket spending accounting for just a quarter of total expenditure. The effectiveness of international price referencing in limiting Slovak prices for on-patent pharmaceutical products is questionable. For products that have gone off-patent and for those with similar chemical structure, a reference-pricing scheme and competition among generic alternatives results in effective price control, although incentives for generic substitution are weak (for patients) and misaligned (for pharmacists). When deciding whether a drug will be reimbursed through the social insurance scheme, the cost-effectiveness of new pharmaceuticals is not assessed.

On the other hand, certain policy goals have been achieved. The accessibility and availability of medicines--including the most innovative products--is good; affordability is supported by relatively low average co-payment levels. While more expensive drugs usually have higher cost-sharing, drugs are not excluded from coverage on affordability grounds.

JEL Classification: I18, I11

Keywords: Pharmaceutical policy; pricing; reimbursement; pharmaceutical market; Slovakia.

RÉSUMÉ

Le présent document examine les différents aspects des politiques et des caractéristiques du marché du secteur pharmaceutique slovaque, et évalue les objectifs atteints.

La part des dépenses pharmaceutiques dans l'ensemble des dépenses de santé est plus élevée en République slovaque que dans tout autre pays de l'OCDE, et la proportion du revenu national consacrée aux produits pharmaceutiques n'est plus forte qu'en Hongrie. Si la modestie relative du revenu national explique en partie cette situation, le présent examen indique que la République slovaque dispose d'une certaine marge de manœuvre pour réduire ses dépenses pharmaceutiques et ralentir la croissance rapide de ceux-ci.

En République slovaque, le financement des dépenses pharmaceutiques dépend davantage du secteur public que dans les autres pays membres de l'OCDE : la participation aux coûts des ménages n'en supporte que le quart. Le recours aux prix de référence externes n'a pas fait la preuve de modérer les prix slovaques des produits pharmaceutiques qui sont encore protégés par un brevet. S'agissant des produits tombés dans le domaine public et des produits ayant une structure chimique comparable, un dispositif de prix de référence et la concurrence avec les génériques permettent une maîtrise effective des prix, même si les incitations à la substitution par des produits génériques sont faibles pour les patients et ne sont pas aligné pour les pharmaciens. Par ailleurs, le processus de décision de remboursement d'un médicament par l'assurance sociale ne donne pas lieu à une évaluation du coût-efficacité des nouveaux produits pharmaceutiques.

D'un autre côté, certains objectifs des politiques pharmaceutiques ont été atteints. La facilité d'accès et la disponibilité des médicaments – y compris les plus innovants – sont satisfaisantes ; l'accessibilité financière aux médicaments est soutenue par la relative modération de la participation aux coûts de l'assuré. Si les médicaments chers sont en général synonymes pour l'assuré d'une participation financière supérieure, le critère de l'accessibilité financière n'est pas un motif d'exclusion de la liste des médicaments remboursés.

Classification JEL : I18, I11

Mots-clés : politique pharmaceutique ; tarification ; remboursement ; marché pharmaceutique; République slovaque.

TABLE OF CONTENTS

Tables

Figures

Boxes

INTRODUCTION

1. This paper examines aspects of the policy environment and market characteristics of Slovakia's pharmaceutical sector, and assesses the degree to which Slovakia has achieved certain policy goals.

2. With only 5.38 million inhabitants and one of the lowest per capita income levels in the OECD[1], the Slovak Republic represents a relatively small market for pharmaceuticals. Yet pharmaceuticals play an important role in Slovakia's expenditure. Although health spending is well below the OECD average when considered as a share of GDP--6% in Slovakia compared to 9% across the OECD in 2005--Slovakia's pharmaceutical expenditure accounts for a relatively very high portion of health spending (nearly double the OECD average share at 32% of spending) and more than 2% of the country's income.

3. Slovakia has a mandatory social insurance system that provides all residents with coverage for primary, secondary and tertiary care, pharmaceuticals and medical devices. Primary care physicians act as gatekeepers to specialist services. Physician density is in line with OECD norms, although the per capita physician consultation rate is relatively high (OECD, 2005). Specialist care is provided through private practices, polyclinics and hospitals.

4. Slovakia's pharmaceutical policy environment has changed significantly over the last decade and is still in a phase of refinement and ongoing implementation. The high proportion of pharmaceutical expenditure within total health expenditure and as a percentage of GDP suggests that pharmaceutical policy, especially the reimbursement scheme, could benefit from further adjustments.

[1] Slovakia's GDP is 50% lower than the OECD average (per capita 251,786 SKK = 14,060 US$ PPP) in 2004 (OECD, 2006). Income is growing at a rate well above the OECD average, however, reaching an exceptional 8.3% growth rate in 2006, up from 4.1% in 2002, according to the Statistical Office of the Slovak Republic (http://www.statistics.sk/webdata).

THE POLICY ENVIRONMENT

5. This section describes pharmaceutical pricing and reimbursement policies in Slovakia, as well as some of the most important related policies and practices concerning pharmaceuticals, including marketing authorisation, coverage, policies to influence pharmaceutical use and policies intended to promote pharmaceutical innovation.

Pharmaceutical product regulatory review procedures and outcomes

6. In accordance with the Act on Pharmaceuticals and Medical Devices (Act no. 140/1998), the State Institute for Drug Control (known by its Slovak acronym, SUKL) is responsible for regulating the safety, efficacy and quality of pharmaceuticals. It operates under the aegis of the Ministry of Health. In accordance with European Community directives, the SUKL coordinates its marketing authorisation efforts with other member countries of the European Economic Area (see Box 1).

Box 1. Marketing authorisation in the European Economic Area

Authorisation for marketing a medicine within the European Economic Area (EEA)[1] is granted through the competent authority of any EEA country – valid within the particular country – or through one of the recognised procedures for obtaining authorisation in more than one EEA country. The holder of a marketing authorisation valid within the EEA must have an established presence within the EEA.

The London based **European Medicines Agency (EMEA)** was established in 1995 to coordinate the evaluation and European market authorisation for both human and animal medicinal products. The EMEA operates under the aegis of the European Commission's DG Enterprise, to which it forwards its opinions for approval for final marketing authorisation in all member states.

There exist three procedures for obtaining marketing authorisation in more than one EEA country: the centralised procedure, the mutual recognition procedure, and the decentralised procedure.

The **Centralised Procedure (CP)** is used to obtain a marketing authorisation valid in all EEA countries. The procedure is mandatory for, but not limited to, biotechnology, AIDS, cancer, diabetes, neurodegenerative disorder medicines, as well as orphan drugs. Applications submitted to the EMEA by manufacturers are evaluated by the Committee for Proprietary Medical Products (CPMP) – comprised of 2 experts nominated by each member state. The CPMP subcontracts the assessment to two rapporteurs selected from a pool of 3 500 drug evaluation specialists in national regulatory agencies. The CPMP has 210 days from receipt of the dossier to provide a recommendation to the European Commission for final approval; however the clock can be stopped when rapporteurs request additional information from the applicant. Total accumulated time during which the clock is stopped generally should not exceed 6 months.

The Decentralised and Mutual Recognition procedures are based on the principle of recognition by other member states of a first approval granted by the authorities of one member state.

Through the **Mutual Recognition Procedure (MRP)**, manufacturers can apply for marketing authorisations in designated "Concerned Member States" (CMS) by validating the marketing authorisation *previously granted in another member state* – the "Reference Member State" (RMS). The competent authority in each CMS has 90 days in which to decide whether it agrees with the RMS' marketing approval decision. In case of disagreement, the RMS sends the concerns to the CPMP; if a consensus is not reached after a further 60 days, the procedure moves into arbitration by the CPMP.

The **Decentralised Procedure (DP)**, introduced in 2005, increases the EMEA's co-ordinating role to facilitate the harmonisation of marketing approvals. Manufacturers of new products *not yet marketed in one of the EEA member*

states (and not obliged to use the CP), as well as generic versions of original products authorised through the CP, designate a Reference Member State to undertake the assessment. Identical dossiers are submitted to Concerned Member States where approval is also sought. The RMS steers the approval process, seeking agreement on elements that must be harmonised in CMSs and provides a decision. A maximum of 210 days is granted (including a maximum of three months for clock stops to allow for applicants to respond to objections raised during evaluation) to the RMS and the CMSs to come to an agreement on the full dossier. If agreement is not forthcoming then an additional 90 days are granted for arbitration, with a final decision by the CPMP. The recommendation is then forwarded to the European Commission for final decision on granting or refusing a marketing authorisation valid in all Concerned Member States.

The main difference between the MRP and the DP is that the latter is sought in cases where no marketing authorisation has been granted in an EEA country. Under the RMS and DP, manufacturers have greater control over the choice of RMS than with the centralised procedure.

A manufacturer can apply for a **national marketing authorisation** for products not obliged to go through the centralised procedure, if it intends to market a pharmaceutical in only one EEA country, or as a first step in the Mutual Recognition Procedure. Recent legislation to increase transparency require that national regulatory bodies make marketing authorisations available 'without delay' and publicly release clinical documentation, assessment reports and reports on the reasons that underlie the decision. Generic manufacturers often seek approval through national procedures for two reasons: (1) expiry dates of patents and supplementary protection certificates differ from one country to another, and (2) original products may have different forms, strengths, and labelling across countries, necessitating different studies to prove bio-equivalence. However, since 2005 generic manufacturers have the option of going through the centralised procedure for originals approved through the centralised procedure.

Notes

1. The EEA is composed of the 27 European Union member countries plus Norway, Iceland and Liechtenstein.

7. The SUKL puts applications for marketing approval into 3 categories: prescription only, prescription by specialists only and over-the-counter (OTC). If a manufacturer wishes to switch classification for a product from prescription to OTC, the pharmaceutical must satisfy the following conditions: it must be proven to be safe and effective, it must have been on the market for a number of years, it must be defined as low risk for users, and it must be free from risk of addiction or abuse. In November 2006, there were 19 693 drugs (excluding homeopathic products) on the market in Slovakia, out of which 90% were prescription-only and 10% were OTC pharmaceuticals.

8. Average delays in obtaining authorisation for bringing pharmaceuticals to market in Slovakia appear to fall within timelines prescribed by the European Commission (EC). However, priority is given to applications made under the EC's decentralised or mutual recognition procedures, to the detriment of national applications (for marketing in Slovakia only).

9. The SUKL is currently treating a backlog of applications (2 990 as of 31 August 2007), most of which are for slight variations (*e.g.* different package size, change in production facilities) for products already on the market.[2] Additional resources have been devoted to clearing this backlog; the general perception among stakeholders is that the SUKL is making adequate progress.[3]

10. The backlog does not appear to have affected Slovakia's standing with respect to EMEA timelines. On the contrary, accession to the EMEA may have helped reduce the backlog, as the SUKL can now benefit from the opinions of other Member States' regulatory authorities. The backlog also does not delay the market entry of generic drugs.

2 According to SUKL officials, 800 delayed applications are for prolongation of an existing marketing authorisation, 1 400 are for variations for products currently on the market, 490 are for indication changes, and 300 are for new applications.

3 The backlog was approximately 7 000 applications in March 2006.

11. Non-licensed medications may be approved for use on an individual basis. The Ministry of Health (and not the SUKL) is responsible for approving non-licensed drugs for use by individual patients under particular circumstances, according to Act 140/1998.

12. There is no direct linkage between marketing authorisation application fees and the SUKL's budget; applicants' fees are directed to the Ministry of Health, which determines the SUKL's annual budget. This treatment of application fees may help insulate the SUKL from undue pharmaceutical industry pressure. On the other hand, in comparison with other countries where the applicant fees accrue directly to the marketing authority, the SUKL has less independent ability to generate resources needed to undertake adequate and timely reviews.

Intellectual property rights

13. Before 1992, Slovak pharmaceutical patents were based on the manufacturing procedures used, not the active ingredient itself; therefore, any substance could be produced (and patented) by generic manufacturers as long as the manufacturing process was modified. Slovakia's intellectual property rights (IPR) protections have since been harmonised with the European Patent Convention (see Box 2) since 1992.

14. Patent protection for pharmaceutical products is ensured for 20 years. Pharmaceutical manufacturers have been able to obtain Supplementary Protection Certificates that extend the period of market exclusivity under certain circumstances.

15. Data exclusivity (see Box 2) is, in principle, enforced in Slovakia. Nonetheless, the Office of the United States Trade Representative put the Slovak Republic on its "watch list" in 2004 based on its judgment that Slovakia did not provide adequate protection for confidential pharmaceutical test data submitted to obtain marketing approval, and the United States has remained concerned about this perceived deficiency.

Box 2. Pharmaceuticals and Intellectual Property Rights in the European Union

Patents

Slovakia is one of 34 contracting states (as of 1 January 2008) to the European Patent Convention treaty (EPC).[1] The EPC provides a legal framework for granting so-called *European patents* – there is no single, centrally enforceable EU-wide patent – via a single, harmonised procedure before the European Patent Office (EPO).

The EPO accepts patent applications in any of the official languages of an EPC contracting state, but processing of the patent is done in one of the three official languages of the EPO (English, French and German).The applicant designates which countries of the EPC it wishes to file for patent protection. A favourable decision by the EPO grants a patent in each of the designated states. However, the determination of ownership, validity and infringement are subject to respective national laws. Furthermore, while a national court may invalidate a patent in one country, the European patent remains valid in the other designated countries. A European patent is, in effect, non-unitary across all European Union (EU) countries and independent in each.

The EPC does impose some limits on its signatories. The basis for determination of validity of a patent by national law is limited to a few reasons, but the standard on which the determination is made is that of national law. The convention also requires all jurisdictions to give a European patent a term of 20 years from the filing date, either the date of filing with the EPO for a European patent or for an international application under the Patent Cooperation Treaty.[2]

Intellectual property rights exhaustion

Beyond the issue of patent protection, the principle of IPR (patent and trademark) exhaustion rights – the concept

by which an intellectual property rights owner loses the rights to control distribution and resale of its product once the first sale has been achieved – is another IPR issue that is relevant to the pharmaceutical industry. From a legal standpoint, the definition of exhaustion regime depends on whether exhaustion is recognised as "national" or "international" exhaustion. Taking trademark rights as an example, in a country which adheres to a national exhaustion regime, once a brand-name medicine is placed for sale on the market in that country by the owner, or by a reseller such as a pharmacy, the trademark owner loses the right to control the sale of that product in that country. The owner can, however, forbid importation of the product. Under international exhaustion, once the owner of the brand-name medicine, or a reseller, places the product for sale in *any country* in which it enjoys trademark protection, it forfeits the right to control sale of that product in *all countries* for which the product enjoys trademark protection. Thus, the trademark owner cannot prevent trade in its product in countries that adhere to an international exhaustion regime (Calboli, 2002).

The member states of the European Union have developed a hybrid of the national and international exhaustion regimes – Community-wide exhaustion. Under this doctrine:

> "once a product has been put on the market in a particular Member State, by or with the consent of the legitimate trademark owner, the owner can no longer rely on his national rights to prevent the importation of the product from that State into another Member State." (Calboli, 2002)

Community-wide exhaustion was adopted in the spirit of harmonizing trade within the EU; it is the IPR issue underlying the parallel trade of pharmaceuticals within the European Union. However, European Court of Justice rulings have made it clear that the principle of community-wide exhaustion supersedes national exhaustion regimes (Calboli, 2002), restricting parallel trade to within the member states of the European Union.

Supplementary Protection Certificate

A holder of a pharmaceutical patent still in force in the European Union can apply for a supplementary protection certificate (SPC), an extension of intellectual property rights for said patent. An SPC is a unique, patent-like IPR that comes into force after the patent expires. An SPC is a tool governments use to compensate manufacturers for the lengthy period of time it sometimes takes for granting marketing authorisation; however, it does delay the entry of generic drugs onto the market.

