

Pharma Poland News

A prime source of market intelligence for pharma professionals

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Circulatory system diseases and cancer still leading causes of death in Poland

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Continued on page 4 ▶

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Overall market performance

After rising at a substantially lower rate in October, pharmacy sales in Poland decreased materially in November. The country's pharmacy market (measured as retail pharmacy sales) was worth a little over PLN 2.22bn (€562m) for the month, a drop of 6.1% compared with October and down by 4.5% year-on-year. However, the annual decline was due in large part to a very high reference base, as in November 2009 pharmacy sales soared by 19.5% y-o-y. It should be remembered that November 2009 marked the peak of last year's flu season, with sales additionally stimulated by media reports about the threat of a swine flu epidemic, whereas in the closing months of 2010 the incidence of flu and upper respiratory tract infections was at a moderate level¹.

In the first 11 months of 2010 the pharmacy market grew by 1.9% y-o-y to about PLN 24.2bn (€6bn). The rate of market growth was thus considerably lower than in the same period a year earlier, when it reached 8.9% y-o-y².

Given the low comparative base and an anticipated improvement in Poles' financial situation (thanks to economic recovery and an improving labour market), we expect a slight revival in pharmacy sales this year. We forecast that in 2011 the Polish pharmacy market will grow by about 4-5%.

Falling sales

The decline in pharmacy sales observed in November was due primarily to weaker sales of non-prescription products, which at PLN 784m (€198m) were 8.2% lower than in October and 10.9% lower than a year earlier (in November 2009 sales in this category jumped by an impressive 34.5% y-o-y). At the same time, reimbursed prescription sales decreased by more than 5% m-o-m, to PLN 1.02bn (€257m), whereas fully-paid prescription sales were down by 4.6% m-o-m to PLN 423m (€107m). In yearly terms the latter two categories recorded an increase of 0.9% and a drop of 3.9%, respectively (in November 2009 both enjoyed double-digit

increases, of 10.4% y-o-y and 15.4% y-o-y). As a result, sales of prescription medicines amounted to PLN 1.44bn (€364m) in November, a decline of nearly 5% versus October and down by 0.6% year-on-year.

In the first 11 months of 2010 sales of non-prescription products rose by 3.8% y-o-y. Reimbursed prescription sales grew by 2.5% y-o-y during this period, whereas fully-paid prescriptions saw a small decline (by 0.3% y-o-y).

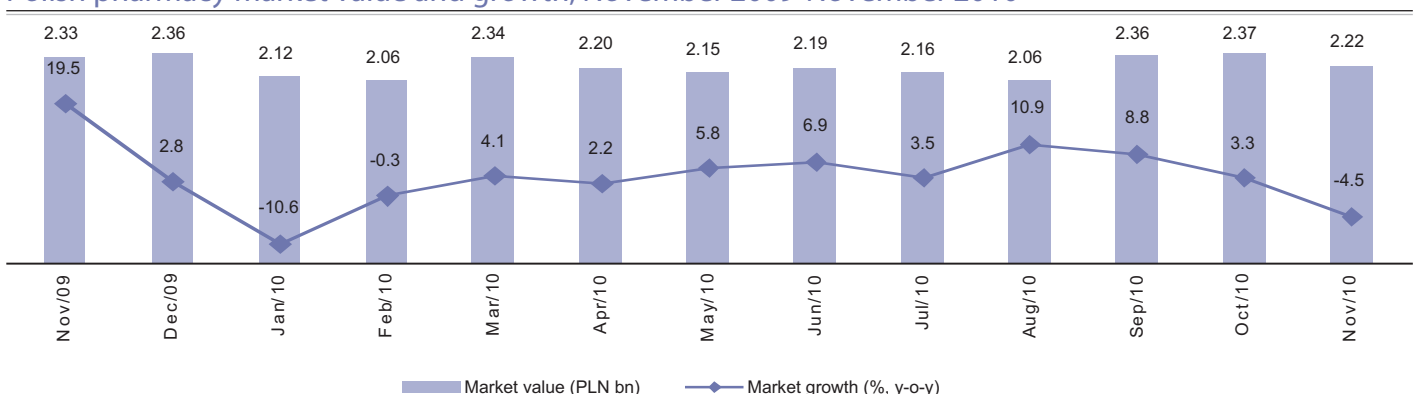
Rising drug prices

November was also the second consecutive month of rising prices. The average price of a medicine sold in a Polish pharmacy was 2.1% higher than in October, driven mainly by an increase in the prices of fully-paid prescription medicines, as the prices of OTC products grew by 1.8% over this period whilst the prices of reimbursed medicines actually fell by 0.6%.

