CANDOLE PARTNERS

ONCOLOGY IN SLOVAKIA

STAKEHOLDER LANDSCAPE REPORT

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1. INTRODUCTION

The purpose of this study is to provide a comprehensive analysis of the Slovak oncology landscape and to deepen understanding of the trends and developments in Slovak healthcare relevant for [the client].

The analysis is based on data gathered in two ways. Analysis of key decision-makers' public statements, public discourse and official documents and information were complemented with the second dataset, which was obtained by conducting one-on-one interviews with senior politicians, heads of state regulatory bodies, top Slovak oncologists, representatives of the industry, think-tanks as well as patient groups and expert organizations.

The first part of the study outlines relevant key policy challenges in healthcare and analyzes the most important issues in the Slovak oncology policy. The second part maps stakeholders, their leaders, reputation and influence in the oncology field. The following section of the report looks at the industry and benchmarks [the client]' competitors. Finally the concluding part of the report sets out risks [the client] is facing, identifies the most important points of engagement and proposes specific activities to be followed to fulfill the defined objectives.

Table 1: List of abbreviations	
ADL (Asociacia dodavatelov liekov)	Association of Drug Suppliers
ALS (Asociacia lekarnikov Slovenska)	Association of Slovak Pharmacists
AOPP (Asociacia na ochranu prav pacienta)	Patient Rights Advocacy Association
ED	Europa Donna
GENAS (Asociacia generickych vyrobcov)	Association of Generic Producers
HPI	Health Policy Institute
HZDS (Hnutie za demokraticke Slovensko)	Movement for Democratic Slovakia
KDH (Krestanskodemokraticke hnutie)	Christian Democratic Movement
LPR (Liga proti rakovine)	League Against Cancer
MAC (MEPs Against Cancer)	European Parliament’s initiative against cancer
MoH	Ministry of Healthcare
NOP (Narodni onkologicky program)	National Oncology Program
NOR (Narodni onkologicky register)	National Cancer Registry
NPOP (Nadacia na pomoc onkologickym pacientom)	Foundation for Supporting Oncology Patients
SAFS (Slovenska asociacia farmaceutickeho priemyslu orientovaneho na vyskum a vyvoj)	Slovak Association of Research Based Pharmaceutical Companies
SDKU (Slovenska demokraticka a krestanska unia)	Slovak Democratic and Christian Union
SKL (Slovenska komora lekarnikov)	Slovak Chamber of Pharmacists
SLK (Slovenska lekarska komora)	Slovak Chamber of Doctors
SLS (Slovenska lekarska spolocnost)	Slovak Doctors Society
SMK (Strana madarskej koalicie)	Hungarian Coalition Party
SMS (Slovenska myelomova spolocnost)	Slovak Myelom Society
SNS (Slovenska narodna strana)	Slovak National Party
SOS (Slovenska onkologicka spolecnost)	Slovak Oncology Society
SSFE (Slovenska spolocnost pre farmakoekonomiku)	Slovak Society for Pharmacoeconomy
SUKL (Statny ustav pre kontrolu lieciv)	State Institute for Drug Control
UDZS (Urad pre dohlad nad zdravotnou starostlivostou)	Healthcare Surveillance Authority
ZPL (Združenie na pomoc pacientom s leukémiou a lymfómom)	Association for Supporting Leukaemia and Lymphoma Patients
ZZP (Zdruzenie zdravotnych poistovni)	Association of Health Insurance Companies

2. EXECUTIVE SUMMARY

Key takeaways: Policy

- Underfunding, insufficient prevention, lack of transparency and prevalence of illegitimate payments are among the most serious problems in Slovak oncology. Healthcare policy and decision making is characterized by incompetence, populism and lack of coherent healthcare strategy.
- [the client] is facing an unfavorable regulatory environment and lacks resources to address threats appropriately; the most important regulatory changes being in pricing and reimbursement and generic substitution. Consistent contact-building and engagement strategy with key policy makers and government officials would make government's measures more predictable, enable [the client] to influence and shape the legislation in preparation and facilitate strategic business planning.
- Cancer prevention and cancer care lacks political support and there are no positive driving forces in oncology policy formation. As a result, a national cancer framework has not yet been adopted or initiated. It is therefore important for [the client] to constructively work with oncology stakeholders and move cancer up the policy agenda.

Key takeaways: Stakeholders

- The chief expert group in oncology - Slovak Oncology Society – is weak, but has potential to lead policy formation. [The client] should become a stable and long-term partner of SOS and foster debate on the National Oncology Program and cancer prevention campaigns within the organization.
- Patient groups suffer from fragmentation, low assertiveness and low respect from authorities. [The client] can assist in their empowerment by organizing education seminars for patient group leaders, involving Slovak cancer groups in EU-wide cancer patient campaigns and facilitating dialogue between patient organizations, doctors and interest groups.

Key takeaways: Industry and competitors

- [Company A] and [Company B] are the most visible and active pharmaceutical companies in the field of oncology. [The client's] competition is also known for back-door dealings with oncology stakeholders and benefits from weak enforcement of SAFS' ethical code.
- [The client's] good reputation is not translated into visibility, but a well-structured PA engagement would help increasing [the client] position among stakeholders.
- Legislative-based ethical code presents an opportunity to increase costs of non-compliance for competitors and to implement [the client's] best practices into legislation.
- [The client's] role within SAFS is rather limited. Since the organization is likely to play an important role in defending the industry against any potential populist attacks from the government, [the client] should consider a more active involvement within the organization.

3. POLICY

3.1. General healthcare policy

3.1.1. Background

Article 40 of the Slovak Constitution states: "Everyone has a right to the protection of his health. Based on public insurance, citizens have the right to free healthcare and to medical supplies under conditions defined by law." Besides the general public notion of free nature of services in healthcare, the Slovak healthcare system continues to display numerous signs of an unreformed system with socialist heritage, namely dominant position of state healthcare providers, prevalence of informal payments in the system and low efficiency of healthcare spending.

Slovakia spends 7.1% of its GDP on healthcare, which is less than the average of OECD countries (8.9%), but close to one third of the healthcare expenditure is spent on pharmaceuticals, which is almost twice the OECD average.[1] At the same time, mean life expectancy in Slovakia has been lower than EU-15 average – 69.9 for males and 77.8 for females compared to EU average of 74.8 and 81.1 respectively.[2] According to a study conducted by the Stockholm Network, 73% of Slovaks believe that other European healthcare systems perform better than the Slovak one, which is the third highest number of the countries surveyed.[3]

Constant efforts to introduce healthcare reforms have characterized the work of all eight Ministers of Healthcare since 1993, from which only two Ministers served the entire 4-year election term. Arguably the most profound reform of the Slovak healthcare system was undertaken by Minister Rudolf Zajac in 2003.

3.1.2. Outline of the 2003 healthcare system reform

Implementation of a healthcare reform package was part of far reaching economic reforms launched by the second Dzurinda government in 2003. The reform was a result of financial problems arising from continuous growth of deficits, increasing debts and prolonging waiting periods and aimed primarily at stabilizing public healthcare expenditures by increasing the role of private sector in health services. One of the explicit reasons for the adoption of the reform was also the changing structure of diseases (from communicable to non-communicable: e.g. 52.5% of deaths caused by cardiovascular diseases and 22.8% by oncological diseases), which the old system was not efficient in fighting.[4]

The reform was based on the following measures:

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1 OECD 2004

2 Eurostat 2002

3 Only Hungarians and Poles felt more inferior about their healthcare systems than Slovaks. The country survey included Britain, Czech Republic, France, Germany, Hungary, Italy, Netherlands, Poland, Slovakia, Spain and Sweden. See "Poles Apart? East European Attitudes to Healthcare Reform," Stockholm Network 2005.

4 See Peter Pazitny, Rudolf Zajac, Anton Marcincin, "Reform Models: Health Reform in Slovakia," Health Policy Institute 2005

1. introduction of co-payments by patients,
2. creation of voluntary health insurance,
3. establishment of state-owned health insurance companies as joint-stock companies,
4. hospital restructuring based on decentralization, taking over hospitals' debts and changing the status of some hospitals from self-managed government institutions to non-profit institutions.

In addition, important stabilizing measures of the reform were changes in drug and reimbursement policy. Besides the introduction of user fees for drug prescriptions, the reform included:

- introduction of a fixed ratio of co-payment by patients to the total price of a drug,
- changes in the categorization of drugs, mainly:[5]
- personal changes in the Categorization Committee (favoring economists over doctors),
- changes in the process of setting maximal prices,
- changes in margins for wholesalers and pharmacies for "very expensive" drugs,
- increasing frequency of categorization and reimbursement process to 4 times a year (based on the Transparency Directive 89/105/EEC),
- introduction of the so-called "fast-track" regime in drug price reductions,
- grouping drugs on the basis of active substances into 122 ATC (anatomical-therapeutical classes) groups,
- supporting the use of generic substitution by lowering the protection period from 10 to 6 years.

The aim of the reforms of drug and reimbursement policy was to limit excessive consumption of drugs and hence rationalize and stabilize drug spending. The Ministry's objective was to increase access to drugs needed for treatment of serious and chronic illnesses and increase co-payment of patients for more common and less expensive drugs. According to the president of SAFS, Zajac's Ministry tried to mitigate the influence of the pharmaceutical industry as much as possible. Even though the Ministry had a clear strategy of drug spending rationalization, "the top officials were not willing to listen to comments from pharma companies."[6] Members of Minister Zajac's former advisory team have stated that 'distancing' from pharmaceutical companies was an inevitable part of a long-term conception to make drug spending more efficient.[7]

Despite the fact that the healthcare reform increased stability and efficiency of public healthcare spending, according to a study conducted by the International Monetary Fund "the reform measures were not sufficiently strong to resolve the financial problems of the health sector."[8]

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[5] Ibid.

[6] Interview with the president of Slovak Association of Pharmaceutical Companies (SAFS), 8 November 2007

[7] Interview with representatives of Health Policy Institute, 26 October 2007

[8] Marijn Verhoeven, Victoria Gunnarsson, Sergio Lugaresi, "The Health Sector in the Slovak Republic: Efficiency and Reform," IMF Working Paper, 2007

3.1.3. 2006 reversal of the reform

The new social-democratic government led by Robert Fico has been a vocal opponent of the reforms introduced by the previous Minister of Healthcare Rudolf Zajac and labelled the reforms as being "anti-social" and "going against the people," since almost three quarters of the population disagreed with the introduction of the reform package.[9] In the government manifesto, the cabinet pledged to address what it perceived to be the most negative consequences of the Zajac's reforms and reversed several key aspects of the reforms. Since the recently introduced Czech healthcare reforms were inspired by and partly modelled after Zajac's reforms in Slovakia, the Czech and Slovak healthcare systems are now characterized by diverging trends.

The most important alterations of the system under the Fico government include immediate changes to reverse the reform and two completely new measures.

Immediate reversal changes

1. abolishment of co-payments for doctor visits and hospital stays and lowering co-payments for drugs;
2. limiting administrative expenditures of health insurance companies to 4 percent (later to 3.5 percent);
3. reduction of the value added tax rate for medicines and medical instruments from 19 percent to 10 percent;
4. flat 6.6% price decrease on all medicines

All these measures have been heavily criticized by the opposition parties for their populist character and for lacking a long-term coherent strategy. According to the Chairman of the Parliamentary Committee for Healthcare, reduction of VAT was a non-systemic and populist measure, which did not have any effect on patients (the prices of drugs have not decreased in the long-term) and decreased budgetary income.[10] According to former Minister's advisors, the lowering of VAT and the flat price reduction were only superficial changes aiming at short-term stabilization of drug spending growth, which will continue to rise in the following years.

Introduction of a minimal hospital network

The minimal hospital network will contain only state-owned hospitals (government regulation on the minimal hospital network adopted in October 2007). The measure was strongly opposed by private hospitals, since health insurance companies will now not be required to conclude contracts with private hospitals, thereby increasing their financial risks. One of the hospitals, whose omission from the list was viewed most negatively, was St. Elizabeth's Oncology Institute in Bratislava. The Institute provides one third of all oncology diagnoses and treatment in the country and 70% of all its medical services are provided to patients outside the Bratislava region. The government, however, argued that the Ministry can only guarantee healthcare in state-owned institutions.

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9 Ibid.

10 Interview with Chairman of Parliamentary's Committee for Healthcare, 15 November 2007

Ban on profit of health insurance companies

Ban on profit (amended Act. No 581/2004 on health insurance companies passed in October 2007) presents arguably the most controversial piece of legislation pushed forward by the Slovak government in the field of healthcare. The most vocal proponent of such ban was the leading governmental party SMER, which claimed that foreign investors should not be able to profit from mandatory health insurance paid by the citizens (see section 4.1.1.). The two other governmental parties, HZDS and SNS, were opposed to such strict limitation on profits, but ultimately succumbed to SMER's pressure since, as the head of SNS Jan Slota put it, "the coalition was more important than our convictions."[11] The Prime Minister Robert Fico has repeatedly stated that the goal of the government is to eventually eliminate private health insurance companies and to have only one state-owned insurance company. The opposition parties as well as health insurance companies called the adopted piece of legislation 'communist' and 'threatening private property rights."

3.1.4. Drug pricing and reimbursement

Categorization

The new government has not altered the composition of the Categorization Committee,[12] but the frequency of Committee's sessions has been changed from four meetings a year to two 'large' meetings annually (re-evaluation of reimbursements + classification of new medicines and generic drugs) and two 'small' meetings (only classification of new drugs) so as to increase stability and predictability of the system, which pharmaceutical companies perceived positively (amended Act No 577/2004). The Ministry of Healthcare (MH) has set up three new working groups, which have an advisory role in categorization of drugs (Working group for medicines policy, Working group for economy and pricing of medicines and Working group for pharmacoeconomy and clinical outputs – so-called 23rd working group). The working groups provide the Categorization Committee with their (non-binding) analyses and the Committee then decides by majority voting. Subjects of the categorization process can appeal decisions of the Committee to the Categorization Council, which consists of vice-chairmen of the working groups (and in case of oncology drugs includes Ministry's Chief Expert for Oncology).

Nevertheless, despite the formally stipulated criteria for decision-making (Act No. 577/2004), the system of categorization is still criticized for the lack of transparency and predictability, which hinders effective long-term planning on the side of pharmaceutical companies. According to the head of the Association of Pharmaceutical Companies, the non-transparent decision-making in the Committee is the result of incompetence of its members.[13] On the other hand, several oncologists we have interviewed see pressures of pharmaceutical companies and back-door dealings with the members of the Committee as the main reason for the unpredictability of the decision-making.