The term of an SPC depends on the time between patent application and granting of the first marketing authorisation in a country of the European Economic Area (EU member states plus Iceland, Norway and Liechtenstein)[3]: (1) if the first marketing authorisation is granted in less than five years than no SPC is granted; (2) if the first marketing authorisation is granted in five years or more, but less than ten years, then the term of the SPC is equal to the time elapsed less five years, and; (3) if the first marketing authorisation is granted in ten years or more than the term of the SPC is fixed at five years. Thus, the total term of the "patent + SPC" protection cannot exceed 15 years from the granting of first marketing authorisation in the EEA. SPC applications are made on a country by country basis, and to the extent that patent application dates (for national patents) differ, terms and end of SPCs may vary from one country to another.

Bolar provision

The use by generic manufacturers of pharmaceuticals still under patent protection for the purpose of submitting information to regulatory agencies for obtaining marketing authorisation has, until recently, been governed in Europe by each member state's national law. The European Commission decided that a provision for generic manufacturers similar to the United States' Hatch-Waxman Act's so-called "Bolar provision" should be permitted for all member states.[4] To this end, the EC revised, in 2004, Directive 2001/83/EC on the Community code relating to medicinal products for human use, to include the following amendment:

> "Conducting the necessary studies and trials … and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products."[5]

Member states had 18 months from April 2004 to implement the Directive into their national laws.

The amendment clearly allows the use of on-patent medicines by users other than the holder of the patent for "conducting the necessary studies and trials" for "consequential practical requirements", but left uncertain the legality of other actions, such as supplying or exporting on-patent medicines to generic manufacturers. By using the ambiguous wording "consequential practical requirements", the EC has apparently left the interpretation to national courts

(Ashurst, 2005).

Data exclusivity

Complementary to Bolar Clause type provisions are legislation that protect the clinical trial data that original product manufacturers are required to submit in their applications to regulatory agencies for marketing authorisation. The original product manufacturers argue that such protection is necessary; otherwise they are at an unfair disadvantage since generic producers can use these rather expensive data at no cost. The generic producers reply that not having access to these data delays the entry of generic products onto the market, thereby limiting the availability of cheaper alternative pharmaceuticals.

One of the 2004 European Commission's amendments to Directive 2001/83/EC revised EU aspects of data protection. It provided that test data supplied by the manufacturer of an original product, as required by marketing authorisation legislations, are protected for a period of eight years following the first marketing approval in a member state. This period of exclusivity is followed by a two-year period during which generic versions of the original product may not be launched on the market of any member state, although marketing authorisation can be granted during this period. Finally, the original producer can obtain an additional one-year period of market exclusivity beyond the two-year period if, during the eight-year data exclusivity period, the producer obtains marketing authorisation for additional indications which bring a substantial clinical benefit compared with existing therapies. In effect, this new regulation creates the so-called "8+2+1" formula which guarantees the original producer a period of market exclusivity equivalent to ten years, with the possibility of extending that exclusivity to 11 years (Sanjuan, 2006).

Member states had until 30 October 2005 to implement the new Directive. In the face of opposition to the new law from prospective member states who were not able to vote on it, these states can request derogation. The law came into full effect in November 2005, meaning that the first generic drugs to be affected by this law will not come on to the market in the European Union until 2015.

Notes

1. The treaty entered into force in Slovakia on 1 July 2002.
2. The Patent Cooperation Treaty provides a unified procedure for filing patent applications.
3. For the purpose of granting an SPC, marketing authorisations granted in Switzerland are also considered since Liechtenstein automatically accepts authorisations granted in Switzerland.
4. In 1984, Roche Products Inc. sued Bolar Pharmaceuticals Corp. Inc. for violating its patent for flurazepam-HCl. Bolar had obtained some of the active ingredient from a foreign manufacturer and had started the bio-equivalency studies necessary for obtaining marketing approval for a generic version of Roche's patented product, prior to the patent's expiration. A court of appeal overturned a lower court's decision, saying that Bolar had violated Roche's patent. This judgment meant that generic manufacturers could not conduct bio-equivalency studies for obtaining marketing authorisation until the patent of the original product expired. In response to the Roche -v- Bolar judgement, the United States Congress passed the Hatch-Waxman Act (Drug Price Competition and Patent Term Restoration Act (Public Law 89-417, 35 U.S.C. paragraph 271(e)(1)), in 1984, which granted drug manufacturers the right to "make, use, offer to sell, or sell … a patented invention" for uses related to submission of information under Federal law regulating drugs.
5. Directive 2004/27/EC, Article 10(6), 31 March 2004.

16. In Slovakia, patent linkage[4] is now a condition for registration of generic drugs. The SUKL has to establish the patent status of the original product prior to granting marketing authorisation to a generic version of that product. Legislation passed in 2005 – pushed through with the help of the US Embassy and the American Chamber of Commerce Local Area Working Group[5] – requires the SUKL to inform the owner of a patent or supplementary protection certificate (SPC) when a manufacturer makes an application

4 Patent linkage is the practice of linking marketing approval for a generic drug to the patent status of the original product.

5 May 4, 2006 press release of the Embassy of the United States, Bratislava, Slovakia (http://slovakia.usembassy.gov/pr060504.html - accessed 4 October 2007).

for marketing authorisation for a generic version of the original product to which the patent or SPC pertains. The SUKL pragmatically relies on the statement the generic manufacturer must include in its application for marketing authorisation as to the owner of the patent for the original product, and the date at which the patent is expected to expire. The SUKL must contact the Institute for Intellectual Property Rights if there is any doubt regarding the information provided.[6]

Pricing

17. The current pricing and reimbursement scheme replaced an earlier scheme that was overseen by the Ministry of the Economy. A key change from the earlier scheme is the move from regulation of manufacturers' prices to regulation of retail prices.

18. Since 2004 the Ministry of Health determines the maximum retail price for reimbursed pharmaceutical products and the maximum manufacturer's price for in-hospital pharmaceutical products. Imported and domestic (generic) products are subject to different pricing rules. Over-the-counter and non-reimbursed pharmaceutical products are not subject to price regulation, although the wholesale and retail margins on these products are regulated. As manufacturers of prescription and hospital medicines have strong incentives to seek reimbursement for their products and thus to submit to price regulation, Slovakia's system can be said to be a form of *de facto* price regulation.

19. The regulatory focus on retail (rather than ex-manufacturer) prices, as explained by officials responsible for pharmaceutical pricing, was strategic; manufacturers are reluctant to make concessions on ex-factory prices, but are more flexible with respect to retail prices. This may reflect concerns about use of prices in international price benchmarking or reflect manufacturers' perceptions of the ability to negotiate lower margins with wholesalers (or to act as wholesalers, collecting the margin).

Pricing process

20. When seeking reimbursement for a pharmaceutical product destined for the pharmacy retail market, a pharmaceutical firm submits an application indicating a proposed maximum retail price, together with a request for the Categorisation Committee to determine the reimbursement level (the share of the retail price to be paid by the social insurance). Applications can be submitted at any time and are published monthly on the website of the Ministry of Health.[7] Two weeks after the publication of the first price proposal, the applicant has an opportunity to submit a revised price, which cannot be higher than the first proposed price. No subsequent proposals are allowed. Companies frequently do submit a revised proposal with a lower price, rather than naming the proposed price at first opportunity.

21. Although the pricing regulation officially pertains to the retail price, the price threshold for imported pharmaceuticals is established by reference to ex-factory prices in a number of European countries. Applicants must include the ex-factory price of their products in nine selected European countries:[8] the country of manufacture, Austria, France, Germany, Italy, Spain, the Czech Republic, Hungary and Poland. Countries in which a price has not (yet) been established are excluded when

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6 During interviews conducted for this study, officials of both the SUKL and the Institute for Intellectual Property Rights expressed concern that this legislation has the potential to shift the legal liability for infringement of pharmaceutical patents to the SUKL. The European Generic Medicines Association is sufficiently worried about the case in Slovakia that it has made an official complaint to the European Commission.

7 http://www.health.gov.sk/; in Slovakian only

8 The Ministry of Health relies on the accuracy of information submitted by the applicants, as it has no capacity to validate the reported foreign price levels.

calculating the ex-factory price threshold, which is defined as a maximum of 10% above the average of the three lowest prices.

22. International price benchmarking could result in high prices in Slovakia, relative to neighbouring countries with similar income levels. The designated comparators include one country that tends to have relatively very high ex-manufacturer prices – Germany[9] – as well as the country of manufacture, which will tend to be a high-priced country, given the production sites for original products.[10] The German price could be one of the three countries used in calculating an average for a particular product if data are unavailable for at least six countries; a plausible scenario given that pharmaceuticals are usually available on the German market very soon after first world launch (Paris and Docteur, 2007). The Ministry of Health can delay a decision until such a time that data from more countries are available, particularly with respect to the neighbouring countries of the Czech Republic, Hungary and Poland, which are given special consideration by the Ministry, although the rules under which such delays are warranted are not explicitly defined.

23. International price referencing by payers in other European countries stands to influence the pricing strategy used by manufacturers of original drugs sold in the Slovak market. Multinational pharmaceutical companies try to avoid lowering the European market-entry floor price in small markets like Slovakia.[11] If the Slovakian price of a drug was the lowest in Europe, payers in some other European countries may reduce reimbursement according to that floor price, and consequently induce price erosion in Europe. Therefore, pharmaceutical companies do not let their Slovakian affiliates launch original products at a price below the European floor price. In fact, as the Slovakian Ministry of Health allows a launch price that is 10% higher than the average price of the three lowest-priced reference countries, pharmaceutical companies are generally able to price their drugs above the lowest price elsewhere in Europe (that is, above the European floor price).

24. International price referencing is never repeated after the initial market-entry price determination in Slovakia. This may leave room for some companies to launch their products in Slovakia before the price is established in other low price countries and to keep the Slovakian price higher than elsewhere in Europe.

25. For locally produced pharmaceuticals all of which are generic products, the maximum price calculation is based on production costs and profit control. No guidance is given in how manufacturers should calculate their production costs. Hypothetically, manufacturers could seek to avoid profit controls by adjusting the import transfer prices of ingredients and export transfer prices of final products to increase apparent local production costs, thus shifting profits from Slovakia.[12] However, generic price competition

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9 Germany does not establish price caps for pharmaceuticals, irrespective of whether they are reimbursed by the social insurance system.

10 These include such relatively high-priced countries as Ireland, Switzerland, Sweden, Denmark and the United States.

11 In Europe, multinational pharmaceutical companies pursue a pricing strategy known as the "pricing corridor". Under this strategy, the prices companies set for their products vary across countries with an upper and lower limit – the price ceiling and price floor. The price ceiling is a "soft upper limit" – the price beyond which there is a risk of incenting parallel imports. The price floor is a "hard lower limit" – the price no subsidiary in any country is allowed to undercut, due to the adverse effects of both parallel trade and external reference pricing.

12 Any gains manufacturers make from artificially reducing their Slovakian profits to obtain the highest maximum price possible must be weighed against the opportunity cost of inflating their Slovakian profits (through transfer pricing strategies) to take advantage of Slovakia's relatively low overall corporate tax rate of 19%.

corrects for this deficiency of the price regulation. Thus, establishing the maximum price level is not as important as it is for original products.

26. The international price referencing scheme is also used for hospital-only products, except there is no 10% mark-up allowance. The maximum ex-factory price is based on the average of ex-factory prices in the three countries with the lowest prices. After the statutory price has been agreed, the actual purchase prices are established through tenders organised by hospital management and/or insurance companies.

27. Manufacturers cannot unilaterally increase the retail prices of pharmaceuticals on the positive list. They can, however, apply to the Ministry of Health for a price increase, so long as it does not exceed the legal maximum price. If the price increase is accepted, the new price is published in the following quarter's reimbursement list. Pharmaceutical companies can submit proposals for price increases for hospital-only products once a year. The requested price increase can be justified by increasing production costs or if there is a five percent or more decrease in the exchange rates of the Slovakian currency. However, the Ministry of Health is not obliged to approve the price increase.

28. As the Slovak crone has become stronger in relation to the Euro or US dollar, the Ministry of Health implemented a mandatory 6.6% cut in the retail price of pharmaceuticals, effective April 2007. The price cut did not affect 1 185 recently launched products (from June 2006 to April 2007) for which the exchange rate had not changed significantly since their launch. Locally produced products as well were not subject to the price cut. The price cut was also extended to generic products that had seen a significant price reduction since their launch due to competition. The Slovak Generic Association (generic manufacturers) appealed against this decision, as the price level of all generic products had been reduced since launch, and therefore the rationale for the price cut does not really apply to these drugs.

29. The Slovakian government does not employ techniques such as clawbacks, mandatory rebates and price-volume agreements, which are used by some other countries to implicitly reduce price levels. Therefore, with the exception of the recent price cut to account for the strength of the Slovak crone, there are no reductions in the retail price paid for covered prescription pharmaceuticals, although agreed ex-factory prices can be implicitly lowered for in-hospital products on a case by case basis through national tenders.

Commercial margins

30. The maximum retail price is approved by the Ministry of Health. It includes the value-added tax (VAT) and the maximum wholesale and retail margins.

31. The Pharmacy Chamber – the body representing the country's pharmacies – has expressed concerns regarding the differential margin scheme (see Table 1). The chamber believes the OTC margin is too low; it cannot be justified on a cost basis, as the workload related to OTC products is similar to prescription products. Furthermore, retail margins for generic products and originals (except those designated as high price) are the same, providing disincentives for pharmacists to substitute cheaper generics for original products. Finally, pharmacies cannot compete by reducing their margins since pharmacy margin cuts are prohibited in Slovakia.

Table 1. Wholesale and retail margin in different drug categories

Categories	Maximum wholesale margin (% of ex-factory price)	Maximum retail margin (% of ex-factory price)
Reimbursed pharmaceuticals available in retail pharmacies (reimbursement category I, S, A)	11%	21 %
High price (>250€) reimbursed drugs available in retail pharmacy (reimbursement category F)	4%	10 %
Reimbursed vaccines available in retail pharmacy (reimbursement category V)	5%	7 %
OTC pharmaceuticals	5%	15 %
Hospital-only drugs (if delivery to hospital is realised via retail pharmacy)	10%	

Source: SUKL, Ministry of Health

32. Some pharmacies share their retail margin with patients through value-added services (*e.g.* point collection customer cards, home delivery) in order to attract patients and increase turnover. These activities reduce the effective retail price.

33. A flat prescription fee in addition to the retail margin increases the patient payment for reimbursed pharmaceuticals (maximum two drugs per prescription). From 2004 the flat fee was 20 Slovak crones (0.5 €); from October 2006 that has been reduced to 5 Slovak crones (0.2 €). Twenty-five per cent of the flat fee is kept in the pharmacy; 75% is paid back to the insurer.

34. The retail price of pharmaceuticals includes 10% VAT. Prior to a change on January 1, 2007, the VAT for pharmaceuticals was 19%, the standard rate for other products.

Coverage of pharmaceuticals

35. Prior to 1995, all prescription pharmaceuticals were fully reimbursed under Slovakia's social insurance scheme. The reimbursement system was reformed in 1995 and in 2004 by limiting coverage to those products selected for inclusion on a positive list. A pharmaceutical is eligible be included on the positive list, and consequently reimbursed, if there is sufficient clinical evidence of its effectiveness and capacity to save life, to cure diseases, to prevent the onset of serious health complications, to prevent deterioration of the severity of a disease or its transition to a chronic state, to serve as an active prophylaxis, or to mitigate the symptoms of disease.