In the period under analysis, the average price of a medicine sold in a Polish pharmacy was PLN 16.18 (€4.1), up 6.5% y-o-y (compared with an increase of 3.2% y-o-y in October), while the price of a reimbursed drug reached PLN 27.83 (€7), up by 1.6% y-o-y (against 2.1% y-o-y the month before). At the same time, the average price of an OTC product was PLN 9.73 (€2.5), 4.1% higher y-o-y (in October the year-on-year rise was 3.2%).

The rate of annual price growth in the pharmacy sector was thus well ahead of general inflation, which in November stood at 2.7% y-o-y.

Polish pharmacy market value and growth, November 2009–November 2010



Source: PharmaExpert, 2011

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¹ According to the National Institute of Hygiene (PZH), in November 2009 nearly 300,000 confirmed and suspected cases of flu were reported in Poland, whereas in the same period of 2010 the figure was a little over 70,000.

² According to preliminary estimates from PharmaExpert, in 2010 as a whole retail pharmacy sales rose by just under 2.8% (compared with growth of 8.3% in 2009).

Higher reimbursement value

Meanwhile Higher reimbursement value, the value of drug reimbursement amounted to PLN 732m (€185m) in November. This was up by 0.8% in relation to October and by 1.7% year-on-year.

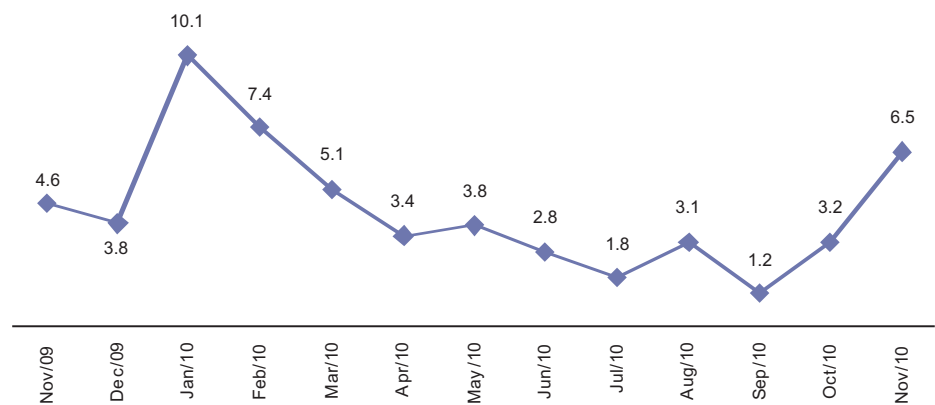
The concurrent sharp decline in overall pharmacy sales pushed the share of reimbursement in total pharmacy sales up by 1.8 p.p. compared with October, to 32.9% (it also represented a 2 p.p. increase versus November 2009). The share of state reimbursement in total sales of reimbursed medicines also grew in November after four straight months of declines: at 72.1%, it was approx. 3.2 p.p. higher than in October (when it sank to a two-year low) and more than 0.5 p.p. higher than a year earlier.

Margins reach record highs

After a temporary dip in October, margins resumed their upward climb in November and reached their highest level in more than a decade. The average pharmacy margin hit 28.2% for the month, up by 1.1 p.p. compared with October and by more than 0.8 p.p. year-on-year. Over the 12 months to November, the reimbursed medicines margin increased by 0.9 p.p. to 22%, whereas the margin on remaining products rose by 1.1 p.p. to 33.5%.

The data used in this article was sourced from PharmaExpert. All data at retail prices. Non-prescription sales include the sales of all products dispensed by pharmacies without prescription, including OTC drugs, dietary supplements, dermocosmetics and other.