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11 HZDS proposed an amendment, which would allow for health insurance companies' profit, but the profit would have to be spent within the healthcare sector. The amendment was rejected.

12 The Categorization Committee consists of 11 members: 3 representatives from the Ministry of Healthcare, 5 from health insurance companies and 3 from expert associations.

13 Interview with the president of Slovak Association of Pharmaceutical Companies (SAFS), 8 November 2007

In addition to the changes mentioned the Ministry plans in the medium term to establish an institute of conciliation procedure for MH and insurance companies on one side and pharmaceutical producers on the other side in order to facilitate communication between the stakeholders and improve the process of categorization. The conciliation procedure would take place before the price-fixing procedure within the Categorization Committee.

Degressive margin

The Ministry plans to introduce degressive margin as of 1 January 2008 with the aim to reduce prices of expensive medicines and save budgetary resources (expected savings amount to SKK 400 mil. in the first year and SKK 700-800 mil. the following years). The measure will mostly affect drug distributors and pharmacies, since their margin will decrease with the increase in price of medicines. As our interview with the Head of Dept. of Medicines Policy at MH revealed, degressive margin should help prevent favouring expensive drugs for speculative reasons.[14] Distributors oppose the introduction of degressive margin since higher margin was claimed to help overcome insolvency of hospitals in paying for drugs. According to the Head of Association of Drug Distributors, “supplying medicines to hospitals will cease to be economically viable.”

Price reference

The current system of price referencing with nine countries in the reference basket and only applying to newly classified medicines is deemed insufficient by the current Ministry of Healthcare.[15] The government hence plans to widen the reference basket to include all EU countries and pricing of medicines will be then based on three cheapest countries from the reference basket (Act No. 577/2004 on the extent of healthcare reimbursement). Moreover, the new price referencing will have retrospective effect as of 1 July 2008, which means that all medicines (not only new entrants) will be subjected to the new system. The Ministry will create a database of medicine prices in the EU, which will be updated annually on the basis of information received from pharmaceutical producers as well as Ministries of Healthcare in EU member states through the PPRI project (Pharmaceutical Pricing and Reimbursement information).[16]

According to a senior official at MH, “there is no reason for drugs in Slovakia to be more expensive than in the neighbouring countries” and claims that it will always be economical to import medicines even with lower margin for producers.[17] The notion that oncology drugs in Slovakia are more expensive than in other EU countries was shared by several of our interviewees. Representatives of Health Policy Institute have asserted that original producers have been able to retain higher profit margins in Slovakia due to effective lobbying and possibly back-door dealings, even though the small size of the market is

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[14] Interview with the Head of Dept. of Categorization, Pricing and Medicines Policy, Ministry of Healthcare and Head of Categorization Commission, 13 November 2007

[15] Interview with the Head of Dept. of Categorization, Pricing and Medicines Policy, Ministry of Healthcare and Head of Categorization Commission, 13 November 2007

[16] Ibid.

[17] Ibid.

often used as a justification for higher prices.[18] For instance [the client]' Glivec has been the most expensive in Slovakia of all EU states. The MEP we interviewed has complained about high prices of some cancer vaccinations as compared to other European countries.

Generic substitution

One of the intentions of new government's medicines policy has been "strengthening the role of generic substitution."[19] The Parliament amended Act No. 140/1998 on medicines and medical aids in March 2007 in order to omit provisions, which made registration as well as provision of generic drugs more difficult than in other EU countries. In addition, the Ministry plans to replace a positive list of generic drugs with a negative one, i.e. all generic drugs not on the list could be replaced by a cheaper generic substance by a pharmacist, which should further facilitate the use of generic drugs. The aim of all these legislative changes was, according to a senior official at MH, to "improve the position of pharmacists by enabling them to provide patients drugs with socially acceptable surcharge and to allow patients to choose drugs with lower surcharge." According to experts, the measure will result in more aggressive marketing campaigns by generic producers, but also increased activity on the side of original pharmaceutical companies to keep their products competitive.

3.1.5. Future regulatory challenges

Besides the legislative changes outlined above, MH has prepared a complex set of regulations with potentially significant impact on [the client] in the future. The framework document "Strategy of medicines policy until 2010" elaborated by MH and approved by the government in December 2007 outlines the most important regulatory changes the Ministry plans to implement by the end of the election term in 2010. The most pertinent future regulatory challenges include implementation of ethical code into legislation, introduction of value added of medicines and standard diagnostic-therapeutic procedures.

Value added of medicines

Another suggested mechanism, which aims at facilitating classification of medicines, their reimbursement in the process of categorization is the so-called value added of medicines. According to the Head of Dept. of Categorization, Pricing and Medicines Policy at MH, "the mechanism of value added should help create a transparent system for all producers of medicines" (amended government Regulation No. 723/2004; expected introduction 1 July 2008).[20] Value added of medicine is taken into account when there are different drug forms for the same effective substance in a preparative, which is already present on the market. Another example would be a combination of two or more molecules, which already exist on the market as monocomponent preparatives. If the effective substances are combined, they produce added value for the patient and take into account compliance for the patient.

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[18] Interview with representatives of Health Policy Institute, 26 October 2007

[19] Statement by Ivan Valentovic, Minister of Healthcare, 6 September 2007, ADL seminar, Bratislava

[20] Interview with the Head of Dept. of Categorization, Pricing and Medicines Policy, Ministry of Healthcare and Head of Categorization Commission, 13 November 2007

One of the most important aspects of the added value mechanism is the relationship between clinical and social value of a specific medicine. The newly established Working groups within the Categorization Committee (especially Working group for pharmacoeconomy) play an important role in elaborating a set of indicators (and their hierarchy) regarding the relationship between clinical and societal contribution of medicines (a form of HTA). According to a leading Slovak oncologist, similar indicators tackling important ethical issues are desperately needed in order to rationalize spending on drugs and making it more transparent.[21] However, it is yet unclear how the added value mechanism will ultimately look and what its effects will be on pharmaceutical companies. According to a representative of the pharmaceutical industry, the final outcome of the discussion on this new instrument of drug policy is unpredictable.[22]

Implementation of ethical code into legislation

According to information received from a senior official at the Ministry of Healthcare, MH plans to implement ethical code addressing relations between doctors and pharmaceutical companies into legislation in 2008. Such relations are currently only addressed by Act No. 141/2001 on Advertising, which stipulates general requirements for advertisements in the pharmaceutical field. The planned ethical code will be stricter than the existing non-binding document of SAFS (and ADL/GENAS) and its violation will be sanctioned by law. According to an oncologist from the National Oncology Institute, "it does not make sense to completely prohibit pharma companies from establishing relations with doctors and cooperating with hospitals (like in the US), since doctors would not be able to receive appropriate education and information about the newest trends in oncology. Most doctors' travel costs to conferences and seminars are covered by pharma companies."[23] Bringing more transparency into the system would, nonetheless, increase the reputation of both doctors and pharmaceutical companies and would also facilitate more predictable business planning for the industry.

Introduction of standard diagnostic-therapeutic procedures

The Ministry's recently adopted "Strategy of medicines policy until 2010" mentions the adoption of standard diagnostic-therapeutic procedures as one of the objectives for this election term. According to Ministry sources, the gradual elaboration of the procedures will begin in the second or third quarter of 2008 with the Department of Categorization, Pricing and Medicines Policy at MH as the coordinating body. Ministry's Section of Health as well as relevant expert groups will be involved in the process. Standard diagnostic and therapeutic procedures will be legally binding and published in the Official reports of the Ministry of Healthcare. As a representative of SAFS has stated, standard therapeutic procedures cannot serve as a regulatory mechanism for drug consumption, since they could further restrict access to medicines; such procedures should only have a recommendatory character. According to the Head of Department of Categorization, the documents will be opened to comments from relevant stakeholders in their preparatory phase, pharmaceutical companies will most likely not be directly able

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21 Interview with the president of Slovak Oncology Society, 7 November 2007

22 Interview with the president of Slovak Association of Pharmaceutical Companies (SAFS), 8 November 2007

23 Interview with oncologist, National Oncology Institute, 7 November 2007

to influence the process. Nevertheless, the entire process of preparation of guidelines is currently in the stage of planning, so it can still be subject to further alterations.

3.1.6. Relevance to [the client]

Table 2: Summary of the current and future regulatory changes relevant for [the client]		
Proposed change	**Impact on [the client]**	**Timing (legislation)**
Categorization: establishment of advisory working groups, conciliation procedure	Improve long-term planning and evidence-based argumentation	2007 (Act No. 577/2004)
Generic substitution: facilitation of registration of generic drugs, introduction of a negative list of generic drugs	Need to influence legislation addressing generic substitution	1Q 2008 (Act No. 140/1998, Government Regulation)
Pricing: introduction of new price referencing system and degressive margin	Significant negative impact on drug prices and margins	1 Q 2008 (Act No. 577/2004)
Value added of medicines: aims to define pharmacoeconomical aspects in drug classification and reimbursement	Need to influence the policy-making process.	2008
Ethical code: implementation of an ethical code into legislation tackling relations between doctors and pharma companies.	Opportunity to implement [the client]' best practice into legislation	2008 (Act No. 140/1998)
Guidelines: introduction of legally-binding standard diagnostic-therapeutic procedures (guidelines)	Opportunity to indirectly participate on the process of elaboration.	2008-2009

Current and future political and regulatory challenges present significant risks as well as opportunities for [the client]:

- The government lacks a consistent and long-term strategy in healthcare, hence its policy measures result from seeking short-term political benefits rather than tackling long-term deficiencies of the healthcare system. This unpredictability and populism can be addressed by developing a consistent public affairs strategy aimed at engagement with key policy and decision makers. Increasing ethical standards in healthcare (implementation of ethical code into legislation), regulatory measures in preparation (generics, value added of medicines) or the impact of recently adopted pieces of legislation (particularly pricing) on the industry are among pertinent debates, which could be used as justifications for one-to-one meetings.
- The establishment of advisory working groups and conciliation procedure within the Categorization Committee has the potential to increase transparency of the system and Committee's decision making and hence facilitate long-term planning and evidence-based argumentation of pharmaceutical companies with regards the categorization process.
- Introduction of a degressive margin can have a negative impact on producers of expensive original medicines, including pharmaceutical companies active in oncology, since distributors will have less resources to cover financial insolvency of hospitals and less incentives to supply expensive drugs. In addition, it is not uncommon that a percentage of the pharmacies' margin for expensive drugs is channeled back to doctors directly or indirectly for prescribing the drug. It is hence reasonable to assume that with the decrease in margins, doctors will be less 'rewarded' for prescribing expensive drugs, thereby increasing pressures on pharmaceutical

companies for side payments. Nevertheless, HPI has welcomed the introduction of degressive margin as a step towards rationalization of medicines policy.[24]

- It can be expected that the alteration in the price referencing system will have the most serious ramifications for [the client] Oncology of all new regulatory measures in the short to midterm. The main reasons are that the measure will most significantly affect pharmaceutical companies selling expensive drugs and that [the client]' products in Slovakia tend to have very high prices compared to other EU countries. The damaging consequences of such measure were highlighted by the president of SAFS, who asserted that such drastic pressure on the reduction of drug prices can force some pharmaceutical companies to leave the market and can also increase parallel imports of medicines.[25]
- Generic substitution presents an important threat for the business of [the client] in Slovakia in the upcoming years.[26] It is therefore absolutely vital for the company to try to influence legislation tackling issues related to generic substitution. For instance, the introduction of a negative list of generic drugs will shift the burden of proof of unacceptability of specific generic alternatives on original producers.
- Efforts to establish legally-binding ethical standards present an opportunity for [the client] to implement its best practice into legislation and gain market advantage.
- It is also important for [the client] to try to directly or indirectly (through third-party stakeholders) influence discussions on future measures related to value added of medicines and standard diagnostic-therapeutic procedures.

3.2. Slovak cancer policy

3.2.1. Background

More than 23% of all deaths in Slovakia are caused by cancer, which is the second commonest cause of death after cardiovascular diseases and the trend is expected to rise. Slovakia is one of the countries with the lowest survival rates for the most commonly diagnosed cancers of all EU countries and has the lowest survival rate for breast cancer – patients diagnosed with breast cancer in Slovakia have 30% lower chance of survival than patients in Sweden.[27] Slovakia is among top 5 countries in the world with the highest incidence and mortality of colorectal carcinoma - 1,700 people die every year of this type of cancer. 23,000 patients are diagnosed with cancer every year in the country and experts estimate cancer cases incidence to increase by 50% by 2020. Nevertheless, malignant tumor incidence in Slovakia is approximately 30% lower than EU average.[28]

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[24] Interview with representatives of Health Policy Institute, 26 October 2007

[25] Interview with the president of Slovak Association of Pharmaceutical Companies (SAFS), 8 November 2007

[26] For instance, a generic alternative to [the client]' Femara will be introduced in 2008, hence a significant drop in the price of the drug and in overall sales is expected.

[27] EUROCARE 3 and ESMO

[28] Interview with a Slovak MEP, member of MAC, 16 November 2007

The scope of healthcare paid from public insurance in Slovakia is not specifically defined and is almost universal, i.e. there is no patient co-payment for essentially all medical operations (except, for instance, voluntary abortion or cosmetic surgery). Universality of healthcare (undefined scope) and scarce financial resources in the system then create uncertainty and inequalities in the provision of healthcare. According to representatives of the Health Policy Institute, procedures with very different cost-benefit ratios are hence considered equivalent (e.g. money is spent on drugs with ambiguous effects and at the same time, there are waiting lists for operations in oncology).[29]

Slovak cancer policy is not guided by a coherent cancer framework and is mostly formed ad hoc and responding to specific issues and challenges.

In sum, low survival rates, underfunding, lack of transparency and absence of coherent cancer framework are among the most serious problems of oncology in Slovakia today.

3.2.2. National cancer policy – strategic documents

Two general healthcare documents serve as strategic guidelines for the healthcare sector: National Health Promotion Program and the National Environmental and Health Action Plan for the Slovak Republic. In addition, the government manifesto sets a general framework for the healthcare policy pursued by the current ruling cabinet. Slovakia lacks a comprehensive national cancer program; the only cancer-specific strategic document elaborated by MH is the “Strategy for healthcare in the field of radiation oncology.” Additionally, there are several strategic documents (e.g. Strategy for the healthcare of geriatric and long-term patients, Strategy for healthcare in the field of palliative medicine, etc.), which are primarily concerned with other medical fields, but are directly or indirectly related to oncology treatment as well.