36. Although there are competing health insurance companies in Slovakia (see Box 3), all insurers reimburse covered pharmaceuticals at the rate defined nationally. Insurance companies have the discretion to cover the costs of non-reimbursed pharmaceuticals (authorised drugs or other drugs in cases where there has been explicit approval from Ministry of Health for use of the drug by a specific patient). The insurance companies make decisions for exceptional coverage based mostly on socioeconomic status of the patients; these are of minor importance in terms of expenditure.

Box 3. The health insurance system in Slovakia

The Slovakian health insurance system has universal coverage through competing social and private schemes with community based premiums. There are six health insurance companies in Slovakia; two of them are public and four are private. The private companies have no public guarantee to prevent bankruptcy. The budgets of the public health insurance companies are approved by the parliament; the budgets of private companies are approved by their supervisory boards.

Health insurance premiums are based on the income of individuals, rather than age, health status or other factors. The government pays the premium from tax revenue on behalf of those residents who have no individual income (e.g. children, disabled, pensioners and the unemployed). A risk-adjustment scheme redistributes the total health care budget among health insurance companies according to the expected health care costs of patients with different age, gender etc.

Slovakian insurance companies are not allowed to spend more than 4% of their revenues on non-medical activities, e.g. on administration.

Health insurers are required to accept new applicants regardless of their individual risks. However, sophisticated cream-skimming techniques used in promotional campaigns of insurance companies might influence low-risk individuals to switch insurance. Evidence of adverse selection (which does not necessarily reflect cream skimming) lies in the disproportionate prevalence of patients with end-stage renal disease. The largest public health insurance company – VsZP – has significantly more patients on dialysis and with renal transplants than two smaller private companies, Dovera and Sideria (Sanigest, 2006a)

No supplementary or alternative coverage is available in Slovakia for individuals to purchase on a voluntary basis , although basic insurers can offer slight enhancements of the basic package as a marketing tool.

Reimbursement policies

37. The Ministry of Health is responsible for determining which pharmaceuticals are reimbursed and at what share of the retail price reimbursement will be made. In the decision-making, the Ministry is assisted by an advisory body called the Categorisation Committee (see Box 4). Decisions regarding the reimbursement level are made once the maximum retail price has been established.

38. A single application is filed for both pricing and reimbursement. Applicants must submit the basic drug information (name, manufacturer, authorisation holder, the pharmaceutical form, pack size and strength), evidence on effectiveness, the daily defined dose (standard therapeutic dose) and the number of Defined Daily Doses (DDDs)/pack.[13] The applicants also present the desired reimbursement rate, the proposed indication and any prescribing restrictions.

39. The Categorisation Committee may place a product on the negative list (no reimbursement) if it deems that the product is of no therapeutic benefit. OTC products are not reimbursed. Several types of therapeutic products are also categorically excluded from the reimbursement list, including oral contraceptives, antiobesity drugs and erectile dysfunction therapies.

40. The reasoning underlying particular reimbursement decisions is not disclosed, which is not a problem when the decision is positive. However, there is no formal process for appeal in the case of negative decisions (there were 19 such decisions in 2006).

[13] Defined Daily Dose (DDD) is a unit of measurement defined as the assumed average maintenance dose per day for a drug used on its main indication in adults.

Box 4. The Categorisation Committee

The Categorisation Committee consists of three representatives from the Ministry of Health, three from the Slovakian Medical Chamber and five representatives of health insurance funds. There is a clear logic behind the number of representatives. The largest group represents the payers; they can be the most vocal within the Committee. However when representatives of the policy makers (Ministry of Health) and the professionals (Medical Chamber) have a unanimous view that is different from the payers' opinion, they can prevail by a 6 to 5 vote. However such a situation is very rare; usually decisions are based on consensus, and are positive in 95% of the cases. Members of the Categorisation Committee have difficulties with making negative reimbursement decisions, as – according to their statements - they believe that they do not have the authority to refuse the reimbursement of a drug on the grounds that Slovakia could not afford it.

As an institution, the SUKL is not involved in the pricing and reimbursement of pharmaceuticals. However, the current Head of SUKL is also the Head of the Categorisation Committee. This dual role is a matter of chance rather than a requirement, as the Head of SUKL had public and industrial experience in pharmaceutical pricing and reimbursement.

The Categorisation Committee is assisted by 2 different boards: the medical and the economic board. The medical board is one of 22 medical expert groups organized by therapeutic areas. The economic board is under-resourced, currently including only the Head of the Categorisation Committee. The economic board is responsible for price comparison, budget impact, and direct costs calculations.

The Categorisation Committee meets four times a year at meetings that usually range in duration from three to four days. Approximately 150-200 decisions are made in each meeting, and 20-30% of the cases are related to original products. In 2006 the Categorisation Committee processed 703 pricing and reimbursement cases. Time is highly limited in the Categorisation Committee meetings, as members can devote less than 30 minutes to an average case.

The Categorisation Committee has been accused of lacking transparency. The grounds upon which this accusation is built are not clear; the transcripts of each meeting of the committee are available on the Ministry of Health's website, and furthermore, there is an audio recording of each meeting that is available from the ministry upon request.

The recommendation of the Categorisation Committee can be overruled by the Ministry of Health. According to a report by the Health Policy Institute, in 2006, during the period of government interregnum, the Ministry of Health did not take into account decisions of the Categorisation Committee, and issued decisions which presumably increased pharmaceutical spending. One hundred and fifty-nine active substance groups including 930 products were affected by the changes (Szalayová, 2006). In his response, the Head of the Categorisation Committee reaffirmed the benefits of the categorisation process. This episode indicates there is room for further refinement of the pricing and reimbursement process.

41. The Categorisation Committee considers several factors when selecting the reimbursement category, which defines the rate of reimbursement: the efficacy, the morbidity and mortality reduction, the indications and contraindications, the incidence of side effects, treatment doses for the given indication, the frequency of administration, the interaction profile, the level of patient acceptance and the relative improvement of the drug compared with current standard treatment options. Cost-effectiveness is not considered. There are six potential reimbursement categories (see Table 2).

42. For those products designated as eligible for partial reimbursement, the decision on reimbursement level is based on three main considerations: the therapeutic benefit of the drug, its retail end price, and the reimbursed prices of other products within its reference category. These three considerations relate, in turn, to three implicit criteria: effectiveness, affordability and relative value.

Table 2. Pharmaceutical reimbursement categories

Category	Reimbursement rate	Characteristic of category
I	100%	Vital pharmaceuticals listed in Annex 4 of Act 577/2004 (e.g. oncology, antibiotics, cardiovascular, respiratory, neurology) at least one in each ATC group is fully reimbursed. (1)
A	100%	Vital pharmaceuticals (e.g. oncology, antibiotics, cardiovascular, respiratory, neurology) and pharmaceuticals used in outpatient ambulances.
S	Partial	Partially reimbursed products with a fully reimbursed reference product in the same 5-digit or 4-digit ATC categories.
F	100%(2)	Very expensive (>250€) pharmaceuticals available in retail pharmacy, pharmaceuticals in specific oncology diseases with restricted use.
V	100%	Vaccines included into country vaccination program by Institute of Public Health.
N	0%	Negative listed pharmaceuticals, including OTC products, oral contraceptives, herbal medicines and pharmaceuticals with limited evidence of therapeutic benefits.

Note: (1) ATC (Anatomic Therapeutic Chemical) classification – a system created by the World Health Organization that categorises drugs according to the organ system on which they act and/or therapeutical, pharmacological and chemical characteristics. (2) There are currently six drugs in category F which are not fully reimbursed.

Source: SUKL, Ministry of Health; Mazag J, SUKL, 2007

43. According to the Act on Scope of Health Care Services (Act 577/2004), the average co-payment rate of all partially reimbursed pharmaceuticals must not exceed 20%. In practice, the average co-payment rate has always been less than the legally acceptable threshold; it is currently about 13% (Mazag, 2007).

44. The positive list usually does not specify the indications for reimbursed products, although some expensive drugs are reimbursed with restrictions, e.g. they can be prescribed by certain specialists only, or in narrower indications than specified by the summary of product characteristics (the description of the product's properties and conditions of use, such as pharmaceutical form and strength, authorised applications, adverse reactions, etc) or, in the case of certain oncology products, only in certain hospitals. Furthermore, when a reimbursed drug is authorised for a new indication, the reimbursement based upon the previous indication(s) remains valid provided there was no limitation on the previous indication. In the case of a previously restricted indication, the reimbursement level would be re-evaluated at the next meeting of the Categorisation Committee.[14]

45. Contrary to what might be expected, pharmaceutical companies clearly prefer obtaining F reimbursement category for their expensive specialist drugs rather than A. Category A means distribution in hospital pharmacies and, due to financial constraints faced by hospitals, the payment conditions are often poor and unpredictable. Consequently manufacturers advocate the inclusion of their products in category F, despite the possibility of limiting reimbursement to restricted usage.

46. The positive list of reimbursed pharmaceuticals is published in a Ministry of Health decree and on the website of the Ministry of Health every 3 months. It lists the products eligible for reimbursement together with the reimbursement category, the actual rate of reimbursement (100%, partial or 0%),

[14] Reimbursement restrictions based on indication limitations apply to the majority of products that underwent type II variation (change of indication) in oncology, respiratory and cardiovascular therapeutic areas.

restricted indications (provided the registered indication is broader than the reimbursed indication) and prescribing restrictions (i.e. when the prescription is limited to certain specialists).

47. There were 716 reimbursement applications made in 2006: 202 were for generics, 214 were for new substances or formulations, 205 applications were made under the accelerated procedure, 76 were for delisting, and 19 applications were withdrawn by the committee because the manufacturer did not comply with one of the conditions set out in the application. Table 3 provides a breakdown of the decisions made on these applications. As Table 3 demonstrates, far fewer generics are rejected for placement on the positive list than are new substances / formulations; where a reimbursement decision was taken in 2006, 99% of applications for generics were approved, against only 79% for new substances / formulations).

Table 3. Reimbursement applications submitted to the Categorisation Committee, 2006

	Generics (1)	**New substances / formulation**	**Accelerated procedure (2)**
Not reimbursed	2	32	1
Reimbursed	145	152	186
Still under review	54	30	n.a.
Total	202	214	205

	Not available on market (3)	Requested by manufacturer	Requested by the Ministry of Health
Delisting	16	2	58

Notes: Data are for applications made between 1 January 2006 and 20 December 2006. (1) Includes one application which was on hold pending a request by the Categorisation Committee for further data. (2) Includes 18 products approved for listing, but subsequently de-listed prior to publishing of the positive list because the manufacturer was not able to provide an adequate supply of the product. (3) No record of the drug being consumed in Slovakia during the past three months.

Source : SUKL

48. Out of more than 17 000 pharmaceuticals approved for marketing in Slovakia, 4 967 were at least partially reimbursed in January 2007 (Table 4). 1 694 (34.1%) products were fully reimbursed, 2 160 (43.5%) were partially reimbursed with less than 100 crones (SKK) co-payment, and 52.0% of reimbursed products were restricted to prescription by certain specialists only. The reimbursed indication was restricted for 32.4% of medicines.

Table 4. Overview of reimbursed pharmaceuticals (January 2007)

Reimbursement category	I	V	A	F(1)	S	Total
Fully reimbursed	613	30	794	257		1694
Co- payment 0-20 SKK					629	629
Co-payment 20-50 SKK					736	736
Co-payment 50-100 SKK				5	796	801
Co-payment 100-150 SKK				1	329	330
Co- payment >150 SKK				11	766	777
Grand total	613	30	794	274	3256	4967

Note: Pharmaceuticals in category F are usually 100% reimbursed. However, in the case of 17 pharmaceuticals, there was a product(s) within its reference group that was cheaper; the reimbursement amount for these 17 drugs was set at the price of the cheapest drug. SKK – Slovakian crone.

Source: Mazag J, SUKL, 2007

49. Prices and reimbursement levels are subject to recalculation in each quarter. The price changes occur at the decision of the manufacturer. Price changes for a particular drug may influence the reimbursement of other pharmaceuticals in the same 5-digit or 4-digit ATC group. However, delisting of a previously reimbursed product is very rare, occurring only when the utilisation of a drug drops to essentially no consumption over a long period, or when the marketing authorisation of the product is withdrawn.

Reimbursement of retail pharmaceuticals

50. Internal reference pricing provides the basis for determining the actual reimbursement amount paid for drugs that have comparators on the Slovak market (see Box 5). Reference pricing is generally applied to drugs with the same active ingredient (5-digit ATC). The actual reimbursement amount cannot be higher than that of the cheapest drug in the same 5-digit ATC category. For some therapeutic groups, internal reference pricing is extended to pharmaceuticals with the same molecular structure (4-digit ATC): the actual reimbursement of products with different active ingredients is linked to the cheapest alternative in that 4-digit ATC category. The price per DDD of the cheapest available drug in the ATC group is the selected reference for reimbursement. The co-payment for other drugs in the reference group with a higher price per DDD is the difference between the actual retail price and the price of the reference product after adjustment for the DDD per pack size.

51. There is a "fast-track" reimbursement option for pharmaceuticals with a proposed price that is at least 10% lower than the reimbursed reference product with the same active ingredient. This "fast track" option facilitates price erosion, as it creates a temporary advantage for generic products on the fast track. It results in frequent changes of the reference product (the product with the lowest price per DDD), allegedly having a negative influence on compliance with prescribing regimens for patients with chronic illnesses. Therefore, the Ministry of Health changed the arrangements. Since October 2006, a 3-month notice is given in advance of changes in reference products.

52. In some cases, 80-90% price erosion has been achieved by generics within 2 years after the launch of the first generic product. For example the price of the cheapest risperidone was 180 SKK per DDD in November 2003, and dropped to less than 20 SKK in October 2005.

Box 5. Reference pricing in Slovakia

Internal reference pricing is used to control reimbursement levels in Slovakia. Reference pricing is easily justifiable when included products are hardly differentiated, i.e. class effect is proven and there is no difference in efficacy, safety, interaction profile and registered indications among products. This is mostly true for generic reference pricing. In ideal cases, patients can be switched from the more expensive product to a cheaper alternative without any medical consequences and monitoring. If the clinical differentiation is more significant among the products, the introduction of reference pricing creates more concerns.

Generic reference pricing and the reselection of the reference product every three months creates strong incentives to reduce prices of generic products and gain market share by having the lowest co-payment on the market in the reference group. The fast track option for reimbursement of generics with 10% price discount efficiently facilitates this generic price erosion.

Therapeutic reference pricing influences the pricing strategy of some original products. In selected therapeutic areas patent protected pharmaceuticals are reimbursed based upon the cheapest product in their 4-digit ATC group. This creates an incentive for price reduction of original products.

Arguments against therapeutic reference pricing have been raised from the research and development perspective (Lopez-Casanovas, 2000). As it does not reward clinical differentiation, new indications or any other added value with a premium price, therapeutic reference pricing places the new drug(s) into a generic position, creating disincentives for research in given classes of drugs. Of course, the small size of the Slovakian market limits its prospective influence on global research and development incentives.

The Slovakian method of therapeutic reference pricing has another strong implication for the local pharmaceutical pricing strategy. Not only products with different active ingredients, but different doses of the same pharmaceutical may obtain a different reimbursement rate. As the reimbursement is linked to the cheapest DDD priced product within the therapeutic reference group, a linear pricing[1] strategy is assumed for drugs with different strengths, otherwise lower doses would have a higher co-payment. In many cases, however, the international pricing strategy of the manufacturer does not allow a linear pricing regime for Slovakia, and consequently flat pricing[2] or regressive pricing[3] is employed. In such cases (e.g. angiotensin II receptor blockers) the product with the highest strength has the lowest co-payment, and consequently, there is a risk that patients would take more than the clinically needed dose. Overdosing may increase the incidence of side-effects, whilst splitting tablets may reduce the efficacy of drugs. Hence, if the reference drug is selected based on the cheapest DDD priced product within the therapeutic reference group, as in Slovakia, public pharmaceutical expenditure may (perversely) be increased (Kaló 2007).