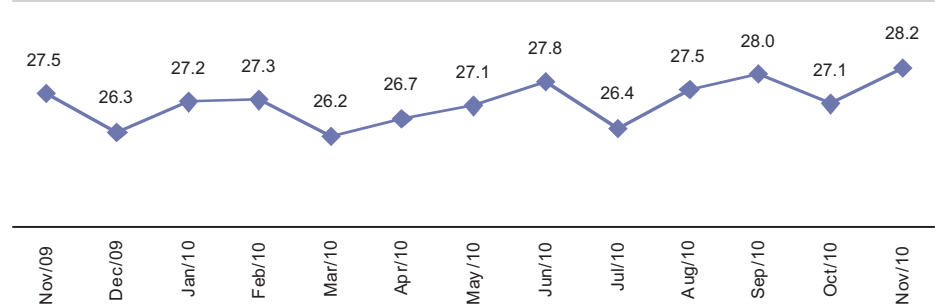
Average price of medicine sold in pharmacy in Poland (y-o-y change, %), November 2009-November 2010



Source: PharmaExpert, 2011

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Average pharmacy margin in Poland (%), November 2009-November 2010



Source: PharmaExpert, 2011

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A D V E R T I S I N G

Circulatory system diseases and cancer still leading causes of death in Poland

Cancer remains one of the leading causes of death in Poland. The country was just behind Hungary, which reported the highest death rate from cancer not only in the Central and Eastern Europe (CEE), but also among all 27 EU Member States. With regard to circulatory system diseases, Poland reported a death rate even higher than that pertaining to cancer, but significantly lower in comparison with the other CEE countries. It is also worth observing that the statistics in Poland, along with all CEE states (with the exception of Hungary), paint a better picture than that of the EU overall in the case of breast cancer.

Total death rates per 100,000 inhabitants in specific CEE countries were at their highest in Bulgaria (995.7) and at their lowest in the Czech Republic (747.1) in 2008, according to recently published Eurostat data, which also showed that Poland was below the threshold of 900 deaths in the year analysed, with 819 fatalities.

Low death rate from circulatory system diseases in Poland in comparison with other CEE countries

Diseases of the circulatory system (including those related to high blood pressure, cholesterol, diabetes, smoking and ischaemic heart disease) were the leading causes of death in the CEE countries during the period in question. Poland reported the highest death rate among all of the diseases analysed, but the figure was significantly lower than those of the other CEE countries and relatively close to the EU average. The highest rate from such diseases was reported in Bulgaria: 611.3, almost three times the EU average.

Among the circulatory system diseases, ischaemic heart disease was responsible for the highest death rates in specific countries, particularly Slovakia and Hungary. In Poland, however the rate of death from ischaemic heart disease was the lowest among all of the CEE countries: 102.2. Furthermore, the rate

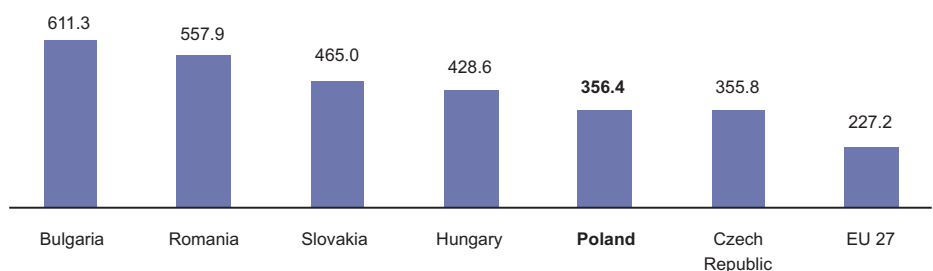
has been falling constantly since 2002, when the figure was 125.8.

Hungary and Poland had highest rates of death from cancer in 2008

Cancer was the second most pervasive cause of death in all of the CEE countries, but Hungary was the most severely affected by this disease, and the figure for this country, 241.7, exceeded not only those of all CEE countries but of all EU members. With regard to the CEE countries, Hungary was followed by Poland, and Bulgaria is the only CEE country whose cancer death rate fell short of the EU average.

Poland is next after Hungary in terms of the cancer death rate but has the National Programme for Fighting Neoplasm Diseases.

Circulatory diseases standardised death rate in CEE countries and EU average rate (per 100,000 inhabitants), 2008



Source: Eurostat, 2010

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The programme began in 2006, when PLN 250m (€65m) was allocated to combat cancer. However, according to the Supreme Audit Office (NIK), some of the tasks within the programme are being carried out incorrectly. The NIK examined the performance of selected tasks between 2006 and H1 2008, and some of them appeared to be unnecessary, incorrectly carried out or failures, particularly in the areas of funding, programme realisation controls, the quality of examinations, training for doctors and prevention. One example of a task incorrectly carried out was the number of mammography examinations, which had fallen year by year. In 2008 there were 755,000 such examinations, which is almost 20% fewer than the year before. Interestingly, however, there have also been successes, such as an increase of number of cervical cancer examinations, from 350,000 in 2006 to 754,000 in 2008. The total amount spent on the programme during this period was PLN 25m (€6m).