National Health Promotion Program (2005)

NHPP provides a general overview of public health status in the country and defines objectives for improvement.

One of the objectives is reduction of incidence of non-infectious diseases; the program stipulates five oncology-related activities needed to accomplish the objective:

- screening of selected cancer types (breast cancer, cervical cancer, colorectal cancer, lung cancer and skin cancer)
- standardization of diagnostic and treatment procedures and their periodic update
- improvement in rehabilitation conditions for cancer patients
- quality enhancement of terminal care of cancer patients
- public education in the form of regular and preventive oncology check-ups

29 See “Basic Guidelines for Healthcare Policy 2007-2010” (Zakladne ramce zdravotnej politiky pre roky 2007-2010), Zdruzenie zdravotnych poistovni, 2007

National Environmental and Health Action Plan for 2006-2010 – NEHAP III

NEHAP III is an EC-tasked document; also serves as a general guideline for the improvement of public health.

The fourth regional priority of NEHAP is defined as focus on decrease of incidence of malignant and benign skin cancer at a later age and other forms of cancer originated in childhood.

Manifesto of the Slovak government (2006)

The Manifesto stipulates government policy priorities for the whole election term (2006-2010).

The document states that "the government will promote a healthcare system focused on prevention and timely diagnosis of diseases and will support implementation of the most important society-wide prevention programs," which implicitly includes development of an oncology program.

Strategy for healthcare in the field of radiation oncology (2006)

The strategy is the only oncology specific strategy document elaborated by a government institution.

Provides a general overview of the state of radiation oncology in Slovakia and includes a forward-looking assessment of trends and developments in the field. The Strategy also identifies current challenges in radiation oncology and considers outdated technology equipment in the clinics to be the most pressing problem.

Lacking National oncology program (NOP)

Slovakia is one of the few EU countries, which do not have a national oncology program providing a holistic framework for a coherent state policy in the field of oncology. The first national oncology program was initiated in 1970s along with the cardiovascular program with the main focus on detection, diagnosis and treatment of malignant tumours. In 1999, the first Dzurinda government approved funding (SKK 500 mil,) for the oncology prevention program, but rather than being a strategic framework document, the program stipulated specific ad hoc measures aimed to improve cancer prevention and cancer treatment. The allocated budget was primarily used for genetic and biochemical prevention program, purchase of cytostatics and bone marrow transplantations.

The current absence of a national oncology program stems predominantly from the absence of policy formation capacities on the side of the state, expert organizations and patient groups. The main reasons for the lack of NOP are the following:

- **Lacking political support:** The new Minister of Healthcare, Ivan Valentovic, has initiated a debate on the cancer prevention program, but as our sources have revealed, the extent of such debate has been rather limited. According to a Slovak representative in MAC who has contacted the Minister in order to facilitate the adoption of a national oncology program, "oncology is clearly not among the priorities of the new Ministry and there is therefore no political will to push forward such program."[30] Lack of competent people at the Ministry in the field of oncology was mentioned by our interviewees as another important hindrance to the national oncology program. The position of a Chief Expert for Oncology appointed by the

[30] Interview with a Slovak MEP, member of MAC, 16 November 2007

Ministry is largely a formal function with no real decision-making power. A national cancer framework requires cooperation of all relevant government institutions, hence strategic coordination on the side of the Ministry of Healthcare is vital in the success of such document. One of the top Slovak oncologists we have interviewed argues that the inability of the Ministry to act as a driving force in the national cancer plan elaboration is the main reason why such document will not be adopted in the short to mid-term future.

- **Passivity of Slovak oncology society (SOS):** The president of SOS has indicated that Ministry officials have contacted SOS in October 2007 in order to start discussing first steps towards a general framework for oncology policy.[31] Nevertheless, according to the president, the lack of a clearly designated expert umbrella organization by the Ministry, which would guide and coordinate such framework, presents an important obstacle to an effective elaboration of such document. Oncologists outside the SOS leadership have, however, pointed out that the oncology organization itself is not as active as it should be in promoting a general framework for oncology policy. Despite the fact that there have been positive developments since the change in presidency, the organization's leadership is overburdened as they are all high-profile oncologists with very limited time devoted to strategic matters of SOS. One of our interviewees has indicated problematic relations between some of the top oncologists and Ministry bureaucrats, which further complicates any long-term cooperation on strategic documents. A strong role of the Czech Oncology Society in initiating and elaborating NOP in the Czech Republic was repeatedly mentioned as an example SOS should follow.
- **Weakness of patient groups:** Patient groups in Slovakia are largely fragmented, which dilutes their messages directed to policy-makers. As an MAC member remarked, "patient groups in Slovakia are isolated, self-centered and not dealing with the most pressing problems of oncology today," like the need for a national oncology framework. Their inability to speak with one voice hampers their influence and potential positive role in the elaboration of a national cancer plan.

Despite the difficulties presented, there is a relative consensus on the general structure of NOP. According to the head of SOS, a national oncology program should be a comprehensive document tackling all aspects of oncology diseases, including medicines policy, preventive programs, patients' treatment and care. Other oncologists have stressed the need for a cross-sectional character of the program emphasizing cooperation of Ministries, self-governing regions, non-governmental organizations and pharmaceutical companies. Several of the interviewed oncologists have, nevertheless, hinted that some pharmaceutical companies have divergent interests regarding the cancer plan and push forward a document focused primarily on medicines policy, which would reflect their business interests.

3.2.3. Financing oncology research

Slovakia spends six times less per capita on oncology research than EU average and only 4% of the UK spending per capita,[32] which demonstrates the fact that cancer research is not amongst priorities of the

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[31] Interview with the president of Slovak Oncology Society, 7 November 2007

[32] MEPs Against Cancer

state health policy.[33] Nevertheless, the Ministry of Healthcare annually updates the list of priority areas in Slovak healthcare research for 2007-2010 and oncology diseases were one of the 8 priorities in healthcare research in 2007. The objective stated was “High quality and timely diagnostics and targeted and safe treatment of tumor diseases for improvement of oncology patients’ lives.” The overall budget allocated for cancer-related research projects in 2007 was app. EUR 1.5 mil.

According to experts in cancer research state financing of research is far from adequate. The state for instance refused to finance a project by the Cancer Research Institute of the Slovak Academy of Sciences, despite the fact that it was very positively received abroad (stem cell treatment of tumours). As several of our respondents revealed, it is difficult to receive financial support from pharmaceutical companies, since they are very hesitant to support research, which is not directly connected to their medicines. This is arguably the case with [the client]’ uncertain support of the bone metastasis research project conducted by one oncology clinic in Bratislava. The research project was initiated by Europa Donna and [the client] pledged to fund the research, although there have been indications that the sponsorship will be withdrawn due to the fact that the subject of the research project is not directly related to [the client]’ products.

3.2.4. Oncology prevention

General cancer prevention is not systematically promoted by MH or other relevant stakeholders. There are, however, two partial oncology prevention programs, which were initiated by the Ministry of Healthcare in 2001 and 2002 and were supported by [the client]’ competitors:

- **Mammodiagnostic program:** initiated in 2001; the first part of the program focused on increasing the number of mammographic examinations, the second part concentrated on the improvement of quality of mammography by establishing Commission for ensuring quality in radiology, which surveyed 46 hospitals conducting mammographic examinations. Financial resources allocated for the program amounted to SKK 44 million. According to a former Minister of Healthcare and currently an active MEP in MAC, Slovakia has the worst survival rate for breast cancer partly due to ineffective prevention programs. The mammodiagnostic program initiated in 2001, for instance, suffered from insufficient media campaign and hence failed to attract adequate attention.[34] There is currently no active breast cancer screening program funded by MH. Avon Cosmetics has been perceived as the most vocal proponent of breast cancer prevention.
- **Colorectal carcinoma screening program:** 5-year program for the population over 50 years of age initiated in January 2002; in the first year of the implementation of the program, a relatively low number of general practitioners participated in the project (less than 20%) due to the fact that they did not get reimbursed for participating in the screening program. Participation of general practitioners started to increase after the introduction of reimbursements in July 2003 (40% participation at the end of 2006). Nevertheless, only 24% of the manageable number of examinations was conducted partly due to insufficient financial

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[33] See interview with Cestmir Altaner, Head of Institute of Cancer Research at Slovak Academy of sciences, Pravda, 10 March 2007

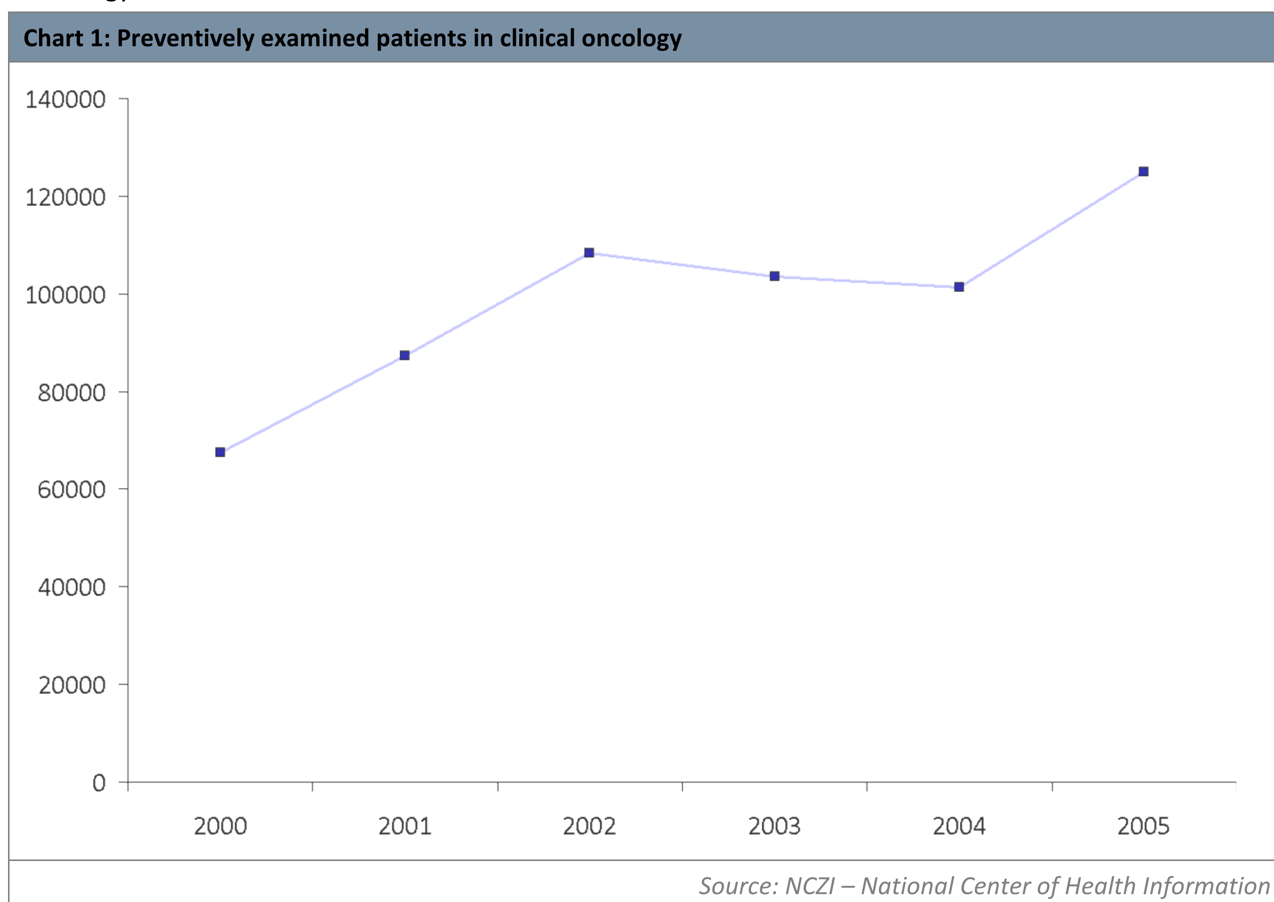
[34] Interview with a Slovak MEP, member of MAC, 16 November 2007

resources (SKK 200 million projected, MH granted SKK 80 mil.). The program was concluded in February 2007. Zentiva was a partner in the screening program.

- **Cervical carcinoma screening program:** there are no other official oncology prevention programs sponsored by MH. However, there have been intense discussions on the cervical carcinoma screening program – the Slovak Gynecologic-Obstetrician Society as well as the Slovak Pediatric Society have recommended implementation of a program focused particularly on cervical cancer vaccinations and the Ministry is preparing a working group, which would develop the project. [COMPANY A] is the most active supporter of cervical screening programs.

The following Chart depicts development in the numbers of preventively examined patients in clinical oncology in Slovakia.

Chart 1: Preventively examined patients in clinical oncology



Source: NCZI – National Center of Health Information

We can see that the number of preventive examinations of oncology patients was on the relatively steep rise from 2000 (29.5% increase from 2000 to 2001 and 24.1% from 2001 to 2002). Given the steady decline of preventive examinations from 2002 to 2004, the impact of the two prevention programs launched in 2001 and 2002 is rather unclear. We can, nevertheless, speculate that the efficiency of the two prevention programs outlined above increased in 2005 due to initial problems with reimbursements, particularly in the colorectal carcinoma-screening program.

3.2.5. Oncology care

High-level oncology research and clinical care is centered in Bratislava (St. Elizabeth Oncology Institute and National Oncology Institute) and Kosice (Eastern Slovak Oncology Institute). There are no official oncology centers in Slovakia, only an informal one, which joints together the National Oncology Institute and the Cancer Research Institute of the Slovak Academy of Sciences. Smaller hospitals perform most of

the oncology care and interventions as large clinics in Bratislava or Kosice despite the much lower occurrence of more specialized cases. According to most oncologists we have interviewed, specialized oncology care should be as centralized as possible, thereby increasing the quality and effectiveness of such care.[35] As the president of a leading cancer patient group remarked, the establishment of a complex oncology center focused on research, clinical care and education is vital in improving oncology treatment in Slovakia.[36] Most of our respondents welcomed and encouraged a strong oncology institute in Kosice, which covers specialized oncology treatment for the whole Eastern part of the country.