Notes

1. Linear pricing: if the price of 30x10mg is 100 SKK, the price of 30x20mg is 200 SKK.

2. Flat pricing: if the price 30x10mg is 100 SKK, the price of 30x20mg is also 100 SKK.

3. Regressive pricing: if the price of 30x10mg is 100 SKK, the price of 30x20mg is less than 200 SKK.

Impact of reimbursement policies on time to market

53. According to the European Commission's Transparency Directive, the combined decision on pricing and reimbursement level for products in retail use should be made within 180 days after the application is submitted. For hospital-only products, the pricing decision is to be released within 90 days.

54. Prior to the implementation of the Directive, Slovakia's pricing and reimbursement process was the second slowest in Europe, with a 500-day average delay.[15] At present, decisions on the reimbursement of drugs sold in retail pharmacies are mostly made within the proposed timelines by the Transparency Directive – i.e. within 180 days from the submission date of the pricing and reimbursement application.

Hospitals' purchases of pharmaceuticals

55. Pharmaceuticals that are administered during an inpatient stay are covered by social insurance and paid for indirectly within the hospital remuneration system. Hospitals are remunerated using DRG payments for acute hospital care[16] and "bed-occupancy" days / daily fees for chronic inpatient care. Some very expensive pharmaceuticals (e.g. drugs to treat hemophilia, erythropoietin and oncology therapies) are covered through a special budget.[17]

15 Based on data provided by the European Federation of Pharmaceutical Industries and Associations to the UK Pharmaceutical Industry Competitiveness Task Force for inclusion in the annual report *Pharmaceutical Industry Competitiveness Task Force: Competitiveness and Performance Indicators 2005*.

16 A cost assessment study conducted several years ago provides basis for the calculation of Diagnosis-Related Group (DRG) cost components, including the pharmaceutical costs. Maintenance of DRG codes is conducted continuously; however, updates may not reflect the actual changes in costs, including drug expenses. The pharmaceutical cost component of DRGs is calculated by assuming that mainly generic products are used.

17 There are frequent efforts to reduce the scope of this special budget by incorporating those drugs into the DRG system through the creation of special DRG codes. In rare cases the hospital management may check with the insurance company as to whether a special expensive drug therapy with no general reimbursement can be applied to an individual patient. Such decisions are at the discretion of the insurer.

56. The hospital management ensures the supply of drugs through public tenders. Although pharmaceutical manufacturers can have a wholesaler licence, they usually take part in tenders only through wholesalers.

57. The majority of hospitals have an official hospital pharmaceutical formulary that is produced by the hospital management, in order to facilitate rational use of pharmaceuticals. The majority of hospital drug formularies are renewed each year. Hospitals may receive drugs free of charge as gifts of pharmaceutical companies, a practice especially common for ones used mainly in chronic outpatient care.

58. With respect to non-licensed pharmaceuticals approved by the Ministry of Health, insurance companies decide for themselves whether or not these will be reimbursed. Such approvals and deliveries are mainly in oncology treatment and are of minor importance from the budget point of view. However, they may represent an important element of the new product launch strategy.

Cost-sharing policies

59. Slovak pharmaceutical policy seeks to induce efficient use of resources by influencing the demand of patients through cost-sharing of retail pharmaceutical payments.

60. Patients are usually charged a co-payment when their physician prescribes the non-referenced medicine; deductibles are not used.

61. Patients have clear financial incentives to request that their physicians prescribe generic drugs and that their pharmacists substitute generics when possible. However, often there is hardly any difference between the co-payment of a generic reference product and a patented alternative with a different chemical structure for the same indication. Consequently when there is an alternative original product with zero or low co-payment, the financial incentive for patients to request the cheapest generic product is not strong.

62. The ratio of co-payment to reimbursement level is fixed. That is, co-payment rates for reference products are fixed. Thus, whenever a product's price decreases, the level of the co-payment and the amount reimbursed will change to keep the ratio fixed; except in the case where a product is no longer the cheapest in its reference category – in which case the co-payment to reimbursement ratio will increase from zero.

63. There is no direct cost-sharing for hospital-only drugs since their costs are fully covered in hospitals' budgets.

Policies and other initiatives intended to influence pharmaceutical consumption

64. There are several approaches used in Slovakia to influence pharmaceutical expenditure by means other than pricing and reimbursement.

Generic substitution

65. Generic price erosion is facilitated by the internal reference pricing and the attractive fast track option, as discussed above. This has the added factor of resulting in a co-payment for original products once they have gone off patent, providing patients with a financial incentive for generic substitution.

66. There is a legal framework for generic prescribing. According to the Act 577/2004 (Act on Scope of Health Care), physicians and pharmacists are required to inform patients about co-payments and options for less expensive drugs.

67. Although medical doctors are supposed to prescribe the cheapest of equally effective therapeutic alternatives, there are no economic or legal incentives for physicians to support this obligation. Physicians are not rewarded for prescribing generic drugs, nor are they sanctioned for failing to prescribe them. Some original pharmaceutical manufacturers have reportedly provided doctors with "do not substitute" stamps. Partly due to the success of marketing by original product manufacturers, generics are often perceived to be inferior in quality to original products.

68. Pharmacists are obliged to inform patients of the availability of an alternative product with lower co-payment, provided there is an interchangeable product with the same active ingredient, and the physician has not explicitly prohibited such substitution on the prescription. In general, pharmacists respect the decisions of physicians and do not want to overrule their proposals as to the prescribed drug therapy.

69. A necessity for generic substitution at the pharmacy level is the validation by an authorised agency of the proof of interchangeability with the original product. The list of interchangeable products drawn-up by the Ministry of Health has two main drawbacks which limit the ability of pharmacists to substitute generic products. First, the list does not contain the brand names of interchangeable products; it only contains active ingredients and administration mode. Second, the Ministry of Health has not updated the list of interchangeable active ingredients since 2005. Therefore, original products whose patents have expired since 2005 are not interchangeable in pharmacies. The 2005 list includes 198 active ingredients, but excludes several important ones, (e.g. alendronate).

70. As generic substitution is not legally mandated and not substantiated by listing interchangeable brands, financial incentives are crucial in implementing a successful generic programme. However there are no financial incentives for pharmacists to undertake generic substitution. On the contrary, the retail margin decreases when the pharmacist substitutes a cheaper alternative to the prescribed medicine. As substitution to a more expensive alternative product is not prohibited by law or subject to financial disincentives, pharmacists are theoretically even better-off substituting to a higher-priced product by referring to the "non-availability" of the prescribed cheap product. There is an ongoing discussion to transform the retail margin system to incentivise generic substitution by a regressive or flat retail margin, or a combined margin based on fixed cost and regressive margin.

Insurance companies' initiatives

71. Insurance companies have tried various initiatives to influence drug use. They have tried to create legally binding, individual drug budgets for the physicians they have contracted with, but physicians have generally resisted these attempts. Instead, insurance companies have created legally non-binding soft pharmaceutical budget targets for physicians. Physicians are provided with regular information about their prescribing patterns (e.g. deviation from the average).

72. The success of these soft budgets is mixed at best. Outliers have no financial incentives, as negative incentives are prohibited by law, and savings in drug budgets of general practitioners are extremely rare. Some insurers hire physicians – normally general practitioners – to analyse prescription patterns, but they garner little respect from specialist physicians in practice and are largely ignored. Some years ago insurers tried to terminate their contracts with those physicians who had a pattern of over-prescribing, with no success.

73. The feedback on prescribing patterns influences the behaviour of certain physicians. The consequences, however, are not straightforward. Some physicians reportedly prescribe cheaper products to keep within the expected budget, while others continue to prescribe higher-priced originals to a minority of patients and curtail prescribing for the rest of their patients.

74. Specialists' follow-up prescriptions – the initial prescription is written by a specialist with renewals written by a general practitioner (GP) – are not automatically counted in the budget target of GPs. There is a 6-month exemption period, so that the 30-day prescription can be repeated six times without financial considerations on the part of the doctor. This leaves some room for pharmaceutical companies to generate primary care prescriptions by influencing therapeutic decisions of specialists and hospital physicians.

75. The soft drug targets may result in other poor incentives, e.g. as vaccinations and other drugs are not separated in the drug target, a high vaccination rate may prevent a physician from keeping within the drug budget target, despite his or her being highly cost-effective in prescribing.

76. Each provider (e.g. a GP or a specialty care unit) has as many different drug budget targets as the number of contracts with health insurance companies. Therefore the attention on a single drug budget is not focused, reducing the importance of individual pharmaceutical budget targets.

Competition among health insurance companies

77. In theory, competition among payers can contribute to efficient use of pharmaceuticals. In practice, the health insurance companies have limited scope to influence pharmaceutical expenditure.

78. Unlike Switzerland, no deviation is allowed from the premium regimes. Therefore, health insurance companies cannot offer a discounted premium to those who are willing to take more risks through increased cost-sharing arrangements, or who are willing to limit their choices in managed care. Furthermore, insurers cannot offer supplementary health care services for extra premium.

79. The health insurance companies are obliged to offer the same comprehensive benefits package. Payers must cover the pharmaceuticals on the positive list published by the Ministry of Health, regardless of whether they agree with the reimbursement decision. They cannot reduce accessibility to reimbursed drugs. Although selective contracting is theoretically possible, the plans are required to contract with all primary care physicians and all pharmacies, as well as a minimum number of specialists and hospitals within each region of the country.

80. The payers, however, can furnish benefits that exceed those specified in the published reimbursement list. Consequently they differentiate themselves by offering relatively inexpensive extra services, and marketing these services in their promotional campaigns. This is almost the only tool for insurance companies to differentiate themselves from each other and to use in marketing appeals describing the benefits of switching to another health insurance company.

81. Health insurance companies have implicit initiatives to increase their economic competitiveness via cream-skimming. One of the health insurance companies offers compensation for non-reimbursed vitamins (up to 500 SKK) or free influenza vaccination. These are efficient tools to attract through self-selection health-oriented people. Another company offers additional coverage for delisted oral contraceptives, targeting relatively healthy young women who seek to avoid pregnancy. These incentives marginally increase pharmaceutical expenditure.

82. Slovakian residents can change their insurance company only once a year. In 2006, 500 000 people, approximately 10% of the total population, changed their health insurance company.

83. The current government has plans to reduce the scope of competition by mandating the selection of public insurance companies for people living on public subsidies/income (e.g. pensioners, children, unemployed etc.). This would reduce the market share of private insurers to 15-20% from the current 32%.

84. The administrative costs of the insurance companies cannot exceed 4% of their total revenues. The relatively low level of administration can be managed only if companies restrict their investments in sophisticated analyses of their spending. Therefore – besides many other areas – the companies have limited information on the value for money of reimbursed health care technologies, including pharmaceuticals.

85. The health insurance companies seem to have little control over doctors' prescribing behaviour because the insurers do not believe they can be competitive in a situation where they selectively contract. Beyond this, their incentives to seek changes in behaviour that result in cost savings are limited in that any such behavioural changes would likely benefit their competitors as much as themselves.

Other initiatives

86. In addition to generic manufacturers, the Ministry of Health and the SUKL also contribute to the promotion of generic prescription by distributing leaflets and other promotional materials.

87. Computer-based prescribing software is used to improve the allocative efficiency of pharmaceutical spending by supporting effective prescribing behaviour of physicians. The software indicates which are the clinically desirable and economically preferable products for certain diseases and conditions. These software products are based on the reference product list controlled by the Ministry of Health; however, they are marketed by private companies. Although the software is used by more and more physicians, its utilisation is not mandated or incentivised; consequently many physicians have not adopted it for use.

88. Therapeutic guidelines can improve the efficiency of prescribing. The Medical Chamber and National Institutes have developed several guidelines, mainly by adapting international (e.g. American College of Physicians) therapeutic guidelines. The guidelines are not mandatory in outpatient care; physicians are neither incentivised nor monitored to follow them. The Slovakian guidelines take into consideration the most recent clinical innovations, but mostly ignore the economic constraints of Slovakia; therefore they cannot be used for cost containment of pharmaceuticals. The health insurance companies expect the Ministry of Health to prepare mandatory prescription guidelines.

PHARMACEUTICAL MARKET CHARACTERISTICS

89. This section reviews various components of the pharmaceutical market in Slovakia, including expenditure trends and components of spending, pharmaceutical production, supply and trade.

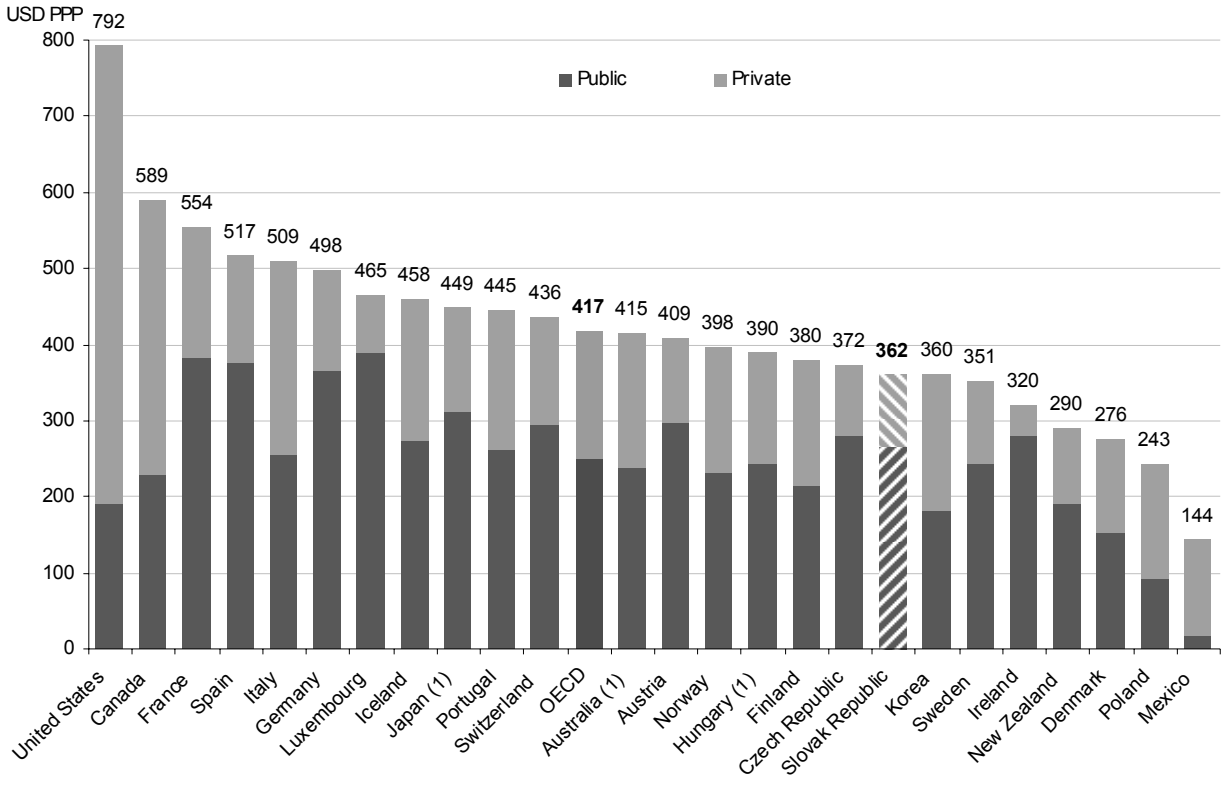
Expenditures

90. Slovakia spent 7.1% of its GDP on health care in 2005, significantly less than the 8.9% OECD average, but comparable to countries with similar income levels.