Furthermore, in 2010 the National Health Fund (NFZ) in Poland established an Oncology Group to define national standards of cancer treatment and monitoring. The Group consists of medical professionals and NFZ representatives.

Poland exceeds EU average rate of death from lung, colorectal and uterus cancer

With regard to the various forms of cancer as causes of death, it is surprising that in Poland death caused by breast cancer was the only kind of cancer below the EU average. With regard to lung, colorectal and uterus cancer, Poland reported death rates above the EU average: 54.5, 22.1 and 12.1 respectively.

At the other end of the scale, Hungary recorded the highest death rates in CEE caused by cancer of other kinds: lung, colorectal and

uterus cancer. Slovakia had the second-highest death rates in CEE in terms of colorectal and uterus cancer but had the lowest rate in CEE in terms of lung cancer as the cause of death.

Poland has average pneumonia death rate but is still above the EU average

Slovakia reports the highest rate of death (30.7) from pneumonia in 2008 among the CEE countries. The death rate in Slovakia, although it remained above 30, has been showing a gradual improvement since 2002.

At the other end of the spectrum, Hungary is the only CEE country whose rate of 4.7 appeared to be well below the EU average (14.8). Poland was placed in the middle of the scale, with a death rate of 19, but still above the EU average. This proves only that the main causes of death in the latter country are still cancer and circulatory system disease.

Poland has comparatively low rate of death from chronic liver disease

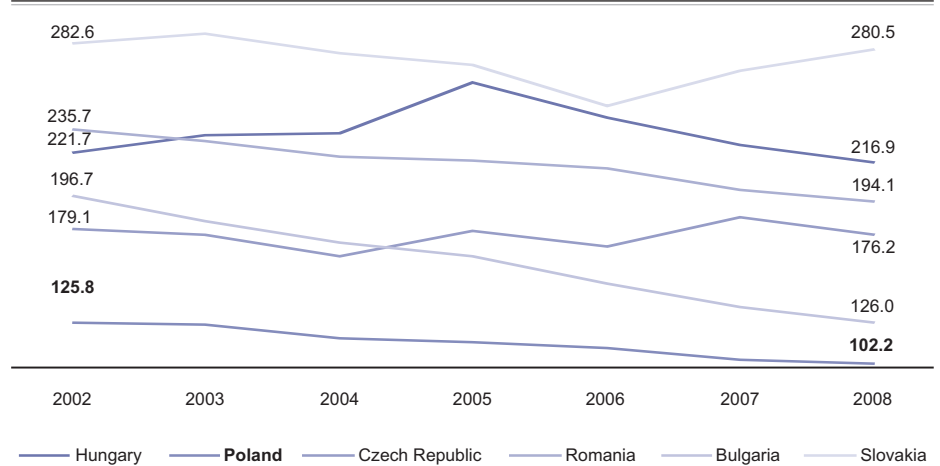
The highest rates of death from chronic liver disease were reported in Romania and Hungary, with both countries above 40. Poland, in comparison with those two countries, reported a relatively low rate, of 17.4, which is very close to the EU average of 13.8.

Diabetes caused more deaths in Hungary and Bulgaria than elsewhere in 2008

The highest rates of death caused by diabetes mellitus in 2008 were reported in Hungary and Bulgaria: 19.4 and 18.1 respectively. These two, along with Poland and the Czech Republic, were above the EU average rate, whereas Slovakia and Romania were well below the average rate.