According to most of our interviewees, oncology treatment in Slovakia has the potential to be of a relatively high level due to the fact that several of the top European oncology experts are Slovaks and work in oncology institutes in Slovakia. Nevertheless, the provision of oncology treatment in Slovakia is hampered particularly by the two following challenges:

- **Lack of financial resources and their ineffective allocation**: one of the most pressing problems of the healthcare system. Low GDP percentage spent on healthcare, underfunded research, obsolete medical technology equipment (particularly in radiation oncology[37]) and high proportion of healthcare expenditures spent on drugs are among the most visible demonstrations of the problem.
- **Absence of guidelines for doctors**: there are no official standard therapeutic procedures (guidelines) in Slovakia, which would assist oncologists in the provision of appropriate treatment and prescription of drugs. According to a vice-chairman of the Slovak Society for Pharmacoeconomy, the introduction of guidelines would provide stability to the system, even if they were non-binding.[38] Official guidelines would not only assist doctors in their decisions regarding the most appropriate care, but would also serve as reference for patients as well as insurance companies on doctors' work. Guidelines would protect patients as they would be able to check if their treatment corresponds with standard procedures, but such rules would also protect oncologists, since "patients often put pressure on oncologists for drug prescription and doctors cannot defend themselves without official guidelines."[39] Drug spending might also be rationalized and made more effective with the introduction of standard procedures. According to an oncologist from the National Oncology Institute, there have been repeated efforts to introduce guidelines, but several top oncologists opposed the initiatives.[40] Introduction of legally-binding standard diagnostic-therapeutic procedures is one of the priorities of MH's medicines policy for the current election term (see Section 3.1.4.).

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35 Interview with the president of Slovak Oncology Society, 7 November 2007

36 Interview with the president of a leading cancer patient group, 5 November 2007

37 Ministry's strategic document entitled "Current developments in the Slovak healthcare" claims that 14 clinics are in emergency condition due to the fact that the last purchase of new linear accelerators for radiation oncology clinics took place in 1991. The Ministry estimates that radiation oncology urgently needs approximately SKK 1.5 bn in order for the situation to improve.

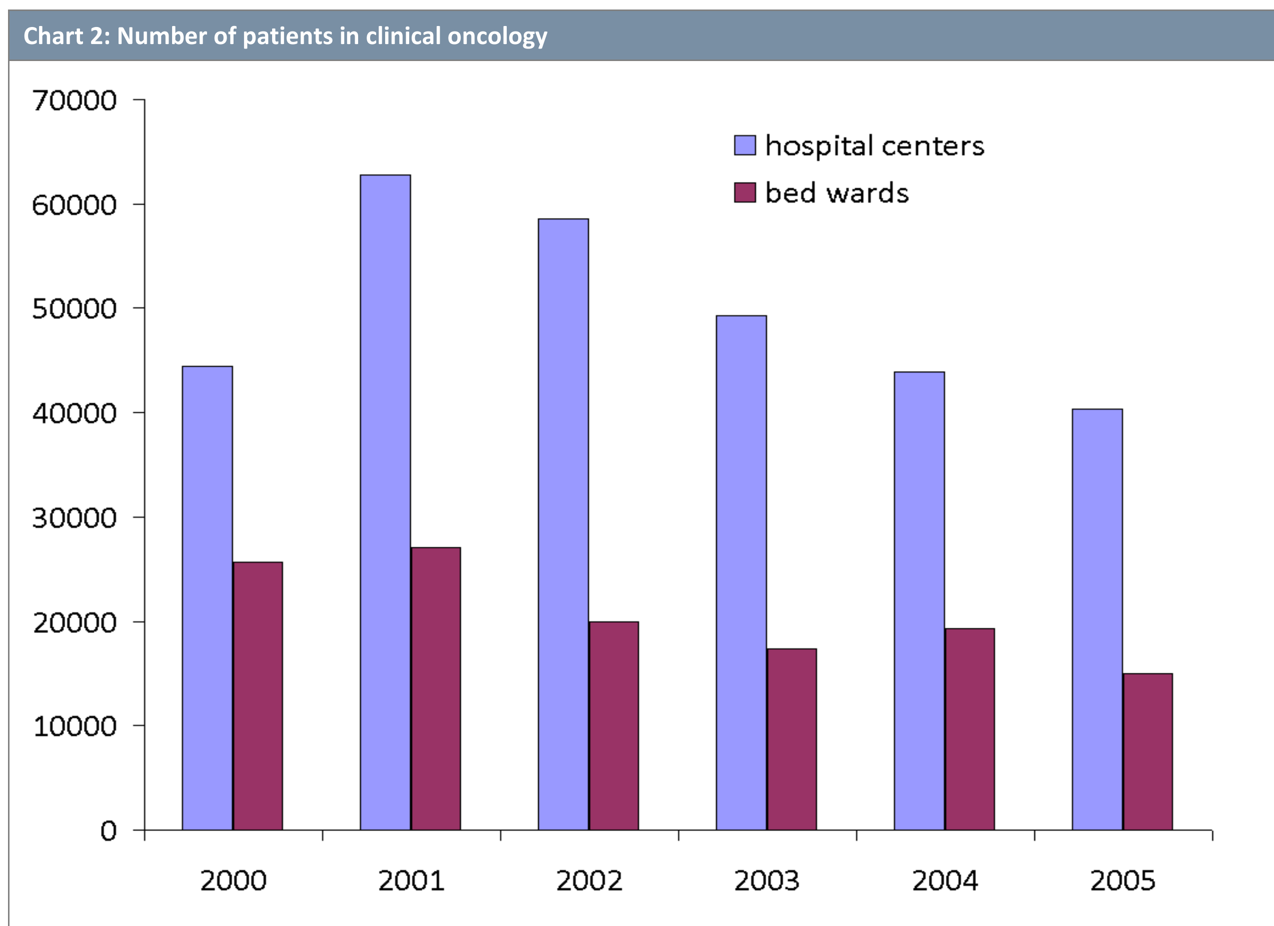
38 Interview with Vice-Chairman, Slovak Society for Pharmacoeconomy (SSFE), 20 November 2007

39 Ibid.

40 Interview with oncologist, National Oncology Institute, 7 November 2007

Chart 2 illustrates the development of number of patients, who received clinical oncology treatment in hospital centers or bed wards. Even though we see a significant rise in the number of patients from 2000 to 2001 in hospital centers, the number is steadily declining from then on and is lower in 2005 than in 2000. We do not have sufficient evidence to explain the initial dramatic increase (over 40%) in treated patients, but the steady decrease corresponds with the healthcare reforms of Minister Rudolf Zajac.

Chart 2: Number of patients in clinical oncology



Source: NCZI – National Center of Health Information

Access to medicines

Slovak legislation allows for early entry of new medicines into the market. According to a leading Slovak oncologist, Slovakia is one of the EU countries with the earliest introduction of newest medicines, but patients' access to drugs is often complicated by the lack of financial resources in the system.[41] It is now rather rare for patients not to receive appropriate oncology drugs due to insolvency of hospitals, but there were repeated media reports on shortages of oncology drugs in the past. In February 2002, media reported on oncology drug supply delays in Banska Bystrica, which resulted in temporary suspension of treatment.[42] Similar cases were reported in Ruzomberok and Kosice, where oncology drugs accounted for 49% of all hospital's drug expenditures.[43] As former advisors of Minister Zajac asserted, access to oncology drugs somewhat improved with the reform package of Minister Zajac, which optimized drug

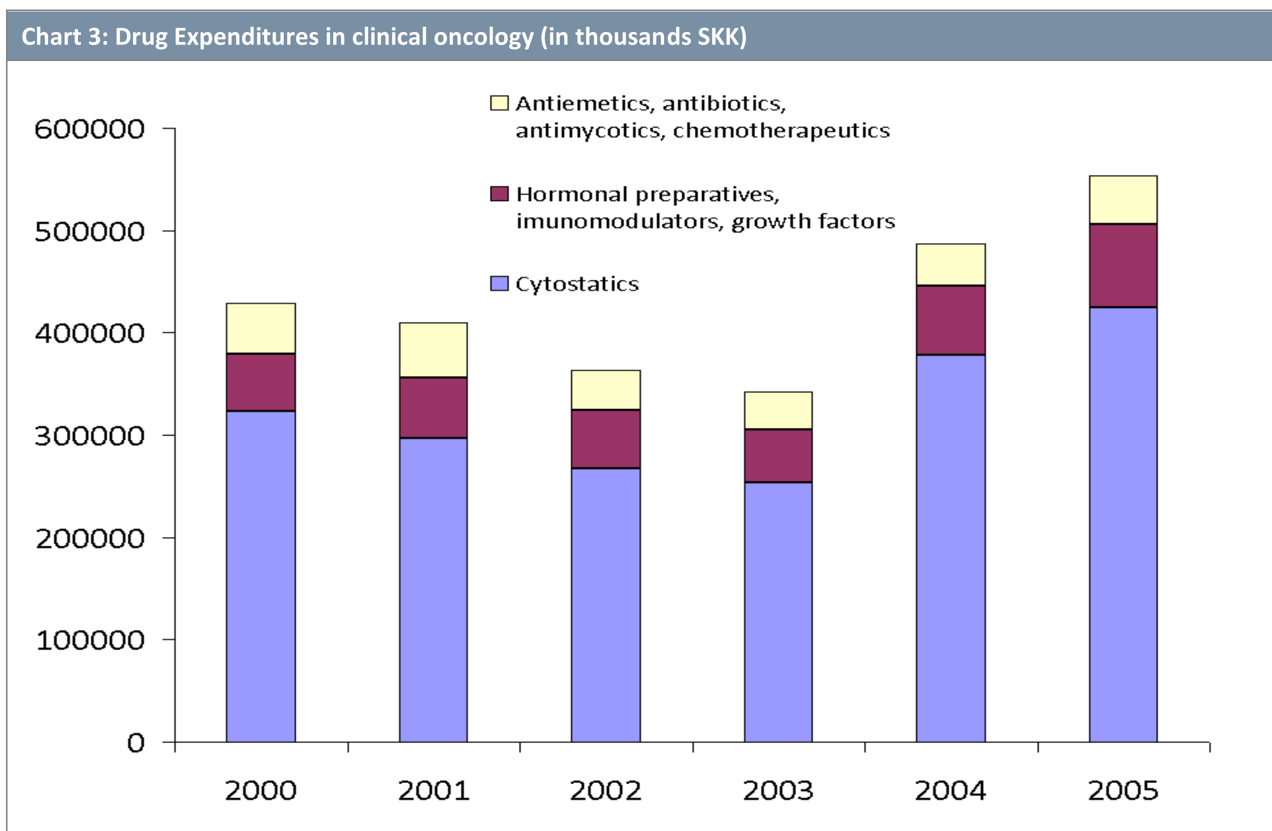
41 Interview with the president of Slovak Oncology Society, 7 November 2007

42 "Problems in oncology departments, situation intensifies" (Problem na onkologiach, situacia sa zhorsuje," SME, 12 February 2002

43 Ibid and "Oncology lacks money" (Onkologii chybaju peniaze), Ruzombersky hlas 2002/04

spending (focus on accessibility of drugs for chronic diseases, co-payments for more common drugs), allocated more financial resources to oncology[44] and pushed for a wider use of generic substitution.[45] The idea that accessibility of drugs has improved in the past years was shared by most oncologists we have interviewed. Chart 3 below shows increasing drug expenditures in the field of clinical oncology from 2002. Increased access to drugs is claimed to be one of the driving forces behind current Minister of Health's legislative changes in medicines.

Chart 3: Drug Expenditures in clinical oncology (in thousands SKK)



Source: NCZI – National Center of Health Information

Objective legislative-based restrictions on patients' access to medicines are:

- **Indication limitations**: Categorization Committee stipulates that a specific medicine is partly or wholly reimbursed from public insurance only in case it is prescribed for an approved indication. Once a drug is approved for a specific indication, doctors can, under some circumstances, prescribe it for other indications not approved by the Categorization Committee (so-called off-label indications), but this has to approved by MH as well as the insurance company in order for the medicine to be reimbursed, which is a rather bureaucratic process. Only oncologists in oncology institutes (about 3% of all oncologists in the country) can prescribe drugs for off-label indications.[46]
- **Prescription limitations**: the restriction implies that medicines can be partly or wholly reimbursed from public insurance only if they are prescribed by a doctor with a specific specialization. Prescription of some medicines (usually expensive drugs) has to be approved by

44 According to Minister Zajac, SKK 750 mil. was spent on the newest oncology drugs during his term.

45 Interview with representatives of Health Policy Institute, 26 October 2007

46 Interview with oncologist, National Oncology Institute, 7 November 2007

a reviewing doctor from the insurance company. Prescription limitations in oncology are often criticized for being too restrictive. Radiation oncologists have, for instance, complained about the fact that prescription limitations do not allow them to prescribe antiemetics or analgetics, which their patients need.[47]

Corruption and unethical behaviour of oncologists is often seen as a reason for deficiencies in oncology care and hindering access to drugs. Patients often exert pressure on oncologists by means of illegitimate payments in order to receive a specific drug or to receive above-standard treatment. In addition, as our interviews have revealed, pharmaceutical companies also unethically 'motivate' doctors to prescribe their drugs, despite the fact that the specific medicine might not be the best available on the market, the most appropriate for the patient or the most cost-efficient. This might be one of the reasons for some oncologists to oppose the introduction of standard therapeutic procedures, since currently, as a HPI representative put it, "it is up to the doctor to decide which medicine he prescribes and to which patient."[48] Due to the fact that there are no official criteria for determining type of treatment for a particular type/stage of illness, it not only provides ample space for corruption and inefficient spending of financial resources, but the lack of standard procedures also hampers patient access to medicines.

47 "Not every oncology is oncology" (Nie je onkologia ako onkologia), sepesi.blog.sme.sk

48 Interview with representatives of Health Policy Institute, 26 October 2007

3.2.6. Relevance for [the client]

Table below summarizes the most relevant oncology policy issues for [the client]:

Table 4: Relevance of oncology policy issues for [the client]		
Issue	**Description**	**Relevance for [the client]**
Financing	Wide scope of reimbursed healthcare, lack of financial resources in oncology, including cancer research.	Lack of resources a challenge due to reimbursement of new expensive drugs. Underfunded research presents an opportunity for engagement.
National Oncology Program	Absence of a comprehensive national cancer framework.	Opportunity for sharing best practices and policy recommendations.
Prevention	Lack of systematic approach to prevention.	Opportunity for engagement.
Treatment/medicine access	Prevalence of illegitimate payments, absence of guidelines, existence of obstacles to drug access.	Challenge to strategic business planning.