Drug spending levels and time trends

91. In 2005, Slovakia ranked in the lowest-spending third of OECD countries in expenditure per capita on pharmaceuticals, although its expenditure was only about 10% below the OECD average (Figure 1). The private proportion of pharmaceutical spending was 26.5% in Slovakia, the fourth lowest share in the OECD after the Czech Republic, Ireland and Luxembourg.

Figure 1. Drug expenditure per capita, public and private spending, 2005



Note: (1) 2004 (Japan and Hungary) and 2004/05 fiscal year (Australia). Expenditures are expressed in US dollars PPP (purchasing power parity), the rate of currency conversion that eliminates differences in price levels between countries.
Source: OECD Health Data 2007, October 07

92. Sales of pharmaceuticals in Slovakia were approximately 31 billion SKK, net of VAT, in 2005 (Table 5). About 90% of spending was for products sold at retail pharmacies, with the remainder representing hospital sales.

Table 5. Slovakian pharmaceutical market sales, 2000 – 2005

Pharmaceutical sales (million current SKK)	2000	2001	2002	2003	2004	2005
Sales at ex-factory price level[1]	9 661	12 426	14 841	15 837	16 318	17 739
Sales at wholesale price level[1]	10 724	13 792	16 474	17 579	18 113	19 691
Sales at pharmacy retail price level	15 176	19 518	23 313	24 877	25 633	27 865
Sales at hospitals	n/a	2 319	2 466	2 313	3 011	3 233
Total sales (pharmacy and hospital)	n/a	21 837	25 779	27 190	28 644	31 098
Sales of generics	7 477	8 478	9 280	9 746	9 566	10 381

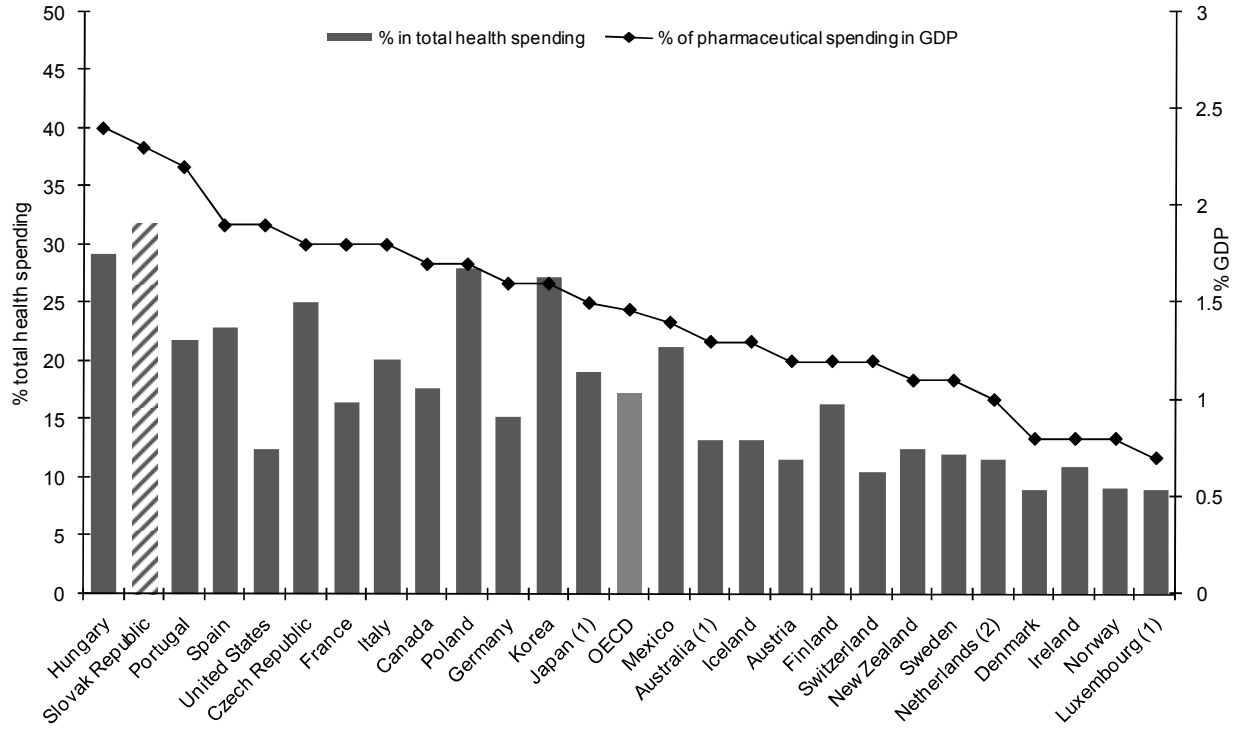
1 Does not include VAT (19% in 2006)

Source: SUKL, Pharmadata

93. Slovakia spent 2.3% of its GDP on pharmaceuticals in 2005, compared to the 1.5% OECD average (Figure 2). The 2.3% is among the highest proportion spent by OECD countries, along with Portugal (2.2%) and Hungary (2.4%).

94. The share of total health expenditure devoted to drugs (32%) in Slovakia is the highest among the OECD countries (Figure 2). In general, lower-income OECD countries tend to have higher than average shares of pharmaceutical spending in total health expenditure (Huber and Orosz, 2003). Similar trends could be perceived geographically, as Hungary, the Czech Republic and Poland also have higher than average pharmaceutical expenditure shares, both in terms of the percentage of GDP and of total health care spending.

Figure 2. Share of pharmaceutical expenditure in total health spending and in GDP, 2005



Note: (1) 2004 (Japan and Hungary) and 2004/05 fiscal year (Australia); (2) 2002

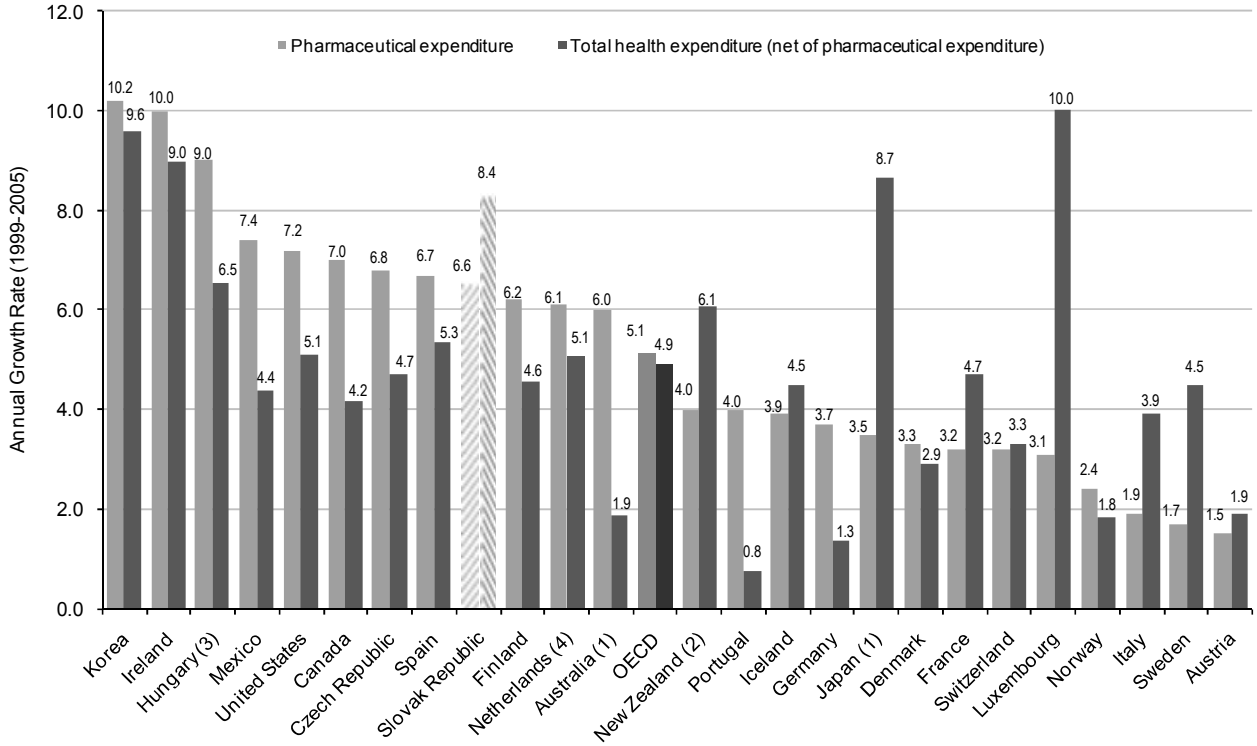
Source: OECD Health Data October 2007

95. The high share of pharmaceutical expenditure in Slovakia can reflect several factors. First, the relatively low salary of health care professionals and consequently low share of hospital expenditure may partly explain the low proportion of non-pharmaceutical health care spending. Second, the price differential of pharmaceuticals (especially the recently launched originals) is likely to be less than the labour cost differentials, as compared with the OECD average.

96. Unlike most OECD countries, Slovakian drug expenditures have been increasing less rapidly than other major components of health expenditure (Figure 3). Between 1999 and 2005, pharmaceutical expenditure grew by 6.6% annually, less than the 8.4% annual growth rate for total health expenditure (net of pharmaceuticals), but greater than the OECD average annual growth rate for pharmaceutical expenditure (5.1%).

97. Slovakian analysts attribute the growth in drug expenditure to factors such as the ageing population, better access to information on diseases, and early detection of diseases. However, these factors are not unique to Slovakia.

Figure 3. Real annual growth in pharmaceutical spending and total health expenditure (net of pharmaceutical expenditure), 1999-2005



Note: (1) 1999-2004 (Japan) and fiscal year 1999/00-2004/05 (Australia); (2) 1997-2005; (3) 1997-2004; (4) 1997-2002. Growth rates are calculated using spending in national currency units at 2000 GDP price levels

Source: OECD Health Data October 2007

Price levels

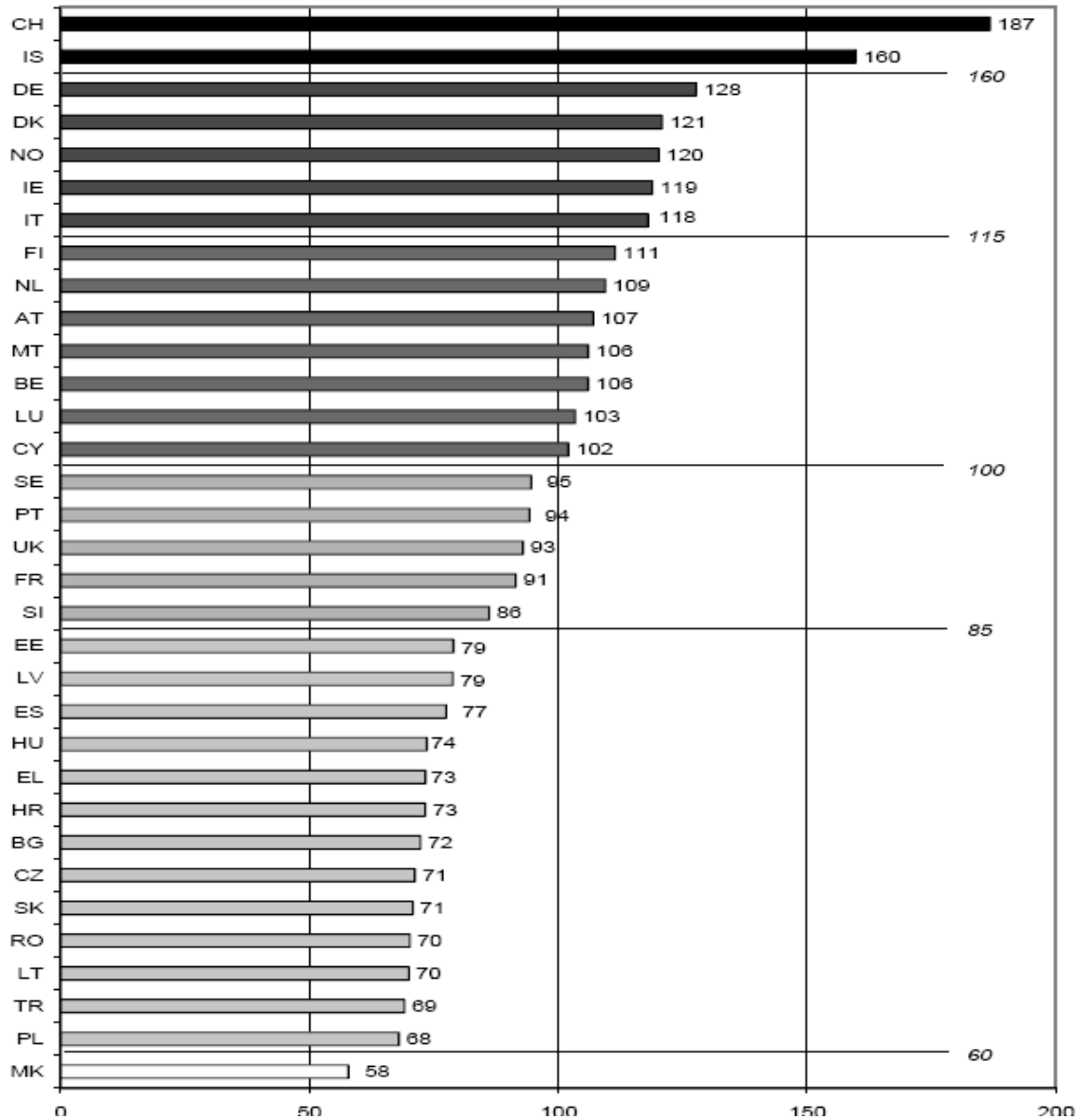
98. A recent Eurostat analysis of European pharmaceutical price indices calculated that the Slovakian retail price level of drugs was comparable to a group of thirteen countries with price levels falling between 68% and 80% of the European average in 2005 (see Figure 4). Results, however, should be treated with care due to the significant methodological challenges in making cross-country comparisons of prices in this sector.[18] Furthermore, comparisons at the level of retail prices are complicated by cross-country differences in wholesale and retail margins, and in the level of VAT included in the price.

99. It is possible that Slovakian price levels have increased relative to European comparators since 2005, when Slovakia joined the European Union. Within the EU, income related price differentiation (i.e.,

[18] Member states were asked to report price data for a subset of 181 best-selling pharmaceutical products, reporting on products that represent the basket of products purchased in the country. Products were listed by their international non-proprietary names. About 75% of the products had no generic alternative.

Ramsey pricing)[19] has become less and less feasible for manufactures due to international price referencing and parallel trade.

Figure 4. Price level indices for pharmaceutical products, 2005 (EU25=100)



Source: Konijn (2007).

100. As further insight into price levels, we compared the ex-factory price of the ten top-selling products on the Slovakian market with prices for the product in some other countries (Table 6). Products were selected based upon July-September 2006 sales. Slovakian prices were calculated by deducting VAT and commercial margins from the retail price (valid between January – March 2007). Results showed that products were sold in Slovakia at prices exceeding those of Hungary in most cases. Slovak prices exceeded

[19] Ramsey pricing is a specific form of price discrimination which maximises social welfare, subject to a targeted profit level for the producer. The producer sets a unique price in each segmented market in inverse relation to its price elasticity of demand.

those of France for four products and Sweden for two products. Confidential rebates used in France may result in lower effective prices for some products.