In Poland, despite the fact that the death rate was relatively low in comparison with the worst two countries, the level of public awareness of the disease – its causes, complications and forms of prevention – is noticeably limited, according to a new report from TNS OBOP and the National Coalition Against Diabetes (KRWC). The study shows

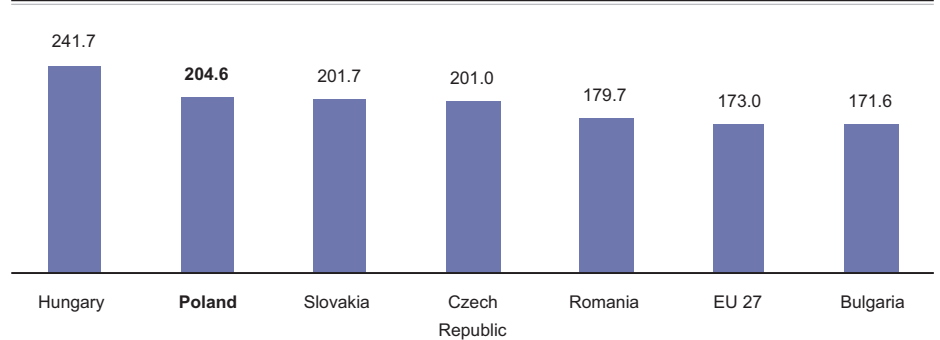
Ischaemic heart diseases standardised death rate in CEE countries (per 100,000 inhabitants), 2002-2008



Source: Eurostat, 2010

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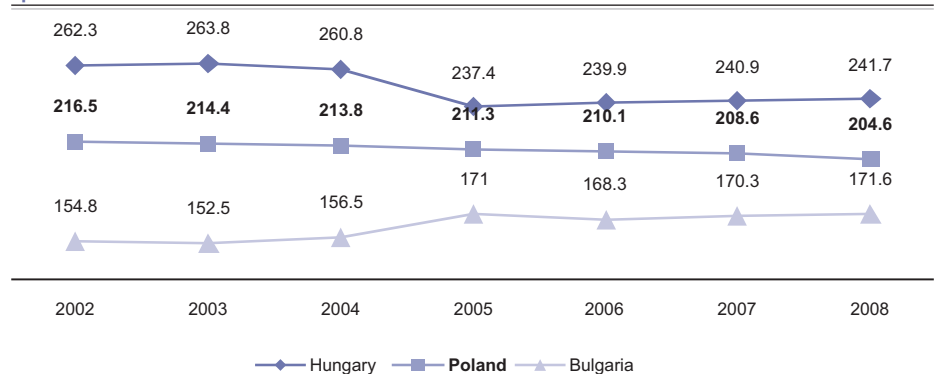
Cancer standardised death rate in CEE countries and EU average rate (per 100,000 inhabitants), 2008



Source: Eurostat, 2010

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Cancer standardised death rate in Hungary, Poland and Bulgaria (per 100,000 inhabitants), 2002-2008