More specifically, the issues concerning [the client] include:

- Wide scope of reimbursed healthcare and lack of financial resources in oncology, present a challenge due to reimbursement of expensive drugs. Underfunded research, on the other hand, opens an opportunity for [the client]' engagement through funding research projects.
- Given the lack of strategic framework documents in the field of oncology, [the client] should support the elaboration of NOP, make policy recommendations and thus position itself as a positive driving force in the field. To achieve this, [the client] should consider:
- initiating and funding a conference on national cancer framework;
- identifying and sharing best practices from other EU countries, especially assist in establishing a close coordination between SOS and Czech Oncology Society;
- supporting establishment of platform within SOS aiming at coordinating and/or elaborating national cancer framework;
- launching a contact-building program with key policy makers and parliamentarians aimed at moving cancer and National Oncology Program up the policy agenda.
- A rather unsystematic approach to oncology prevention and a failure to implement commitments from general strategic documents by the state authorities presents an opportunity for [the client] to initiate and support oncology prevention and position itself as a persistent proponent of cancer prevention programs. Other pharmaceutical (and cosmetic) companies have already been active in supporting cancer prevention campaign ([COMPANY A], Zentiva, Avon). [the client] can support oncology prevention particularly by:
- initiating and becoming the main partner of an oncology prevention education at schools co-organized by a reputable cancer patient group (e.g. League Against Cancer);
- together with SOS, initiating a debate on launching or re-launching cancer screening programs corresponding with [the client]' products and co-funding selected program;

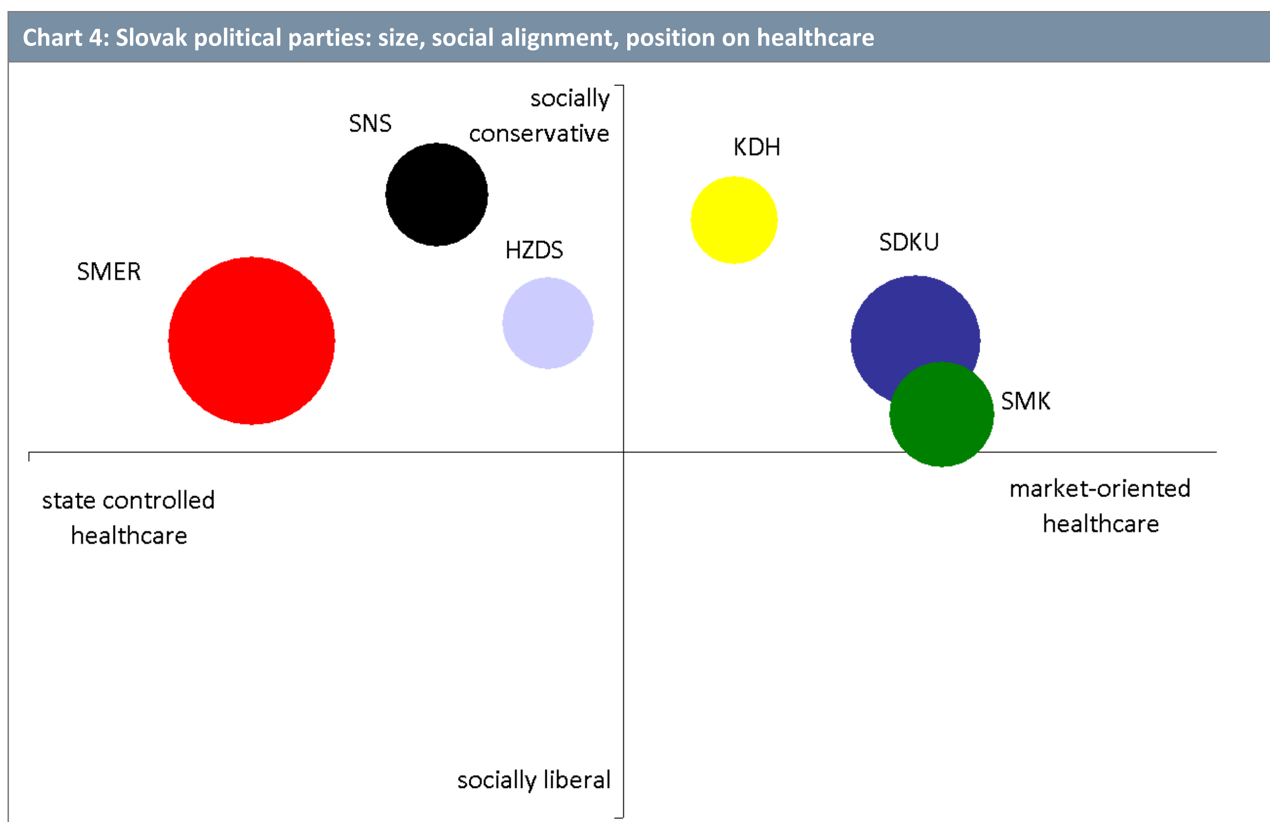
- capitalizing on the long-term partnership with Europa Donna – co-sponsor a nation-wide breast-cancer information campaign and make [the client] visible alongside Avon Cosmetics;
- setting up an information web-page focused on cancer prevention.
- With regard to access to medicines, [the client] can push forward measures, which make the system more transparent and facilitate long-term business planning, particularly strive to:
- influence the elaboration of diagnostic and therapeutic guidelines;
- implement its best practices into legally binding ethical code;
- lobby for the adjustment of regulations, which hinder patients' access to drugs (some prescription or indication limitations).

4. STAKEHOLDERS

4.1. State/government

4.1.1. Political parties

Chart 4: Slovak political parties: size, social alignment, position on healthcare



Source: own research

SMER

SMER, being the major coalition party, possesses control over the Ministry of Healthcare. Minister Ivan Valentovic, although not a member of SMER party, is a nominee of this centre-left and populist political group.

SMER has built up its election program and policy agenda on a fight against foreign capital benefiting from the policies of the former libertarian government at the expense of the lowest and weakest social strata. Thus, SMER views any sign of "inadequate margins" or "inappropriate profits" extremely negatively and sensitively. As a result, therefore, similarly to a price war that has been declared on energy 'monopolies,' SMER, led by Prime Minister Fico, has pushed forward a controversial amendment in October 2007 prohibiting insurance companies to make profit. By getting the amendment approved, SMER has accomplished a principal task from its election program on healthcare, i.e. to bring health insurance companies back to its public service role and not to allow incorporated companies to make profits on healthcare provision. Profit-making issue related to health insurance companies has been dominating the political agenda in this field for some time and is also the one that allows us to compare positions and standpoints of both coalition and opposition parties on healthcare sector (see Chart 4).

Generally speaking, SMER is most supportive of enhanced state control at all levels and in any area of the healthcare system, thus weakening the element of responsibility with other entities in the system, be it patients, pharmaceutical companies, distributors, doctors, health insurance companies, etc. SMER has been the major critic of the healthcare reform introduced by the former Minister of Healthcare Rudolf Zajac. SMER and SDKU stand on the extremes of the imaginary axis ranking political parties according to their standpoints on healthcare issues.

Regarding institutional issues related to the financial structure of the system, SMER's election program proposes a joint fund to be established by the state together with health insurance companies in order to finance costly medical treatments, such as transplantations or oncology diseases. In addition, the election program promises an elaboration of the most important prevention programs, such as national plan for cardiovascular diseases, cancer diseases, etc. According to SMER, drug prices shall be determined only by experts free from the influence of various interest groups.

Over the last 18 months, SMER has abolished co-payment fees, strengthened competencies of the government with regard to the Healthcare Surveillance Authority, decreased the VAT rate on drugs from 19 to 10 percent and has facilitated the entry of generics into the Slovak market.

Within the SMER parliamentary caucus, MP Jozef Valocky and MP Jan Zvonar are in charge of healthcare issues (both members of the Committee on Healthcare). It has to be noted, however, that the current speaker of the National Council of the Slovak Republic, Mr. Pavol Paska, is said to be the most important player in the SMER party in healthcare issues, and so owing to his former business activities in the sector.

HZDS (Movement for Democratic Slovakia)

Minor coalition party positioned close to the center of the axis of political parties according to their standpoints on healthcare issues (Chart 4). The election program of HZDS is largely vague, proposing a three-pillar system of healthcare insurance that would make it possible to abolish co-payment fees while maintaining the same amount of financial resources in the system.

During the parliamentary vote on the controversial amendment proposing a ban on profits for health insurance companies, HZDS maintained a much more liberal standpoint in comparison with SMER and was channeling health insurance companies' interests until the very end. HZDS has been also the first political party to reveal that the government's battle with entities making profit within the healthcare system will not cease with the health insurance companies. On the other side, however, HZDS is constantly against the very existence of the Healthcare Surveillance Authority, considering it useless and a waste of money.

Although generally more liberal and pro-market oriented than SMER, HZDS' positions and standpoints often lack consistency and a coherent strategy, thus preferring rational political choices determined by short-term opportunistic gains over long-term systematic approach and ideological consistency.

HZDS has two prominent MPs on healthcare issues: MP Milan Urbani (member of the Committee on Healthcare) and Jozef Halecky (Chairman of the Committee on Social Affairs).

SNS (Slovak National Party)

Minor coalition party, without significant expertise in and influence over the healthcare issues. SNS standpoints are generally very traditional and conservative on the moral and value issues, while having

slightly more liberal views on economic ones. As a result, SNS tends to act like HZDS in a number of issues (including the vote on the controversial amendment proposing a ban on profits for health insurance companies), balancing the policy of SMER and channeling some pro-market interests. Similarly to HZDS, however, SNS' steps lack consistent approach and their political activities often correspond more with its vested interests than official agenda and/or party program.

SNS' party program strongly advocates the existence of one state-owned insurance house, which would administer all the funds under the obligatory health insurance scheme. SNS party program stresses the importance to allocate financial resources for prevention programs aimed at early diagnosing of diseases, being a tool for faster and cheaper treatment.

SNS chief expert in healthcare policy issues is MP Stefan Zelnik (member of the Committee on Healthcare).

SDKU (Slovak Democratic and Christian Union)

Major opposition party conflicting with SMER on virtually all issues, primarily with the aim of defending pro-market reforms introduced by the former government, including the healthcare reform. SDKU strongly favors market forces and competition over the centralist and state-controlled system.

The SDKU's election program emphasizes the importance of increasing financial means within the healthcare system to a level comparable with other EU countries, i.e. to some 7-8 percent of the GDP. Also, with regard to issues of our concern, SDKU wants to pursue a more transparent drug policy with a proportionate and well-defined co-participation of patients. SDKU would like to pay special attention to highly specialized institutes dealing with diseases such as cardiovascular or cancer.

SDKU, as a leader of the current opposition and formerly the major coalition party, has a natural bias against any corrective measures adopted by this government against the reforms introduced during the last election period. However, regardless of its current defensive position and standpoint, SDKU has also viewed critically some proposals and modifications introduced by former Minister of Healthcare Rudolf Zajac, the then nominee of another minor coalition party ANO (Alliance of a New Citizen).

SDKU's chief expert in healthcare issues is MP Viliam Novotny (Chairman of the Committee on Healthcare). SDKU, being always open towards cooperating with think-thanks, may, to a certain extent, also lean on the expertise and skills of the HPI team.

KDH (Christian-Democratic Movement)

For KDH, healthcare policy issues fall short of their primary interest and agenda. Being an opposition party for the time being, KDH sides with SDKU on a majority of issues. Nevertheless, KDH's position on healthcare issues is much more patriotic and quasi-corporativist; it has been KDH to voice its opposition most loudly within the coalition when former minister Rudolf Zajac launched his healthcare reform. KDH has always been very cautious about the introduction of co-payment fees and some of its MPs have welcomed the decision to abolish them. Also, KDH viewed negatively the establishment of Healthcare Surveillance Authority.

KDH's chief expert in health policy issues is MP Maria Sabolova (vice-chairman of the Committee on Healthcare)

SMK (Hungarian Coalition Party)

Even though SMK's primary political goal is to help protect Slovakia's Hungarian minority, its position on healthcare is very similar to that of SDKU. SMK supports market forces within the healthcare system and strongly endorses competition within the sector as the best means to increase a more effective allocation of financial resources.

The chief healthcare expert within the party is MP Klara Sarkozy (member of the Committee on Healthcare).

4.1.2. Ministry of Healthcare (MH)

MH is the primary state policy-making institution with regard to healthcare issues, including oncology. The Ministry is led by Ivan Valentovic, a former CEO of Spolocna zdravotna poistovna (state health insurance company) and a nominee of the social-democratic SMER party.

Based on the numerous interviews conducted, we identify three most salient challenges pharmaceutical companies with oncology product portfolio are facing vis-à-vis MH:

- **Lack of coherent oncology policy**: oncology is not among the top priorities of the Ministry. There is no specialized unit or a department at the Ministry, which would be responsible for cancer policy. The position of Ministry's Chief Expert for Oncology is mostly formal with limited powers regarding policy making in the field of oncology, which is illustrated by the fact that the person currently holding the position – dr. Igor Andrasina – serves full-time as the Head of the Oncology Clinic in Kosice. As has been previously mentioned, neither a comprehensive National Oncology Program nor a cancer prevent program has been elaborated or initiated.
- **Populism**: policies pursued by the Minister of Healthcare have closely corresponded with the political orientation of the Robert Fico's ruling cabinet. MH has pushed forward populist measures, which aimed at mitigating the role of private capital and competition in healthcare and enhancing state control of the system (e.g. attack on health insurance companies). In drug policy, the Ministry has exerted considerable pressure to lower the prices of medicines (e.g. decreasing VAT, flat 6.6% drug price decrease, changes in the referencing system). These were all measures, which closely corresponded with public sentiments of the government's electoral base and have in recent months become one of the cornerstones of government's rhetoric. According to several of our interviewees, coalition's hostility towards foreign investors can in the short to mid-term turn to pharmaceutical companies as well, since, as a representative of the industry has remarked, the Ministry deems industry's profits as 'inappropriately high.'
- **Incompetence**: the Ministry lacks a long-term vision of the healthcare system, hence its steps are perceived as incoherent. According to a prominent doctor, "the Minister is neither a doctor nor a good manager and therefore business interests and populist motivations of the ruling coalition take over the agenda of the Ministry." Lack of leadership and competence on the side of the Ministry was remarked by most of our interviewees.

As to ramifications of these challenges for the pharmaceutical industry, these problems open space for ad hoc interference in the policy-making, but significantly inhibit long-term business planning. It is therefore vital for [the client] to elaborate a comprehensive strategy of engagement with key policy and

decision-makers, which would not only make their decisions predictable, but would also open space for a long-term influencing of these policies.