Table 6. International ex-factory price comparison of the ten top-selling pharmaceutical products in Slovakia, 2007 (prices in SKK)

Country				Slovakia[1]	France[2]	Sweden[3]	Hungary[4]
Currency				SKK	EUR	SEK	HUF
Exchange rate (1 SKK = ?)				1	0.02969	0.27448	7.36108
ATC code	**Active ingredient**	**Brand name**	**Formulation and dosage**				
B03XA01	Erythropoietin	Neorecormon 30000 IU	sol inj 4x0,6 ml/30000 IU	42628	36697	40434	40740
R03AK06	fluticasone/ salmeterol	Seretide Diskus 50/500	plv inh 60x50/500	2077	1762	2301	1625
C09AA04	Perindopril	Prestarium 4 mg	tbl 30x4 mg	221			169
N05AH03	Olanzapine	Zyprexa 10 mg	tbl flm 28x10 mg	3813	3203	4318	3468
C01EB15	Trimetazidine	Preductal MR	tbl mod 60x35 mg	250			293
M05BA07	Risedronic acid	Actonel 35 mg	tbl flm 4x35 mg	1038	828	1020	957
C09AA10	Trandolapril	Gopten 2mg (BLIST.)	cps 28x2 mg	195	455	412	196
L01XE01	Imatinib	Glivec 400mg	tbl flm 30x400mg	99567	78269	83100	80326
R03AK07	Budesonide/ formoterol	Symbicort Turbuhaler 200/6 ug	plv inh 1x120	1829	1457	1883	
N06AB10	Escitalopram	Cipralex 10 mg	tbl flm 28x10 mg	727		788	557

Note: tbl – tablet; flm – film; mod – modified release; plv inh – dry-powder inhaler ; cps – capsule; sol inj – solution for injection; mg – milligram; IU – international unit

Source: 1 Official report, Ministry of Health of the Slovak Republic, Special edition, 30 December 2006, No. 54; 2 http://www.codage.ext.cnamts.fr/codif/bdm_it/index_presentation.php?p_site=AMELI 3 www.lfn.se 4 www.oep.hu

Volume of pharmaceutical consumption

101. The DDD adjusted volume of Slovakian drug utilisation is generally high (see Table 7). Among selected main therapeutic areas, only utilisation of nervous system drugs was lower than the OECD average in 2005.

Table 7. Daily pharmaceutical consumption in selected therapeutic areas in DDD per 1000 inhabitants (2005)*

	Alimentary tract & metabolism	Cardio-vascular system	Nervous system	Musculoskeletal system	Respiratory system	Anti-infectives
Slovak Republic	246.3	428.7	148.4	143.5	155.3	29.5
Average**	177.8	425.2	168.6	74.7	104.4	24.4

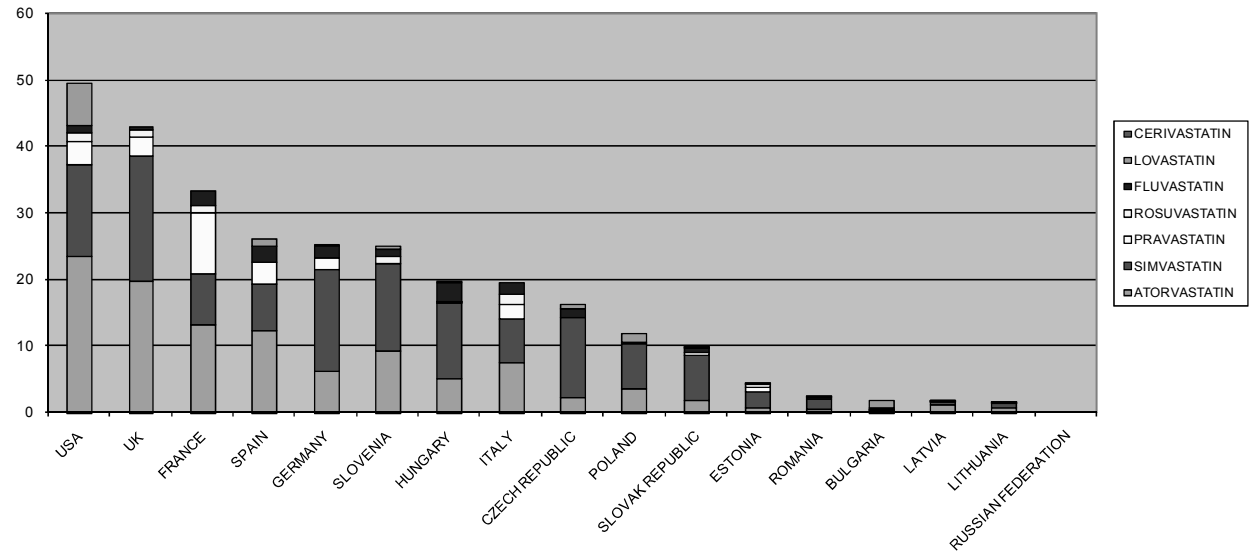
* Data for Greece pertains to consumption in 2004.

**Average of the following OECD countries: Australia, Belgium, Czech Republic, Denmark, Finland, Germany, Greece, Iceland, Luxemburg, Norway, Portugal, Slovak Republic, Sweden

Source: OECD Health Data July 2007

102. While the broad picture shows high drug consumption, in some subcategories the consumption is relatively very low, suggesting that consumption may be less than what is medically needed, as in the case of statins, medicines used to lower cholesterol (Figure 5).

Figure 5. Consumption of statins (ATC C10A1), defined daily doses (DDD) per capita, per year, 2005



Source: Wieser C (2007), How can generic drugs contribute? GENAS, presentation 29 March 2007.

103. The low co-payment level and relatively poor health status may partly explain high drug utilisation in Slovakia. In addition, the practice of setting a price per DDD in the reimbursement scheme not only influences the pricing strategy of pharmaceutical companies, but also likely influences the utilisation patterns. Higher doses of the same substance became cheaper for the patients after the introduction of the reference pricing system.

Drug utilisation patterns

104. There has been a divergence between the volume and value in generic drug utilisation between 2000 and 2005 (Table 8). The market volume share of generics (measured by the number of prescriptions) has been steady, representing between 60-65% of total prescriptions. By contrast, the value market share of generics sales has declined from a 49% share of total pharmaceutical sales in 2000 to 37% in 2005. Generic penetration may be stronger in Slovakia than in most European countries, but the generic share of the market in other Eastern European countries – most notably Poland, Hungary and Lithuania – is still stronger than in Slovakia.[20]

Table 8. Development of the generic market in the out-patient sector, 2000 – 2005

Generic market share in %	2000	2001	2002	2003	2004	2005
Volume (number of prescriptions)	65	63	60	63	65	65
Value	49	43	40	39	37	37

Source: SUKL, Pharmadata

[20] Based on data from the European Generics Association (http://www.egagenerics.com/doc/fac-GxMktEur_2004.pdf – accessed 5 October 2007).

105. Although data were not available by which to assess patient price sensitivity, Slovakian experts described geographical variation in price (or more correctly co-payment) sensitivity of patients. Around Bratislava individuals are less sensitive to the magnitude of co-payments, whilst in the rural areas patients are more price sensitive. In an interview with representatives of the Slovak Generic Association, they advocated establishing co-payments for all pharmaceuticals, eliminating 100% reimbursement for certain prescription drugs.

Financing pharmaceuticals

106. Seventy-four per cent of pharmaceutical expenditure was financed by social insurance contributions and general tax revenue in 2005. Out of the 26% of expenditures that were privately financed (against an OECD average of 40%),[21] approximately half represents spending on OTC drugs and half is the co-payment for partially reimbursed pharmaceuticals. Voluntary health insurance does not contribute to pharmaceutical spending in Slovakia.

107. The share of OTC drugs in total sales declined from nearly 20% in 1996 to only 9% in 2002 (Biehunek 2003). The rate of self-medication shows a decreasing trend. This partly explains why private pharmaceutical spending is low in Slovakia compared to other OECD countries.

108. According to the interviewed representatives of pharmaceutical companies, the psychological barrier for patients is 100-150 SKK co-payments. Beyond that co-payment threshold, products cannot be successful in the Slovakian market.

Pharmaceutical industry presence and activities

Pharmaceutical Production

109. Since the political transition of Slovakia, the pharmaceutical production and distribution sector has gone through a privatisation process. The presence of the pharmaceutical industry is not strong in Slovakia, and has been declining since the mid 90s. In the late 1980s local production counted for 80% of the domestic pharmaceutical market, whereas in 2002 it only counted for 18% (Mazag J, 2007).

110. Sales of pharmaceutical producers in Slovakia represented 1.45% of industrial sales in 1997; by 2001 this share had fallen to 0.9% (Biehunek, 2003). Over 40 pharmaceutical companies had Slovakian production facilities in 2007, producing mainly generic drugs (Mazag, 2007).

111. Output of the pharmaceutical industry in Slovakia comes from three key companies: Zentiva,[22] Biotika and Hoechst-Biotika. These three firms accounted for fifty percent of domestic sales in 2001 (Biehunek, 2003). In addition to these three companies, the rest of the industry consists of small local companies whose influence on the development of the sector is negligible. These companies produce mainly OTC drugs and nutritional preparations. There are 40 – 50 subsidiaries of international pharmaceutical companies with no production sites, only sales, marketing, medical and administrative units (Mazag, 2007).

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21 The share of privately financed total health expenditure in Slovakia (26%) is similar to the OECD average of 27%.

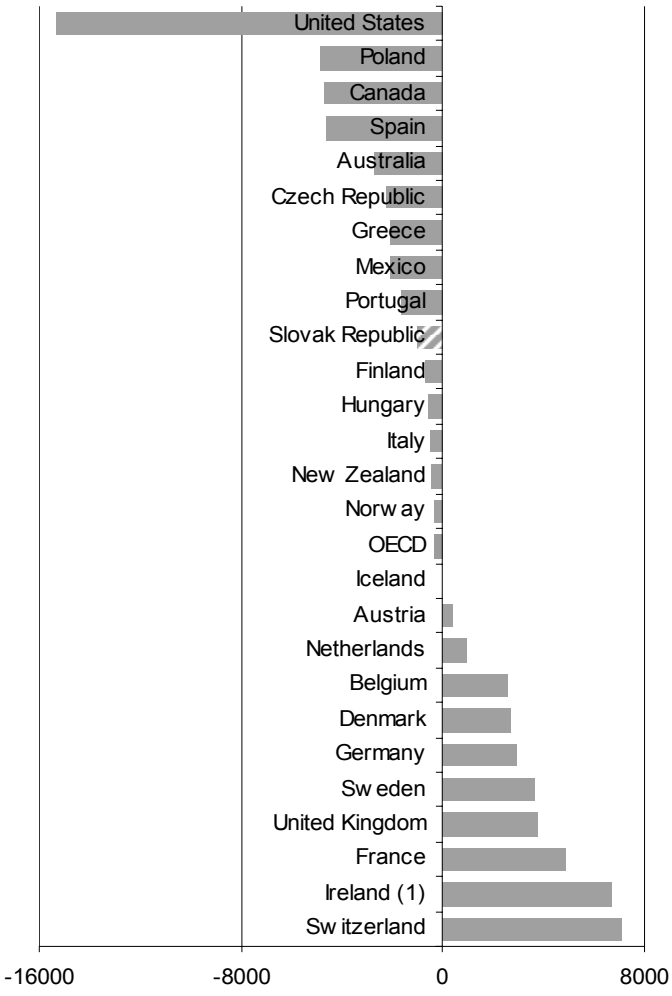
22 Zentiva was created through the merger of the Slovakian firm Slovakofarma and the Czech firm Léčiva. It produces generic drugs especially for cardiovascular and gastro-intestinal diseases and analgesics.

Pharmaceutical Trade

112. From the trade balance point of view, the pharmaceutical industry had never been among the strongest performing sectors in Slovakia. Within COMECON (the economic organisation of the former communist countries) other industrial sectoral duties were allocated to the former Czechoslovakia.

113. As the current pharmaceutical production is low in Slovakia, the trade balance is negative (See Figure 6). The Czech Republic is the most important trading partner for Slovakian pharmaceutical exports. Slovakofarma exported 57% of its Slovakian production to the Czech Republic in 2001 (Biehunek, 2003).

Figure 6. Pharmaceutical industry trade balance in OECD countries, million USD PPP, 2003



Source: Note: (1) 2002. Expressed in US dollars PPP (purchasing power parity), the rate of currency conversion that eliminates differences in price levels between countries.

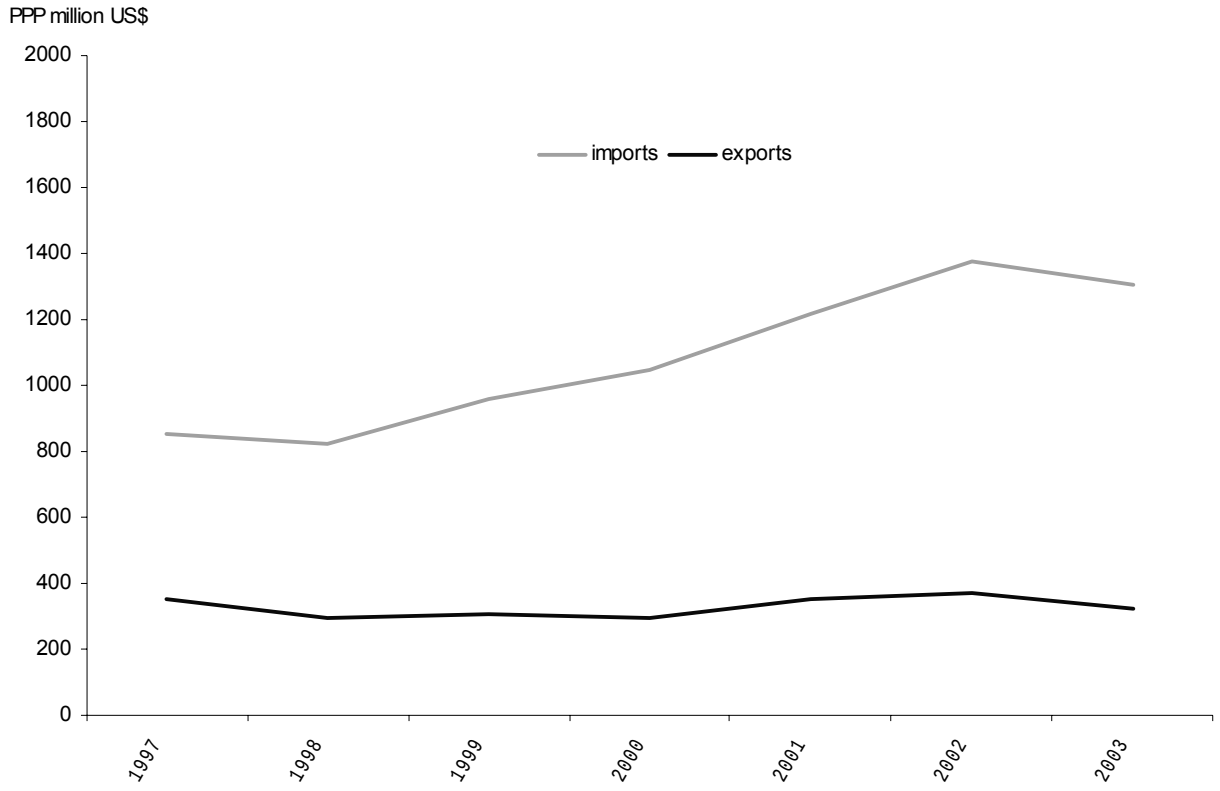
Source: OECD Health Data October 2007

114. Pharmaceutical production is steady; therefore, with increasing pharmaceutical expenditure, imports been growing (Figure 7). The imported drugs are mostly originals from Western Europe (Germany, France and Switzerland) and generics from the neighbouring countries of Central and Eastern Europe. The increasing gap between the Slovakian drug export and import increases the deficit of the

pharmaceutical trade balance. Imported drugs represented approximately 3% of total Slovakian imports in all sectors.