4.1.3. SUKL

State Institute for Drug Control (SUKL) is a state administration body which controls, standardizes and evaluates the process of assessing quality, efficacy and safety of drugs; supervises pharmacies, wholesalers and manufacturers of pharmaceuticals and medical devices and prepares assessment reports on medicinal products for human use. SUKL is the principal regulatory body in terms of pharmaceutical registration and supervision; it keeps the complete database of all the registered drugs and medicinal devices in Slovakia. SUKL also has the right to control ethics in advertisements on pharmaceuticals and medicinal devices. Moreover, every pharmaceutical firm is obliged to provide SUKL with a sample of all advertisements issued by the company with explanatory information. Unlike other relevant institutions and state administration bodies, SUKL – given its statute and organization structure – has a more technical role that leaves smaller space for interferences and external influences. According to a representative of HPI, the role of SUKL has significantly decreased since Slovakia's accession to the European Union on May 1, 2004, because 90 per cent of all medicines are now registered centrally by the EU.

Nevertheless, SUKL, having one voting member in the Categorization Committee of MH, is also involved in setting prices for pharmaceuticals. In the spring 2007, SUKL decided to decrease prices of drugs arbitrarily by 6.6 per cent – a figure that was never justified and/or properly explained. According to representatives of the pharmaceutical industry, SUKL's spring decision is another piece of evidence confirming the inexistence of a consistent policy of the current government elite in the field of healthcare and, specifically, drug policy, since it is an ad hoc measure only temporarily decreasing state's drug expenditures.

4.1.4. UDZS

Healthcare Surveillance Authority (UDZS) is a state administration body established through Act 581/2004 on Health Insurance and Healthcare Control. The establishment of such Authority complemented other proposals and modifications within the overall reform of the healthcare system launched by the former minister Mr. Rudolf Zajac. The main reason to found the Healthcare Surveillance Authority was to increase transparency of the healthcare system and to create a relatively depoliticized body acting as a quality supervisor that would, thus, enhance the economic forces within the system.

The Authority is currently presided over by Mr. Richard Demovic, a doctor serving at the Authority almost since its beginning. Over the years of its existence, the Authority has been actively stepping in and remedying cases of mishandled or inadequate medical treatment, wrongdoing and/or inappropriate therapy.

4.1.5. National Cancer Register (NCR)

NCR is a population register established in 1976 covering selected data of oncology patients since 1968. Mandatory reporting of malignant tumors was introduced in 1952. Act No. 576/2004 Coll. now provides a legislative basis for reporting of oncology diseases.

The aim of the NCR is to provide a long-term and comprehensive database of oncology patients in Slovakia. The NCR collects, analyzes and statistically interprets incidence of tumor diseases in Slovakia, conducts epidemiological studies indicating the distribution of oncology diseases and their causes as well as forecasts future development. NCR data are used for application of preventive and interventional programs in the fight against cancer.

According to a Slovak representative in MAC, the Slovak NCR was one of the most comprehensive oncology registers in Europe in 1970s and 1980s. Nevertheless, according to the MEP interviewed, the register has since 1990s suffered from the lack of a complex strategy in the fight against cancer on the side of the Ministry.[49] The president of a leading umbrella patient organization has asserted that the current NCR suffers from many deficiencies and therefore “insurance companies only have a very vague idea about the effectiveness and overall cost of treatment.”[50]

4.1.6. Health insurance companies

There are 4 private and 2 state health insurance companies operating on the market on the basis of mandatory public healthcare contributions. The main principles of the plurality-based Slovak health insurance market is freedom of choice (of insurance company and healthcare provider), obligation to insure all applicants, compensation of insurance stock’s risk structure and competition.

The ruling government has been a vocal critic of private insurance companies, since such enterprises, according to the cabinet, “make profit out of mandatory public insurance and do not bear any business risks.” Even though cabinet’s pressure to abolish health insurance system based on the plurality of providers by establishing one state insurance company did not meet its objectives, the government limited health insurance companies’ administrative costs to 3.5% and banned profit of insurance companies altogether in November 2007.[51] The ban on profit was strongly criticized by the companies themselves as well as the opposition parties for “interfering with private property rights.”

Association of Health Insurance Companies (ZZP)

ZZP was founded in 1994. The role and objectives of the Association were subject to certain modifications over the time, depending on the evolution of and modifications within the health insurance system itself. Yet, the Association now represents all private health insurance companies and acts as a common interest and advocacy body. In addition, the Association coordinates communication among the health insurance companies, facilitates information and expertise exchange, actively comments on legislative drafts and regularly cooperates with relevant state administration bodies. ZZP was actively lobbying against the recently passed amendment to the Act on Health Insurance that prohibts health insurance companies to create profit. As a result, ZZP is viewed very negatively in the eyes of the current government.

ZPP has been a member of the Association Internationale de la Mutualité (AIM) and the International Federation of Health Plans (IFHP) since 1995.

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49 Interview with a MEP, member of XXX, 16 XXX 2007

50 Interview with the president of XXX patients group, 7 XXX 2007

51 The profit can only be used to cover healthcare by the end of the following year.

4.2. Professional organizations

4.2.1. Doctor associations

Slovak Oncology Society (SOS)

SOS associates more than 600 oncologists and oncology experts, presided over by an oncologist from the National Oncology Institute Jozef Mardiak. The principal objective of SOS is to facilitate exchange of information and to improve oncologists' expertise by organizing various conferences, workshops, seminars, etc. (e.g. Bratislava Oncology Days). As a result, SOS provides a platform for expert debates and discussions on pharmaceutical products, thus attracting the attention of pharmaceutical companies sponsoring such events – [Company A], [Company B], [Company C] and [the client].

The views on the role and activities of SOS slightly differ, but a majority of them seems to indicate that the Society has a significant potential to grow, to enlarge its activities, strengthen its role and to follow the example of the very active Czech Oncology Society. Such position was stressed by the Vice-chairman of the Slovak Society for Pharmacoeconomy (SSFE) and an oncologist from the National Oncology Institute. In the view of the latter interviewee, a generational change was very much needed in the leadership of SOS – something that has already fully materialized with prof. Koza leaving the presidency of the Society. New leadership has the potential to lead the organization forward; however, lack of permanent staff, which would coordinate organization's program and be able to develop its activities, seems to be one of the main obstacles to make the organization more active. According to several of our interviewees, SOS should be more active and should act as the chief driving force behind positive changes in the field of oncology, e.g. development of the National Oncology Program.

As our interview with the head of SOS revealed, pharmaceutical companies have a strong tendency to support only SOS' activities, which are directly related to their product portfolio. Long-term support of independent expert debate from the pharmaceutical industry is thus missing.

[the client] Oncology cooperates with SOS on a number of projects and sees the performance of SOS in a positive light, considering it relatively effective and cooperative.

Slovak Doctors Society (SLS)

SLS, established in 1969, is a non-governmental umbrella organization of specialist medical and pharmaceutical companies, and regional associations of doctors and pharmacists. It has nearly 20,000 members (doctors, professors, hospitals' staff, etc.). SLS publishes and presents positions on issues connected with research, diagnostics and treatment, ethics and legislation. Internally, the entire organization consists of several small associations structured according to the field of specialization, e.g. Association of Anaesthetists, etc.

Slovak Chamber of Doctors (SLK)

SLK, established in 1969, is a non-governmental, autonomous and apolitical professional organization. The Chamber acts as an interest group advocating the interests of doctors in Slovakia, thus supporting their claims, protecting their professional credit and guaranteeing and supervising the expert qualities and capabilities within the doctors' profession. The Chamber once used to feature substantial corporativist characteristics and, unlike SLS, imposed an obligatory membership. Nevertheless, in the

transitional period of the 1990s Chamber's activities ceased for some time. In 2004, as a part of the former minister Rudolf Zajac's healthcare reform, obligatory membership within the Slovak Chamber of Doctors was abolished due to Ministry's systematic efforts to weaken the influence of professional organizations.

SLK and SLS have together three members in MH's Categorization Committee (2 permanent, 1 non-permanent).

Slovak Chamber of Doctors is a member of the Standing Committee of European Doctors (CPME) and the European Association of Senior Hospital Physicians (AEMH). The Chamber's objective has always been to create a strong interest group fully in control of its members – an objective that has failed to meet the reality so far. It seems that the existential problems of the Chamber in the 1990s have not only weakened its position, respect and relevance, but also enabled pharmaceutical companies to substitute for some of the roles of the chamber and, thus, exposed the doctors to the all-encompassing interests of pharmaceutical companies. Protracting weakness and clumsiness of the Chamber, confirmed recently by a fiasco related to bargaining for a better annual contract with the largest insurance company, helps to explain the excessive influence of pharmaceutical companies on doctors, be it related to education, training or drug prescription.

4.2.2. Expert groups

Slovak Society for Pharmacoeconomy (SSFE)

SSFE was founded in 2004 as a member of the Slovak Association of Doctors. It is also a member of ISPOR – International Society for Pharmacoeconomics and Clinical Outcomes. Both SLS and SUKL are official partners of SSFE.

Slovak Society for Pharmacoeconomy serves as an expert basis in the given field for specialists and officials from MH, health insurance companies, WHO bureau in Slovakia, pharmaceutical companies and other relevant entities. The Society also participates in the drug categorization procedure through Categorization Committee's Advisory Group for Pharmacoeconomy, whose members are nominated by SSFE and have a right to vote. The organization is allowed to comment on legislative drafts and exerts pressure on the Categorization Committee of the Ministry of Healthcare, so that it takes into account pharmacoeconomical aspects in classification of new medicines.

Slovak Chamber of Pharmacists (SKL)

SKL was established 1991 and is now presided over by Mr. Peter Mihalik. The Association, a member of the Pharmaceutical Group of the European Union, acts as an interest group advocating and representing pharmacies and pharmacists. The Chamber is also active in educational programs and training schemes, organizes a number of conferences and seminars. Moreover, it operates a register of pharmacists.

The Chamber was highly critical of the reforms proposed by the former Minister of Healthcare Mr. Rudolf Zajac; it opposed the foundation of the Healthcare Surveillance Authority, transformation of health insurance companies to joint-stock companies as well as liberalization of the health insurance market and the introduction of co-payment fees. SKL has also been objecting the introduction of a degressive margin and was proposing to keep the money within the drug chain by supporting smaller rural pharmacies instead. In 2003, MH proposed to suspend President Mihalik's pharmacist license due to the alleged violation of pharmacists' ethical standards.

Association of Slovak Pharmacists (ALS)

ALS is a non-governmental organization associating owners of pharmacies from around Slovakia. ALS supervises the quality of pharmaceutical services, communicates with MH, health insurance companies, employees, etc. The Association also comments on legislative drafts, mostly related to taxation and accounting.

Association of Drug Suppliers (ADL)

ADL was established in 1992 and represents the interests of distribution companies, drug producers, drug and health-care suppliers and owners of pharmacies. ADL has 157 members (3 distributors, 55 producers, 99 owners of pharmacies), among them also [the client] – nominee of which is the vice-president of the Association. ADL is regulated by its own ethical code. The organization comments on legislation in preparation, even beyond its scope of expertise – a point highlighted by the Chairman of the Parliamentary Committee on Healthcare. ADL applies its proactive approach not only to stakeholders and decision-makers, but also to the public and specialized media, which the association cooperates with on a regular basis.

ADL has been objecting the introduction of a degressive margin for having a negative impact on suppliers distributing drugs to hospitals.

ADL is a relatively powerful organization, marked as competitor by SAFS.

Health Policy Institute (HPI)

HPI is a non-governmental think tank promoting values, which "support financially sustainable health systems responding flexibly to the needs of the population and promoting client-oriented approach to the insured and the patients." HPI supports market mechanisms in the health sector and promotes a system of compulsory public medical insurance. HPI consists primarily of people who used to work in a team of advisors of the former Minister of Healthcare. Being unacceptable for this government, the Institute has decided to pursue its activities at a professional, independent platform as a think-thank. At present, they provide consultancy and advisory services to several governments reforming their healthcare systems (Czech Republic, Hungary), hospitals (both public and private) and comment on legislative drafts. HPI also prepares health system analyses and is very active in the media, acting as persistent critics of the current government. The team of people in HPI is generally considered as a truly expert one in the field of healthcare in the V4 region.

HPI is of the opinion that, despite their bad reputation and image, pharmaceutical companies have gained more power and influence with this government in power, and so thanks to their expert basis and capability to provide the Ministry of Healthcare with 'easy' solutions. Once again, similarly as in the Slovak Chamber of Doctors, pharmaceutical companies skilfully benefit from the lack of expertise and inferior quality of other bodies/components of the healthcare system.

4.3. Patient advocacy

4.3.1. Patient position and rights

The Slovak government adopted a "Charter of patients' rights in the Slovak Republic" in April 2001. The document consisting of a preamble and 10 articles was elaborated on the basis of similar documents of

international organizations, particularly the UN, WHO, Council of Europe and the EU. The Charter prohibits any form of discrimination in the provision of healthcare, stipulates patient rights in obtaining information, defines patient's consent and confidentiality of information. In addition, the document defines general conditions in the provision of healthcare and addresses the issues of care of incurable patients, filing complaints and compensation for a damage.

The quality of provided medical treatment is supervised by the state Healthcare Surveillance Authority (UDZS) (see Section 4.1.4. for details).

Despite the formally adopted set of standards tackling the issue of patients' rights, oncology patients' position is challenged by fragmentation of patient groups (to be discussed in 4.3.2.) and **lack of information**. According to a study conducted by the Stockholm Network, 95% of Slovaks believe that having enough information to make an informed choice about their treatment is important, but only 24% believe the Slovak healthcare system is good at delivering the information (compared to e.g. 39% in Hungary). Also, 70% of the Slovak population believes that giving patients more information about their illnesses is more likely to increase standards of care, which is more than any other reform.[52] According to the president of SAFS, part of the problem is the nature of doctor-patient relationship in Slovakia, which is one of super- and subordination: "Slovak doctors have a strong tendency to talk to patients authoritatively and do not expect to be asked questions; patients, on the other hand, succumb to this style of conversation too quickly."[53] Since Slovak healthcare is perceived to be 'free', patients tend to ask for information less than if they paid for the service and, as a former Minister of Healthcare asserted, inadequate financial renumeration of doctors results in their apathy.[54] A representative of a cancer patient foundation sees insufficient number of oncologists as another reason behind absenting information.[55] According to several of our interviewees, general population also lacks appropriate information about cancer and cancer-related diseases due to insufficient cancer prevention programs and their inadequate media coverage.

With regards to patient rights advocacy, League Against Cancer has been pushing for the implementation of the European Guidelines for Oncology Patients' Rights, but has been unsuccessful in achieving the goal so far.