115. In an effort to prevent the re-importation into the EU-15 countries of patented pharmaceuticals that were not subject to patent protection in the accession countries at the time of their launch, the European Commission has instituted a derogation on parallel exports from accession countries to the EU-15 countries. The derogation applies for products that were patent-protected in the EU-15 and available in Slovakia (and other accession countries) prior to establishment of patent protection (1991 in Slovakia).[23] Parallel trade exports to increase wholesalers' profits do not occur in Slovakia. Because the Slovakian market is small, wholesalers cannot accumulate significant stocks for parallel trade. Manufacturers can easily measure (and control) differences between their ex-factory and wholesaler sales. Wholesalers export pharmaceuticals only when, due to reimbursement changes (e.g. the reference product changes), the demand for drugs with significant stocks decreases; however, this type of parallel export has been reported to be non-significant by both wholesalers and manufacturers.

Figure 7. Trends in pharmaceutical imports and exports in Slovakia



Note: Expressed in US dollars PPP (purchasing power parity), the rate of currency conversion that eliminates differences in price levels between countries.

Source: OECD Health Data October 2007

[23] Any distributor that intends to import a product to which the derogation applies into an EU-15 country from an accession country must notify the patent holder at least 30 days in advance. This provision allows the patent holder to take legal action if the terms of the derogation are infringed before the imported product hits the market.

Pharmaceutical Innovation

116. Total Slovak research and development (R&D) expenditure is less than 1% of the GDP and shows a decreasing trend. Pharmaceutical R&D is also far below the average of OECD countries. Slovakian pharmaceutical companies spend only 4% of their total revenues on research and development (see Table 9). Only Slovakofarma operates a notable drug research institute (VULM).

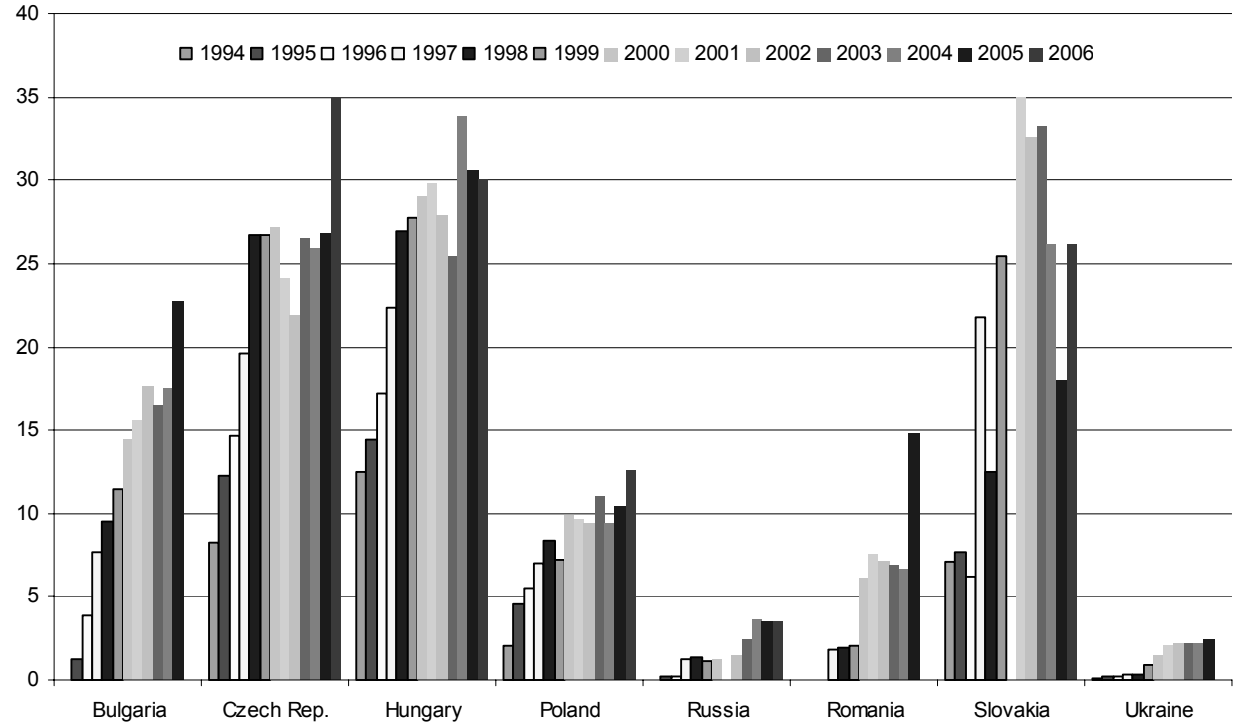
Table 9. Expenditures of domestic pharmaceutical producers on research and development

Pharmaceutical R&D expenditure	1997	1998	1999	2000	2001
SKK million	214	268	268	315	368
% of sales	3.1%	4.0%	3.6%	4.1%	4.2%

Source: AFV SR — Association of pharmaceutical producers SR

117. As opposed to basic and pre-clinical research, there is significant clinical trial activity in Slovakia (Figure 8). There are several reasons why pharmaceutical companies place their clinical trials in Slovakia. The academic training of specialists is solid, as is their commitment to participate in clinical trials, partly due to the relatively low salary of physicians. It should be noted, however, that the local value added by clinical trials is significantly less than by basic or pre-clinical research and development.

Figure 8. Number of approved clinical trials per million inhabitants, Eastern Europe



Source: Kanka and Antal (2007); J. Antal, personal communication, Clinical Trials Managers' Society, Hungary (data for 2006).

118. Clinical trials are also premarketing tools. Having patients on an investigational medical product after clinical trial completion may have an impact on reimbursement decisions by creating a patient and physician constituency for the product.

119. The strong clinical trial activity and local clinical experience prior to marketing authorisation contributes to the fast market penetration of newly reimbursed innovative medicines in Slovakia.

Efforts by manufacturers to influence physicians' prescribing behaviour

120. Pharmaceutical manufacturers use a range of strategies to influence physicians' prescribing behaviour in Slovakia, ranging from the deployment of sales representatives to physicians' offices (a practice known as detailing) to inform them about products, to sponsorship of continuing medical education activities relating to treatment of conditions and use of pharmaceutical products. Manufacturers also advertise products to physicians through print and other media.

121. Sales representatives of pharmaceutical companies are allowed to promote licensed products to health care providers. The information they provide must be in line with the approved summary of product information and patient leaflet. The SUKL is authorised to control such activities and promotional material.

122. The declared purpose of having sales representatives is to provide recent scientific information on manufacturers' products to prescribing physicians. The sales representatives of research-based pharmaceutical companies are relatively successful in influencing prescribing behaviour towards more expensive patented products. As pharmaceutical policy allows branded generics, generic manufacturers also promote their products by extensive sales forces. . They may serve to increase physician awareness of generic alternatives to products, and seek to alleviate any negative perceptions of quality. This, in turn, likely results in increased generic prescribing, although by adding to costs of generic manufacturers it may increase the generic price floor.

123. Distribution of free samples by each sales representative is limited to 3 boxes/units of pharmaceuticals per physician per year. Records of the samples distributed are required.

124. Therapeutic decisions of hospital physicians (e.g. in oncology and cardiology) can induce prescriptions in the outpatient sector, especially since therapies initiated by specialists are not counted for 6 months in the drug budget target of GPs. Therefore manufacturers often donate their drugs to hospitals in order to facilitate sales in the outpatient sector or primary care.

125. Pharmaceutical manufacturers can also donate drugs whose expiration dates are expiring or new products during their launch campaign. As free drugs reduce the pharmaceutical spending of hospitals, donation is also not discouraged by hospital managers.

126. The association of pharmaceutical manufacturers' has developed an ethical code, a self-regulating guidance on pharmaceutical promotional activities.

127. There is no restriction or control on promotional expenditure of pharmaceutical companies.

Efforts by manufacturers to influence pharmacists' dispensing behaviour

128. In Slovakia manufacturers are not allowed to give further reductions to bulk purchase prices and to give natural rebates or discounts to wholesalers or pharmacies.

129. Sales representatives visit pharmacists to promote OTC products.

Direct-to-consumer advertising

130. Direct-to-consumer advertising is allowed only for non-prescription products in Slovakia. Public advertising is, however, prohibited for OTC products with the same brand name of their prescription counterpart, or if the OTC product is reimbursable for any groups of patients.

Supply/distribution of pharmaceuticals

131. The number of authorised pharmaceuticals increased from 22 685 (or 13 411 excluding homeopathic drugs) in 2002 to 29 385 (or 19 693 excl. homeopathics) in 2006 (Mazag, 2007). Almost all non-patented and patented pharmaceuticals are available in Slovakia. Marketed pharmaceuticals are sold in retail and hospital pharmacies, and wholesalers distribute products between manufacturers and pharmacies.

132. The timing of product launches on the Slovak market may well be influenced by the use of international price benchmarking. In general, pharmaceutical companies launch their products in those EU countries where they are able to obtain relatively high price levels (Germany, etc), or in those countries where early launch will prevent a lower-priced country from being a reference point. Submitting a pricing and reimbursement application in Slovakia early enough to avoid obtaining the final price in the nine reference countries may result in a higher price in Slovakia, as international prices are not re-considered or reviewed after the initial price referencing.

Wholesalers

133. Before 1997 only one company (MEDIKA) provided pharmaceutical wholesaler services in the Slovakian market. After liberalisation of the wholesaler sector, 260 companies had been granted a wholesaler licence; this had been reduced to 236 by 2005. Eleven private wholesalers dominate the market with a 95% market share.

134. Some pharmaceutical manufacturers have a wholesaler licence, but direct distribution of their drugs is not the common practice.

135. Wholesalers can provide pharmacy deliveries several times a day. Some offer the option of fast delivery (within an hour) in urgent cases.

136. Changes in the prescription patterns due to the quarterly revision of the positive list and reference products impose financial risks on wholesalers. If wholesalers have stocks of the previous reference products with limited expected sales after changes in the co-payments, manufacturers do not compensate wholesalers for the expected loss. They usually inform wholesalers about the expected reimbursement changes, however. In addition the wholesalers can trade their stocks abroad. This has been almost the only type of parallel export in Slovakia.

137. In addition, some companies manage to keep low stock levels by harmonising the Czech and Slovakian stocks. Several stakeholders confirmed that parallel trade which arbitrages between ex-factory price differentials in other European countries virtually does not exist in Slovakia.

Pharmacies

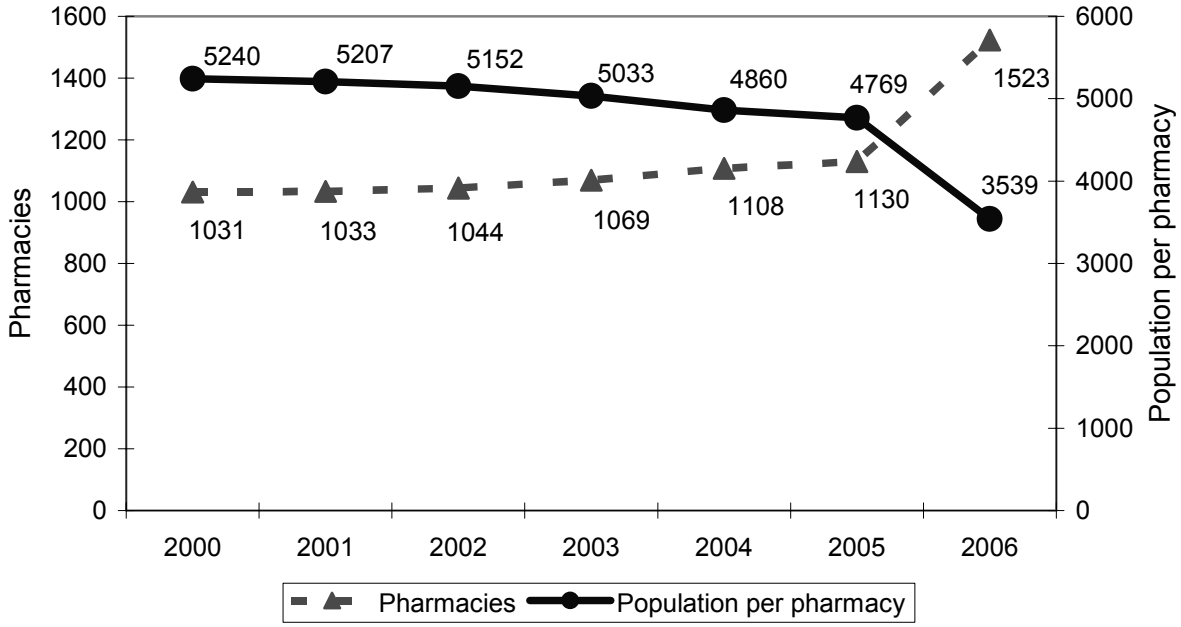
138. Pharmaceuticals in Slovakia are sold through pharmacies and branch pharmacies. Internet pharmacies are not allowed. Physicians are also not allowed to dispense pharmaceuticals. Every pharmacy can operate a branch pharmacy in those villages where there are no other pharmacies and there is no need to operate the pharmacy in full working hours with emergency services or to provide individual preparation of medicines.

139. Pharmacies have been privatised since 1993. Privatisation resulted in an increase in the number of retail pharmacies (from 500 in 1993 to 1044 in 2002).

140. Hospital pharmacies are operated directly by the hospitals and form an integral part of the hospitals, so ownership depends on the status of the hospital.

141. Until 2005 local pharmacies had monopolistic positions. No pharmacies could be opened in the neighbourhood of an existing pharmacy, and only pharmacists could own pharmacies. In 2005 the regulation for pharmacy operation was liberalized; ownership of pharmacies was no longer limited to pharmacists, and distance and minimum population per pharmacy limits were abolished. As a consequence the number of pharmacies increased from 1 130 in 2005 to 1 523 in 2006, resulting in a decrease in the population per pharmacy (Figure 9). The increased number of pharmacies and the strong competition has improved the accessibility and the service level from the patients' point of view; however, it has also reduced the earnings of pharmacies. If a pharmacy goes bankrupt, the wholesalers to whom it is indebted may well take it over.

Figure 9. Number of retail pharmacies and inhabitants per pharmacy, Slovakia, 2000-2006



Source: Mazag J, SUKL, 2007

142. The number of hospital pharmacies (serving in-patients only) was reduced from 81 in 2004 to 74 in 2006 due to mergers or closing of hospital pharmacies.

143. Community pharmacies represent 91% of sales in units and 90% in value (see Table 10).

144. Since 2005 SUKL is responsible for the approval required for pharmacy operation.

Table 10. Pharmacy sales in Slovakia (2005)

Sales	Community pharmacies	Hospital pharmacies	Total
Number of units (% of total)	136 074 915 (91%)	14 027 842 (9%)	150 102 757
Value in billion SKK (% of total)	27 865 (90%)	3 233 (10%)	31 099

Source: Mazag J, SUKL, 2007

145. Remuneration of pharmacists is provided through mark-ups on all products and prescription fee payments. The mark-up is linear and provides no incentive to pharmacies to reduce the pharmaceutical expenditure by improving the efficiency of pharmaceutical provision (including generic substitution or offering lower-priced OTC products with equal efficacy).

146. Manufacturers and wholesalers are prohibited by law from offering rebates or discounts to their purchasers. Pharmacies usually select one wholesaler, as financial discounts and favourable delivery time is subject to a minimum order.

147. Changes in the prescription patterns due to reimbursement changes (see above) impose financial risks also on pharmacies. As the quarterly list of new reimbursement levels is issued only shortly before the list comes into force, the pharmacy stock levels are usually reduced around those dates.

ACHIEVEMENT OF POLICY GOALS

148. This section describes the degree to which certain policy goals relating to pharmaceuticals are being achieved in Slovakia and attempts to assess the impact of Slovakia's pharmaceutical pricing policies on the attainment of these goals.

Containment of drug expenditures

149. Slovakia's spending on pharmaceuticals has grown at an annual rate that is 30% higher than the OECD average in recent years. Nevertheless, Slovakia appears to have been more successful in containing pharmaceutical costs than it has for all other healthcare.

150. Although per capita pharmaceutical expenditure is not high in Slovakia relative to other OECD countries, Slovakia's pharmaceutical expenditure is very high as a share of national income and as a share of total health expenditure. It also represents a significant burden on the public purse in that three-quarters of the Slovakian pharmaceutical expenditure is publicly financed.

151. Several factors explain the importance of pharmaceutical expenditure in Slovakia. First, pharmaceutical utilisation (expressed in DDDs) in some important (and costly) therapeutic areas is higher than the OECD average. Second, pharmaceutical co-payment levels are relatively low, resulting in low price sensitivity of patients and relatively greater levels of moral-hazard induced demand. Third, although prices were subject to a one-time cut to account for improvements in the strength of Slovak currency, Slovakia does not use tools such as mandatory rebates to obtain lower effective prices. Finally, drugs are not excluded from coverage on affordability grounds.

152. Lastly, the lack of means to influence the prescribing behaviour of physicians and control the inappropriate use of medicines also play a role. The deficiencies of the generic programme include the absence of generic substitution incentives for pharmacists.

153. There is certainly some further potential for constraining manufacturers' prices for innovative products, as the price is considered only prior to the reimbursement being granted. The basis of the price comparison is the data submitted by the manufacturer based upon the currently available European prices. The Ministry of Health has no capacity to validate the information. If the Slovakian pricing and reimbursement application is submitted before the ex-factory price is agreed in other EU countries with low pharmaceutical prices, pharmaceuticals in Slovakia are liable to be reimbursed at a price higher than the European average price level.

154. Policies to control pharmaceutical consumption by health insurance companies appear to have limited effect at present. Insurance companies perform analyses of drug consumption per diagnosis, per doctor and dose of the prescribed medicines. These analyses could be used to monitor the prescription habits of specified doctors and to set prescription limits by benchmarking prescription outliers to the average of doctors. Information on their own prescription budget and pattern is available to all physicians; however, insurance companies have no mandate to employ sanctions against physicians with inefficient prescribing practices.

Sustainability and equity of financing for pharmaceuticals

155. Slovakia's failure to contain pharmaceutical expenditure growth has encouraged policy makers to take steps to shift the burden of financing expenditures in order to maintain the sustainability of the system. Nevertheless, generous health insurance coverage has ensured a fairly equitable system of financing for pharmaceuticals. The prescription fee and co-payment rates are low and there is a fully reimbursed drug in each ATC group. As physicians have no direct incentives to consider the patient fee, co-payments can be burdensome for some patient groups in Slovakia. There are no exemptions for the poor or those with chronic or high-cost illnesses and no caps on out-of-pocket spending. This can place a significant burden on the poorest households; a study on equity in health care financing in Slovakia showed that the share of net income of the poorest twenty per cent of households – in terms of discretionary income – devoted to health care was at least three times greater than that of the other eighty per cent of households (Sanigest, 2006b).[24] Whilst the Slovakian pharmaceutical reimbursement system ensures the availability of inexpensive drugs in all therapeutic areas, inequity exists due to the lack of enforcement of efficient prescribing.

Efficiency of expenditures

156. Evidence suggests that Slovakia's pharmaceutical expenditures do not result in the most cost-effective outcomes. At present, the main effort to obtain value for money in drug spending comes at the level of reimbursement decisions by the Ministry of Health and the Categorisation Committee or purchasing decisions by tenders of hospital drugs. However, the use of economic analysis in these decisions is not considered. As the fourth hurdle (cost-effectiveness criteria) is not mandated, several potentially not cost-effective pharmaceuticals have been reimbursed in Slovakia. It is especially true if we consider that strategic pricing of the innovative products are not based on small markets with low purchasing power (like Slovakia). The price level of new drugs is adjusted to wealthier countries with greater willingness to pay for a quality adjusted life year gain. Therefore, even if a drug is cost-effective in Germany or in the United Kingdom, it still may not be cost-effective in Slovakia.

157. As health insurance companies are not allowed to spend more than 4% of their revenues on administration, they have limited capacity to analyse the efficiency of their expenditures. In addition, hardly any deviation is allowed from the mandated benefit package. It is difficult to obtain health insurance records for independent research purposes. Quality indicators of health care providers are not being considered. In general, the efficiency of the utilisation of scarce health resources is not thoroughly monitored.

158. The Slovakian generic drug pricing policy has been quite successful. Due to the reference pricing and the fast track reimbursement option, the generic price erosion has been strong since 2004. Despite the lack of strong financial incentives, physicians continue to prescribe more generics than original brand-name pharmaceuticals. Compared to some of its Eastern European neighbours, Slovakia could still do better. However, the lack of incentives for pharmacists and patients somewhat limits the success of the generic programme.

159. The relatively rapid generic price erosion may create negative incentives for the utilisation of generics. Changing the reference product every 3 months and the consequent switch in therapy that may entail stands to decrease patient compliance.

[24] Pharmaceuticals accounted for approximately two-thirds of out-of-pocket expenditures on health care for all households.

Availability of pharmaceuticals

160. A number of factors suggest that most pharmaceuticals that are available in the developed countries of the world are also available in Slovakia on a fairly prompt basis. Approval times are according to the standards of EMEA, delay can be expected only with national registration procedures. The efforts of the SUKL to reduce the backlog in applications have been acknowledged by its commercial stakeholders.

161. Until the implementation of the Transparency Directive, the length of time from market authorisation until reimbursement was among the longest in Europe. The timelines according to the Transparency Directive have been kept recently.

162. As parallel trade and a lower-than-average pharmaceutical ex-factory price level do not threaten the European profits of multinational companies, the majority of drugs registered at EMEA are launched in Slovakia. The exceptions are certain patent-protected pharmaceuticals which would be likely to be included in therapeutic reference pricing groups with an expected co-payment over 150 SKK.

Accessibility of pharmaceuticals

163. For the majority of patients pharmaceuticals are accessible and affordable in Slovakia. This is facilitated by low cost-sharing for pharmaceuticals and by the policy requiring that there is a product with full reimbursement in each major ATC category.

164. Innovative products are reimbursed without respect to their cost. Products without major competitors (i.e., products in new therapeutic classes) have no or insignificant co-payments. New "me-too drugs" are included in reference groups and are reimbursed, although often with significant co-payment.

165. Oncologists confirmed that they can provide the most recent and most expensive therapies to their patients. Oncology centres have more problems with the availability of low-cost medical items (disposables, chronic drug therapies of hospitalized patients, etc) than they do with the accessibility of expensive new drugs.

166. Existing reimbursement restrictions (e.g. expensive oncology products can be prescribed only in selected hospitals) could reduce accessibility somewhat, as physicians with no prescription license for the special therapy may not want to lose their patients by referring them elsewhere.

167. The competition among pharmacies for patients is strong, and the number of pharmacies has been increasing since the liberalisation of the pharmacy market. Consequently, there have been improvements in patients' access to pharmacy services.

Quality of care, health outcomes

168. There is very little evidence by which to assess the quality of care and health outcomes relating to use of pharmaceuticals in Slovakia, much less to make the link between findings and policies. No information is available on errors resulting from the misuse of pharmaceuticals, including medication errors in hospitals, physicians' prescribing errors, errors in prescription medications dispensing, and patient errors in using medicines appropriately.

169. Quality indicators have not been assessed on a regular basis in Slovakia; health insurance records are generally not accessible for research purposes. Some analyses suggest that there is room for improvement in the quality of health care services. Pharmaceuticals are often administered inappropriately; a survey some years ago showed 36% resistance to antibiotics due to abuse of macrolides (Mazag, 2003).

Public satisfaction with pharmaceutical policies and outcomes

170. Since 2004, the accessibility of innovative products has been improved. The number of fully reimbursed pharmaceuticals has been increased by 4.2% and the consumption of pharmaceuticals has been increased by 8.4%, whilst patients spend 9.5% less on co-payments for partially reimbursed pharmaceuticals. Increased public satisfaction towards pharmaceutical policy may be expected; however, no public survey is available to substantiate this hypothesis. After the 2006 election, the new government introduced the popular measure of decreasing reduction in the prescription fee of 75%.

171. Besides the general public, almost all involved players are generally satisfied with the pharmaceutical policies and outcomes; however, several of them have some concerns. The insurance companies would like to increase their ability to influence reimbursement decisions, as they would like to reduce their drug expenditures. Pharmacists are unhappy about the liberalisation of pharmacy operations, and they complain about the low margins for OTC drugs. The generic manufacturers would like to increase the practice of generic substitution, but too rapid price erosion causes problems and uncertainty in their business. Innovative pharmaceutical companies dislike the therapeutic reference pricing.

Industrial policy goals

172. The Slovakian flat tax rate reform (i.e. 19% tax rate in all categories including personal income tax and corporate tax) was quite successful in boosting the Slovakian economy; the competitiveness of the country has improved. Several multinational companies have invested in Slovakia.

173. This positive trend, however, has not changed the position of pharmaceutical investors. There is no sign of increasing investment in building new production or research and development sites. The favourable tax rate is just one factor; the lack of a specific pharmaceutical industrial strategy of the government, the low availability of skilled human resources, and the concerns about enforcement of intellectual property protection may also contribute to the steady state of pharmaceutical industrial presence in Slovakia. The pharmaceutical trade balance is increasingly negative; with growing imports, the export level has been constant since 1997.

174. In clinical research, however, Slovakia could successfully attract additional clinical trials. This could increase the revenues of clinical research organisations and investigators, and alleviate pressures on the pharmaceutical budget of hospitals by delivering investigational medical products free of charge.

175. The research-based pharmaceutical companies have been successful in advancing policies to support their marketing objectives in Slovakia. The change in the maximum retail price from being based on ex-factory prices (thus more comparability with other countries) to retail (where margins distort cross-country comparisons) using the regressive mark-up scheme has reduced potential risks of differential pharmaceutical pricing in Slovakia on the European market. It is also favourable for the industry that the external reference pricing is still based on a number of high-priced countries with no further assessment once the launch price has been established. Finally research-based manufacturers were successful in enforcing the requirement that patent linkage should be a condition for registration of generic drugs, which potentially complicates the entry of generics to the Slovakian market compared to other EU countries.

KEY FINDINGS AND CONCLUSIONS

176. This paper has made a comprehensive review and assessment of Slovakia's pharmaceutical pricing and reimbursement policies and the market and policy environment in which those policies operate. The findings point to a number of successful accomplishments, as well as outstanding challenges. Among the key findings are these:

- There appears to be scope for reducing expenditure on drugs and getting better value for money in drug expenditures. Pharmaceutical expenditures in Slovakia are almost 32% of total expenditure on health and drugs represent 2.3% of GDP.

- EU regulations have very likely been responsible for diminishing the practice of differentiating prices of innovative pharmaceuticals between EU countries, with inflationary results in Slovakia. International price referencing of many European countries and the EU free trade policy reduce the willingness of multinational companies to decrease the prices of their drugs in Slovakia compared to the EU price levels. Of course, this raises the question as to whether European price levels are themselves at an appropriate level, an issue beyond the scope of this case study, but an important consideration in the larger policy project to which this case study will contribute.

- In Slovakia as elsewhere, changes in the mix of medicines that are prescribed and consumed favouring new and higher-priced products over old ones are contributing to expenditure growth. Pricing and reimbursement policy has played an important role in the high penetration rate of innovative products in the domestic market.

- The international price referencing system would benefit from revision; the selection of countries is not clearly justified and conclusions of the initial price assessment are not reconsidered following the initial assessment.

- The effective power of the Categorisation Committee is limited in that the Committee is not empowered to reject reimbursement applications on the grounds that Slovakia cannot afford a product with a high price. Economic evaluations are not included into reimbursement decisions; therefore, the local value for money is not taken into account.

- Slovakia does not use mandatory rebates or clawbacks to achieve lower prices.

- Generic price erosion has increased since the enforcement of referencing pricing and the fast reimbursement track for products with at least a 10% discount price. However, stronger generic penetration in other Eastern European countries indicates greater savings from generic drug utilisation are possible. The lack of incentives to implement generic substitution limits what could be achieved.

- Therapeutic reference pricing of patented products is based upon cost per DDD, which increases the dosing of non-linearly priced pharmaceuticals, and consequently pharmaceutical spending.

- Differentiated reimbursement rates are not sufficient incentives to induce efficient prescribing. The level of reimbursement is mainly driven by price differentials within each internal reference group.

- Drug utilisation analyses are conducted. However, in the absence of therapeutic protocols developed by insurance companies or others, the focus of these analyses is on the average cost per patient, a weak standard for comparison.

- Evidence suggests that availability of medicines on the Slovakian market is both comprehensive and prompt.

- The Slovakian coverage scheme promotes access to medicines. The low co-payment rate of reimbursed products results in easy access to highly priced patented products. There is always at least one treatment available in a therapeutic class with no co-payment. However, there are no exemptions from co-payments for any patient groups. Consequently low-income or chronically ill patients may have inadequate protection against the risk of catastrophic spending on drugs.

177. These findings regarding Slovakian pricing and reimbursement policies have been drawn on the basis of an assessment of the direct impact of the policies in Slovakia. However, an important consideration of ongoing work in the area of pharmaceutical pricing policy is the so-called global and cross-national impact of policies. Impacts of interest include the hypothetical effect of pricing and reimbursement policies in one country on prices and availability of medicines elsewhere, and the impact of pricing and reimbursement policies on investment in pharmaceutical R&D and the resulting impact on pharmaceutical innovation. These issues have been alluded to in this report without being thoroughly assessed. This case study of Slovakia will provide input into OECD work to assess the hypothetical global and cross-national impact of different pricing and reimbursement schemes and policies.

LIST OF ACRONYMS

ATC – Anatomic Therapeutic Chemical Classification
CMS – Concerned Member States
COMECON – Council for Mutual Economic Assistance
CP – Centralized Procedure (for marketing authorisation)
CPMP – Committee for Proprietary Medical Products (a committee of the European Medicines Agency)
DDD – Daily Defined Dose
DP – Decentralized Procedure (for marketing authorisation)
DRG – Diagnosis-Related Group (payment scheme for acute inpatient care)
EEA – European Economic Area
EC – European Commission
EPC – European Patent Convention Treaty
EPO – European Patent Office
EMEA - European Medicines Evaluation Agency
EU – European Union
GDP – Gross Domestic Product
GENAS – Slovak Generic Association
GP – General Practitioner
IPR – Intellectual Property Rights
MRP – Mutual Recognition Procedure (for marketing authorisation)
OTC – Over-the-counter (non-prescription) drugs
PPP – Purchasing Power Parity
RMS – Reference Member State
R&D – Research and Development
SKK – Slovakian crone (national currency)
SPC – Supplementary Protection Certificate
SUKL – State Institute for Drug Control (Štátny ústav pre Kontrolu Liečiv)
VAT – Value-Added Tax
WHO – World Health Organization

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