4.3.2. Patient advocacy groups – key issues

Fragmentation of patient groups

According to a president of one patient organization, disunity of patient groups in Slovakia is one of their defining characteristics.[56] According to an MEP we have interviewed, "patient groups are isolated, self-

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52 Respondents were also asked to comment on the following reforms: increasing number of medicines and treatments, giving patients more control over public spending on health, increasing range of doctors and hospitals and making it easier for patients to spend their own money on health. See "Poles Apart? East European Attitudes to Healthcare Reform," Stockholm Network 2005.

53 Interview with the president of XXX XXX, 8 XXX 2007

54 Interview with a former Minister of XXX, 16 XXX 2007

55 Interview with the founder of a patient foundation, 6 XXX 2007

56 Interview with the president of a patient group, 7 XXX 2007

centered and not dealing with the most pressing problems in oncology."[57] Rivalry among patient groups stems from the struggle for financial resources as well as personal animosities. According to a representative of an oncology patient foundation, the leading cancer organization – League Against Cancer – is reluctant to cooperate with other organizations, partly due to concerns over budgeting. According to industry representatives, fragmentation of patient groups inhibits effective cooperation and more pro-active position from the side of pharmaceutical companies. As our interview with a MAC member revealed, pharmaceutical companies themselves can and should play an active role in facilitating communication and collaboration among patient groups. Fragmentation of patient groups weakens the position of patients and is also one of the important reasons for the lack of targeted and well-publicized cancer prevention programs.

Low respect from authorities

Even though the role of patient groups is mostly endorsed by the industry, relevant stakeholders as well as the authorities, patient organizations are often viewed as not competent enough as to be interfering with policy-making and medicines policy. The attempt to add a representative of patient groups to the Categorization Committee two years ago was not reflected upon by MH. According to a senior Ministry official, patient group representatives are not experts in the field of medicines policy and therefore should not be interfering with strictly expert and evidence-based decision-making of the Categorization Committee. The position was shared by the Chairman of parliamentary Committee for Healthcare.

Low assertiveness of the leadership

Another challenge, which hampers effective functioning of patient organizations is low assertiveness of their leadership. As many of our interviewees noted, leaders of patient groups are "not used to pro-actively lobby for the interests of patients since most of them are older people" and arguably acquired the habit during the communist period. According to an industry representative and several oncologists, patient groups with younger leadership tend to be more successful in influencing policy-making (e.g. cystic fibrosis or muscular dystrophy patient groups). According to a MAC representative, a generational change would considerably improve the power of patient groups, particularly change in the leadership of the League Against Cancer. One of the relevant ramifications of the low assertiveness of patient groups is their inability to voice their concerns at the EU level and press for a wider recognition of cancer patients-related issues specific to the post-communist region.

Funding

Most patient groups use multiple sources of funding, which includes sponsorship from pharmaceutical companies. Nevertheless, a systematic approach to funding of patient groups from the side of pharmaceutical companies seems to be missing. Representatives of patient groups have complained that most funding from the industry is ad hoc and relatively short-term and companies are hesitant to establish long-term partnerships with patient groups. One interviewee has pointed out that most patient groups leaders are unable to apply for EU grants due to their incompetence. Supporting training of patient groups' leadership or providing a platform for such education should therefore be considered by pharmaceutical companies.

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[57] Interview with a former Minister of XXX, 16 XXX 2007

4.3.3. General Patient Groups

Patient Rights Advocacy Association (AOPP)

AOPP is an umbrella organization of many of the disease-specific patient organizations, presided over by Ms. Anna Rehakova. AOPP's primary ambition is to defend patients' rights by influencing legislation, improving information channels towards patients and providing counselling to patient groups and individuals. However, AOPP includes only two cancer organizations, and so it is not primarily involved in cancer advocacy. The most famous cancer organization – LPR - being disinterested in working with AOPP, is not a member of this Association either.

Although not directly cooperating with pharmaceutical companies, AOPP maintains contacts with the industry through various project-oriented activities, which are also supported by ADL and SAFS. [Company A] is the most active pharmaceutical company in cooperating with AOPP, followed by [Company B]. [the client]' outreach towards AOPP seems to be rather limited.

According to representatives of AOPP, the current Minister of Healthcare Ivan Valentovic - unlike the former Minister – to a large degree ignores communication with AOPP. Moreover, AOPP has been also critical of some of Mr. Valentovic's measures with respect to healthcare system reforms introduced by his predecessor Rudolf Zajac.

AOPP operates a webpage www.informovanypacient.sk, which provides general information about rights and duties of patients.

4.3.4. Cancer Patient Groups

Foundation for Supporting Oncology Patients (NPOP)

NPOP focuses on informing oncology patients about oncology diseases, possibilities of appropriate treatment, suitable oncology centres, etc. It also provides psychological advisory.

NPOP was founded and is now presided over by a former cancer patient Ms. Anna Valachova and a prominent Slovak oncologist prof. Ivan Koza. NPOP, aiming its activities more at the patients suffering from cancer than at the general public as such, is individual-oriented. Therefore, unlike LPR, it does not hold mass public campaigns such as the well-known Daffodil Day, but concentrates on individual education of oncology patients. Due to this specific focus, NPOP's cooperation with other cancer groups and patient organizations is less frequent and limited only to larger mutual projects, for which the NPOP acts as an umbrella coordinating organization. This also explains why NPOP is less known and enjoys less publicity even though two of the most Slovak famous actors are members of NPOP's board of directors.

NPOP cooperates with pharmaceutical companies such as [COMPANY A], [Company G], Jansen-Cilag and [Company B]. Representatives of the Foundation very much appreciate cooperation with [COMPANY A] and [Company B] for their helpfulness and responsiveness. According to the founder of the Foundation, cooperation with [the client] Oncology ceased two years ago after personal changes in the management of the company. Given organization's endorsement by many oncology experts and professionals, who praised NPOP's activities and potential to grow, we advise considering re-establishment of a partnership between [the client] Oncology and the Foundation.

League against Cancer (LPR)

LPR is the leading cancer organization in Slovakia and, thanks to many successful activities, also the one perceived by the public as an embodiment of the fight against this disease. The League was founded and is still presided over by a former oncologist, Ms. Eva Siracka. Ms. Siracka has been a prominent activist in the fight against cancer and was acknowledged for her life-long activities and overall contribution in this field by receiving state honours award from the Slovak president in 2006.

LPR has been a member of the European Association of Leagues against Cancer (ECL) and the International Union Against cancer (UICC) since 1990. LPR enjoys the status of a charitable and non-profitable organization. Its activities may be divided into three principal categories: 1) education, information and prevention; 2) care for oncology patients and their families; 3) clinical and research projects. LPR organizes a wide range of events and activities such as oncology education in primary and secondary schools or the Oncology Patients Forum. As mentioned earlier, the best-known one and the most popular both with the laymen and expert community, including the media, is the Daffodil day, supported by [Company D], [Company B] and [Company F] Oncology. As a consequence, most professionals and experts hold LPR and its activities in great esteem and the organization is generally highly appreciated. Moreover, LPR is the only NGO in Slovakia participating in the European Program against Cancer. On the other hand, however, LPR has been subject to criticism by NPOP and AOPP for not willing to cooperate with other patient groups. The reason for statements like these may be, nonetheless, the very leadership of the LPR. Slovak representative in MAC has revealed to us the need for a generational change in the presidency of the LPR in order for the organization to grow.

LPR is also an umbrella organization for autonomous associations of breast cancer patients called **Venus clubs,** which exist in a number of towns around Slovakia. The Clubs provide a platform for meetings and information exchange of breast cancer patients. [the client] is among sponsors of these clubs.

Association for Supporting Leukaemia and Lymphoma Patients (ZPL)

ZPL provides information for Leukaemia and Lymphoma oncology patients about the disease and appropriate treatment. ZPL is a member of AOPP and is presided over by Ms. Eva Madajova.

Slovak Myelom Society (SMS)

SMS facilitates access to information and supports education about the disease, including the most appropriate therapeutical solutions and procedures. SMS also produces its own clinical studies, supports myelom research, co-operates with the Czech Myelom Association and prepares a register of myelom patients.

Europa Donna (ED)

ED is part of the reputable pan-European breast-cancer organization. ED was founded by Andrea Kalavska in 2005, a cancer patient herself. The objective of ED is to provide a practical information basis for patients and to assist in fundraising financial resources for oncology hospitals. Nevertheless, ED’s activities are relatively modest due to the fact that its personal capacities are limited – the only person working for ED is Ms. Kalavska, who has a regular full-time employment besides her work at ED. [the client] has been one of ED’s three principal sponsors (Avon and Slovenska sporitelna are the other two). According to Ms. Kalavska, cooperation with [the client] was more vigorous at the beginning of organization’s operation.

Dobry Anjel (Good Angel)

Good Angel is a foundation primarily supporting socially disadvantaged families with one or more family members being cancer patients. In addition, Dobry anjel provides funding to children's oncology hospitals. The organization was founded by a prominent Slovak entrepreneur Andrej Kiska, who was granted a 'manager of the year 2006' award by the Trend weekly and the foundation has an excellent reputation. Most of the financial supporters are private citizens and no pharmaceutical company has been among foundation's donors. According to our sources, the founder of the organization plans further activities in the field of oncology, particularly establishing an oncology hospital.

Table 5 summarizes the influence of relevant non-state stakeholders in healthcare.

Table 5: Relevant non-state stakeholders and their influence

Institution	President	Influence
SOS	Jozef Mardiak	Low to medium with potential to significantly grow
LPR	Eva Siracka	Medium, well-known and respected
AOPP	Anna Rehakova	Low to medium, umbrella patient organization, lack of assertive leadership
NPOP	Anna Valachova	Low to medium, focused on individual patients
SLK	Milan Dragula	Moderately influential, voices concerns of doctors
ADL	Sina Niku	Medium to high, comments legislation in preparation, arguably the most important voice in the 'drug chain'
HPI	Peter Pazitny	Low to medium; its power decreased with the new Minister, seen as the opposition to the current health policies

5. INDUSTRY & COMPETITORS

5.1. Industry

Pharmaceutical companies are relatively well perceived among the Slovak public. According to a poll conducted by the Stockholm Network, 63% of Slovaks consider the industry to be the most reliable source of health information (the same as official statistics), while 30% of the population considers such information unreliable. The difference (termed 'credibility gap' by the Stockholm Network) - 33% - is almost twice the average of the countries surveyed (16%).[58]

Slovak Association of Research Based Pharmaceutical Companies (SAFS)

Original pharmaceutical companies with no more than 30% of their annual revenue in generics are associated in SAFS**.** Being established in 1997, SAFS is a member of EFPIA – European Federation of Pharmaceutical Industries and Associations - and is currently headed by Ms. Sona Strachotova (formerly working for [Company C]). SAFS represents pharmaceutical companies vis-à-vis the regulator and state institutions primarily by commenting draft legislative proposals. According to its president, the Association pursues goals agreed upon on the basis of the "lowest common denominator" of all its members; hence its ability to represent specific interests is limited. Nevertheless, it is not uncommon that interests of one company are followed at the expense of other members within SAFS. It has been the case in the past (e.g. 6.6% reduction of drug prices in the spring 2007) that SAFS - rather than representing common interests of its members – sided with one specific company, which made a bargain with the Ministry, to the detriment of others. Another limitation of SAFS, although connected with the previous one, is the fact that there exist two groups of companies within SAFS – one pushing for more transparency in the system, the other wishing to benefit from shady practices and back-door dealings within the system. Hence finding consensus on crucial issues regarding system's transparency is often difficult. Nevertheless, SAFS has managed to elaborate an ethical code, which was also signed by GENAS and ADL. Yet its character is self-regulating and declaratory, so it is not uncommon that members of SAFS themselves breach the rules stipulated in the ethical code (see Section 5.2). [the client] is a member of SAFS, albeit not present on the 5-member Board, so its role within the organization is rather limited.

Association of generic producers (GENAS)

An association grouping generic producers – **GENAS** - was founded in 2000 and merged with the Association of Pharmaceutical Producers in 2004. GENAS acts as an interest and advocacy body for its members, representing them vis-à-vis state administration bodies, other relevant institutions and decision-makers. GENAS has one non-voting member in MH's Categorization Committee. The primary interest of GENAS is to promote and facilitate the entry of generic drugs into the Slovak market – a mission that it has managed to fulfil with success over the last election period. As our interview with the Vice-Chairman of the Slovak Society for Pharmacoeconomy has revealed, generic companies in Slovakia are known for more brut-force and shady practices than original producers. The Chairman of GENAS is Igor Novak of Zentiva – a company repeatedly charged with unethical behavior by our respondents due

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58 See "Poles Apart? East European Attitudes to Healthcare Reform," Stockholm Network 2005.

to local links with decision-makers (Zentiva is the owner of the Slovak pharmaceutical producer Slovakofarma Hlohovec). Current Head of the department of categorization at MH and also the Head of the Categorization Committee used to work for a generic producer ([the client]' Sandoz) before she joined the Ministry.

5.2. Competitors

[Company B]

[Company B] is perceived to be very active in communicating with all relevant stakeholders. Nevertheless, some of our interviewees considered [Company B] to be 'very flexible' in terms of using shady practices and informal payments in order to maintain above-standard relations with key oncologists and relevant decision-makers. [Company B] is one of the few pharmaceutical companies employing a public affairs strategist, an active PR manager and expanding its corporate affairs team in order to increase effectiveness of its communication. According to our discreet sources, the short to mid-term goal of [Company B]'s Slovak management is to position the company as the leading oncology player in the country. [COMPANY A] is considered [Company B]'s most serious competition.

[Company B] has successfully participated in public procurement – it supplied the Administration of State Material Reserves with Tamiflu vaccines worth SKK 249.7 mil. (app. 756 000 EUR).

[Company B] is very active in supporting web portals on cancer illnesses: www.tvojanadej.sk containing information on colorectal carcinoma, www.lymfom.sk on malignant lymphomas, and www.vedietviac.sk on breast cancer. In addition, [Company B] co-operates with the Slovak Oncology Society and with the League against Cancer on various ad-hoc projects and financing of brochures (recently sponsored CD release for children with cancer).

The president of one of the cancer organizations appreciated [Company B]'s active attitude and long-term support. Slovak MEP has also voiced her positive experience with the European headquarters of [Company B].

[COMPANY A]

[COMPANY A] is the most visible pharmaceutical firm in the Slovak media. Besides being awarded in employment-related competitions (9th place for [COMPANY A] Slovakia on the list of Best Employers of Central and Eastern Europe 2006/2007, 3rd in the Best Corporate Philanthropist in Slovakia competition), [COMPANY A] is the chief sponsor of one of the most popular Slovak TV series (set in a gynaecological hospital; [COMPANY A] was accused of product placement, which is prohibited in Slovakia). [COMPANY A] sponsors cancer-related web portals like www.mediforum.sk or www.[Company A]mednet.sk targeting primarily professional community, or anti-smoking portal www.fajcenie.sk.

According to oncologists as well as cancer patient groups, [COMPANY A] is the most active pharmaceutical company in cooperation with patient organizations. In general, [COMPANY A] is the best-perceived pharmaceutical company in Slovakia regarding ethics, support for patient groups and philanthropic activities.

Like [Company B], [COMPANY A] has supplied the Administration of State Material Reserves with Relenza drug (47,000 EUR).

[Company D]

The association of [Company D] with oncology is rather weak in the eyes of stakeholders, even though the company is active in supporting patient groups and cancer-related prevention campaigns. The bulk of [Company D]'s activities with regard to patient groups is focused on lung cancer – the firm recently co-organized an anti-smoking campaign in the Slovak parliament and funds an anti-smoking webpage www.prestatfajcit.sk. [Company D] is a partner of League Against Cancer on various projects (The Day without Tobacco) and it is the only pharmaceutical company supporting League's main fundraising event – the Daffodil Day. In 2005, [Company D] received a philanthropy price Via Bona Slovakia from the PONTIS Foundation.

[Company D] is active in trade associations, particularly the American Chamber of Commerce (AmCham).

[the client]

[the client] is a well-perceived pharmaceutical company in Slovakia, but its association with oncology is somewhat weak among stakeholders not directly working in the field (MPs, general patient organizations, interest groups). Although generally seen as an ethical firm, one interviewee directly indicated Slovak management's breaching of SAFS' ethical code by organizing generous trips for oncologists and their families. Another interviewee considered [the client] Oncology's centralization of decision-making in Prague ineffective and hindering active cooperation with oncologists in Slovakia. Lack of an active PR team as well as person responsible for 'systemic' legislative lobbying are also seen as deficiencies of [the client] Oncology in Slovakia.

In terms of media coverage, [the client] received negative publicity when the Slovak Press Watch issued an article on a conflict of interests of one of the former top [the client]' representatives Andrej Rainer, who was also a TV host of a program on health issues. Allegations of [the client]' hidden advertisements in the media were also voiced.

Compared with other pharmaceutical companies, [the client] has an internet web-site with poor information content for both patients and professionals.

According to the Slovak management of [the client], the company cooperates with SOS on regular basis.

The following table provides an overview of company funding of key patient groups relevant to oncology. However, the table has only informative character and is not exhaustive, since most patient groups do not openly disclose their sponsors.

Table 6: Company funding of patient groups

	[COMPANY A]	[Company B]	[Company D]	[Company C]	[Company E]	[Company F]	[Company G]	[the client]
Foundation for Help for Oncology Patients (NPOP)		X			X		X	X
League against Cancer (LPR)		X	X			X		
Venus clubs								X
Europa Donna (ED)								X

Association for the Help to Leukaemia and Lymphoma patients (ZPL)				**X**				
Slovak Myelom Association (SMS)					**X**			

6. CONCLUSIONS AND RECOMMENDATIONS

6.1. Risks summary

Table 7: Risks and engagement recommendations summary

Scope	Risk	Recommended [the client] engagement
AREA 1: Policy, regulatory environment		
STRATEGIC	Government's populism and lack of long-term strategy in healthcare	Consistent contact-building and engagement strategy would facilitate strategic business planning and make government's measures predictable.
	Lack of political support for cancer prevention and cancer care	Constructively work with cancer stakeholders toward moving cancer higher on the political agenda.
TACTICAL	Pricing (changed referencing system), generics	[the client] can develop an advocacy strategy, engage with legislators, build a compelling case and try to facilitate adoption of legislation, which would mitigate or neutralize negative effects of the new pricing arrangements.
	Future potentially unfavourable regulation (value added of medicines, generics)	Adopt an engagement strategy with relevant decision makers in order to influence and shape the legislation in preparation so as to reflect [the client]' interests and best practices.
AREA 2: Expert Community		
STRATEGIC	Lack of state comprehensive cancer policy framework	Position [the client] as a positive driving force in the field.
	[the client]' good reputation not translated into visibility	Become active partner of expert groups, take initiative.
TACTICAL	Lack of research funding	Engage as a constructive partner and offer funding and cooperation on projects.
	Weakness of Slovak Oncology Society – no capacity for experts to substitute state in policy formation and implementation	Initiate and support activities of SOS and shape its agenda, become a reliable ally.
AREA 3: Patient Advocacy		
STRATEGIC	Lack of systematic approach of [the client] towards patient organizations, modest support and visibility	Systematic engagement strategy needs to be developed. [the client] should increase support and be made more visible among patients and patient groups.
TACTICAL	Fragmentation and weakness of patient groups	Provide education for patient group leaders, engage with umbrella organizations.
AREA 4: Industry & Competitors		
STRATEGIC	Weak enforcement, brute force competition	Increase cost of non-compliance for competitors, implement best practice into legislation.
TACTICAL	Slovak association of pharmaceutical companies	Increase [the client]' voice within the organization, take initiative.

AREA 5: Internal issues		
STRATEGIC	Lacking PA capacity	Establish PA team and develop a comprehensive and long-term PA strategy.
TACTICAL	CZ+SK management	Re-assess synergies and problems stemming from this based on rigorous analysis.
	Ethical conduct	Address indications of [the client]' unethical behavior vis-à-vis oncologists.

6.2. Engagement recommendations

6.2.1. Policy, regulatory environment

Findings

Government's criticism of healthcare reforms introduced under the previous Dzurinda government has resulted in a number of regulatory measures significantly affecting the pharmaceutical industry (e.g. categorization, pricing). The government lacks a consistent and long-term strategy in healthcare including oncology, hence its policy measures result from seeking short-term political benefits rather than tackling long-term deficiencies of the healthcare system (populism and unpredictability). [the client] has not developed a comprehensive strategy of engagement with key policy and decision-makers to detect threats and address challenges appropriately.

Objectives

- monitor developments of government's policy regarding the reversal of the previous healthcare reforms as well as cabinet's populism vis-à-vis the foreign capital (e.g. drive against 'excessive profits' of multinational corporations);
- manage regulatory and public policy threats (generics, value added of medicines) and capitalize on opportunities (standard diagnostic-therapeutic procedures, ethical code);
- constructively work with policy makers to mitigate negative effects of already adopted legislation (e.g. pricing);
- move cancer and National Oncology Program up the policy agenda – help create a coalition of policy and decision-makers supporting the plan;
- raise reputation of [the client] in key policy circles.

Activities

- monitoring and intelligence gathering regarding government's healthcare policy to ensure that [the client] is kept abreast of thinking of decision makers as this evolves. Early detection of threats (e.g. government's drive against foreign capital re-directed on pharmaceutical companies) can help [the client] mobilize resources in order to tackle risks appropriately;
- contact-building (one-to-one meetings) in order to ensure efficient communication of [the client]' key messages to decision-makers. Contact-building program constitutes a key in achieving an advantageous regulatory and legislative framework, makes the plans of decision-makers more predictable and increases the potential of influencing government's policies in

the specific area. Timely briefing of policy makers has the potential to assure that [the client]' concerns are taken into account in the process of legislation preparation. Importantly, contact-building program increases reputation of the company in the eyes of legislators (Members of the Committee of Healthcare and party leaders);

- moving cancer up the policy agenda and elaboration of a National Oncology Program are the most important justifications for one-to-one meetings. The aim of [the client] should be to create a coalition of policy makers (MPs as well as Ministry officials) endorsing a nation-wide cancer framework;
- organizing educational activities (conferences, seminars) for members of parliament (particularly members of the Committee for Healthcare) and party experts in close cooperation with oncology experts, dissemination of convincing arguments among politicians and officials and public information campaigns should play a vital role in [the client]' strategy to include cancer among the priorities of the healthcare policy. In addition, [the client] should make policy recommendations based on identification and sharing of best practices in national cancer plans in other EU countries (particularly using COS and Czech NOP as an example);
- increasing ethical standards in healthcare (implementation of ethical code into legislation), regulatory measures in preparation (generics, value added of medicines) or the impact of recently adopted pieces of legislation (particularly pricing) on the industry are among other pertinent debates, which could be used as justifications for one-to-one meetings;
- launching an advocacy campaign upon identification and definition of threats (e.g. pricing) or opportunities in order to minimize negative impacts of proposed legislation or capitalize on opportunities it presents.

6.2.2. Expert Community

Findings

Slovakia lacks a comprehensive national oncology plan, which presents an opportunity for [the client]' engagement. The Slovak oncology community is not active in policy-making and does not substitute the state in policy formation due largely passive Slovak Oncology Society, hence there is no visible positive driving force in the field. Although [the client] enjoys a relatively good reputation among experts, it is not translated into visibility and initiative.

Objectives

- profile [the client] as a thought leader and position the company as a positive driving force in the field;
- establish strong and lasting relationships with experts, engage beyond activities connected with supporting a specific product;
- support elaboration of National Oncology Program;
- help moving oncology higher on the political agenda.

Activities

- support education-related activities for oncologists and sponsor research projects; get Slovak oncologists involved in international clinical studies and fund internships abroad;
- establish a stable and long-term partnership with the Slovak Oncology Society – provide support for a platform fostering independent expert debate and not necessarily connected with specific [the client] products; [the client] will thus become distinguished from other pharmaceutical companies and will boost its reputation;
- initiate and sponsor a conference on national cancer framework (to include the expert community, policy makers, parliamentarians, patients and other third party stakeholders) and support establishment of platform (working group) within the Slovak Oncology Society aiming at coordinating and elaborating national cancer framework;
- together with SOS, initiate a debate on launching or re-launching of society-wide cancer prevention campaigns and co-fund selected program;
- provide support (financial, organizational) to update and upgrade SOS' internet website in order to serve as a comprehensive and independent source of oncology-related information for both patients and experts; there is currently no cancer-related internet information portal and SOS' website provides only the most basic information on its activities; lack of information related to cancer is considered a significant problem in Slovak oncology;
- assist top oncology experts in moving cancer up the public policy agenda by organizing educational activities for decision-makers.

6.2.3. Patient Advocacy

Findings

Patient organizations in Slovakia are largely fragmented, have weak leadership and suffer from low respect from authorities. Their leverage in policy formation and fostering debates is low largely due to poor dialogue with other oncology stakeholders and self-centered leadership. [the client] sponsors only minor cancer patient groups and is generally not visible in supporting patient advocacy. Education of patient groups and coordination of stakeholders present an opportunity for [the client] to increase its voice in the patient community.

Objectives

- make [the client] visible among cancer patients and patient groups;
- facilitate dialogue between patients and stakeholders (doctors, industry, policy-makers) in order to strengthen the role of patient groups and increase their leverage in policy making;
- establish relations with patient groups as a means to foster debates on cancer prevention and national cancer framework;

Activities

- establish long-term partnerships with important cancer patient groups, such as League Against Cancer and Association for Supporting Oncology Patients and initiate debates on cancer prevention and national cancer plan;
- consider supporting innovative modes of patient group funding (foundation for provision of project-based grants, percentage of revenue of pharmaceutical companies given to patient groups, etc.);
- organize education seminars for patient groups and their leaders, report on best practices in other countries, support involvement of Slovak cancer groups in EU-wide cancer patient campaigns, sponsor their participation on international meetings;
- organize joint forums for patient groups, doctors and interest groups – consider developing a standing platform for coordination and facilitation of mutual dialogue;
- initiate and become the main of partner of an oncology prevention education at schools co-organized by a reputable cancer patient group (e.g. League Against Cancer);
- capitalize on the long-term partnership with Europa Donna – co-sponsor a nation-wide breast-cancer information campaign and make [the client] visible alongside Avon Cosmetics.

6.2.4. Industry & Competitors

Findings

The industry has a relatively good reputation among the public. Nonetheless, given the perception of pharmaceutical companies to have large profit margins, government can focus its pressure on the industry in order to score political points among its electorate. It is therefore important to establish innovative drug producers as society's benefactors to prepare grounds for potential government attack on industry's 'inappropriate profits.' [the client]' competitors are known for back-door dealings with oncology stakeholders and benefit from weak enforcement of SAFS' ethical code. SAFS is often used as an instrument for interest advocacy of [the client]' competitors.

Objectives

- establish original pharmaceutical producers as companies benefiting the society;
- distinguish [the client] from its competitors and boost company's reputation;
- increase non-compliance costs for competitors;
- increase [the client]' role in SAFS and use association's leverage;
- use other relevant associations to create synergies in interest advocacy;

Activities

- based on effective communication with key decision-makers, support implementation of [the client]' best practice into legislation-based ethical code in order to increase cost of non-compliance for the competition;

- increase [the client]' voice in the Slovak Association of Pharmaceutical Companies by becoming a member of SAFS' Board and use its leverage in advocating regulatory changes (e.g. pricing, generics);
- become an active member in relevant trade associations, particularly the American Chamber of Commerce.

6.2.5. Internal issues

Findings

[the client] lacks a PA person responsible for legislative lobbying and a comprehensive PA strategy, which would systematically tackle government relations. Given the diverging Czech and Slovak healthcare systems, centralization of [the client] Oncology in the Czech Republic might present a hindrance to effective management of the company in Slovakia. Compared with competitors, [the client] significantly lags behind in provision of oncology-related information. Questions were raised about the effectiveness of internal communication of company' ethical code and compliance with SAFS' ethical code due to allegations of organizing generous trips for oncologists and family members.

Objectives

- improve external communication capabilities (PA, PR);
- increase efficiency of internal communication and decision-making;
- enforce ethical code internally;

Activities

- appoint a person responsible for public and regulatory affairs in order to address political and regulatory challenges appropriately;
- develop a comprehensive public affairs strategy for favorable legislative changes, build coalitions of interests, develop key messages;
- constructively and consistently work with the media (PR) in order to ensure appropriate coverage of positive news (e.g. innovations) pertinent for [the client] and to prevent unfavorable coverage if a negative issue arises;
- set up and fund an information internet web-site focused on oncology-related information and cancer prevention;
- re-assess synergies and problems stemming from concentration of decision-making in CZ based on rigorous analysis;
- address indications of [the client]' unethical behavior vis-à-vis oncologists by increasing enforcement of employees' compliance with company's internal ethical code and fostering efficiency of internal communication.