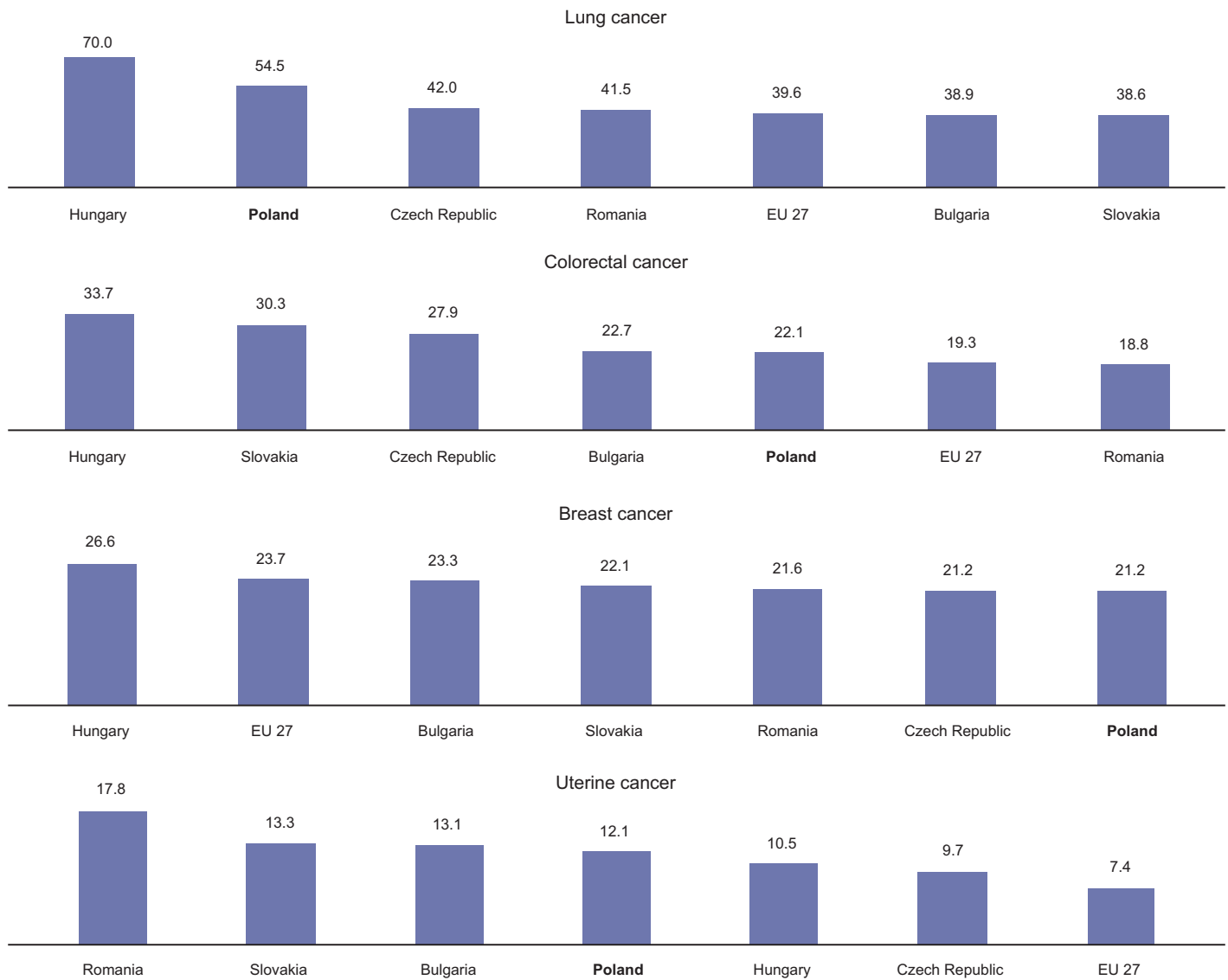
Source: Eurostat, 2010

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that few Poles link diabetes to lifestyle factors, and that 5% of the public actually believe that the disease spreads by contagion. Furthermore, as many as 35% of the respondents were unable to name even a sin-

gle symptom of diabetes, and one in five had never had a blood glucose test. This low level of awareness makes prevention efforts difficult, and leads to a situation in which an estimated 30% of people with diabetes, i.e. some

Standardised death rate from different forms of cancer in CEE countries and EU average rate (per 100,000 inhabitants), 2008



Source: Eurostat, 2010

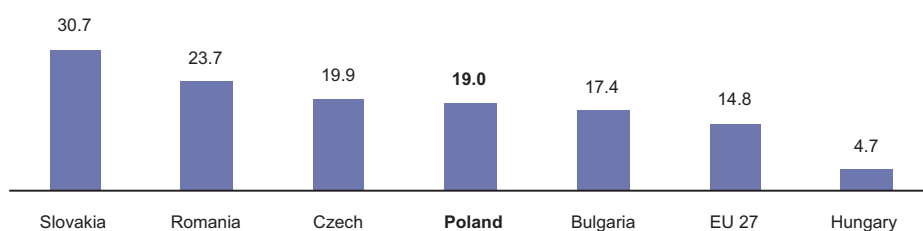
750,000 Poles, have not been diagnosed with it. Andrzej Bauman, the CEO of the Polish Diabetes Association in Poland, told Pharma Poland News that there has never been a diabetes prevention programme which would increase awareness among the Polish public, and the association therefore perceives the awareness level as being very low.

Methodology note

Data on causes of death (COD) provide information on mortality patterns and form a major element of public health information. COD data refer to the underlying cause which – according to the World Health Organisation (WHO) – is “the disease or injury which initiated the train of morbid events leading directly to death, or the circumstances of the accident or violence which produced the fatal injury”. Causes of death are classified in terms of the 65 causes of the “European shortlist”. This shortlist is based on the International Statistical Classification of Diseases and Related Health Problems (ICD).

COD data are derived from death certificates. The medical certification of death is obligatory in all Member States. Countries separate the information provided in the medical certificate pertaining to cause of death into ICD codes in accordance with the rules specified in the ICD. Data are broken down by sex, 5-year age groups and cause of death. The death rate of a population is adjusted to a standard age distribution.

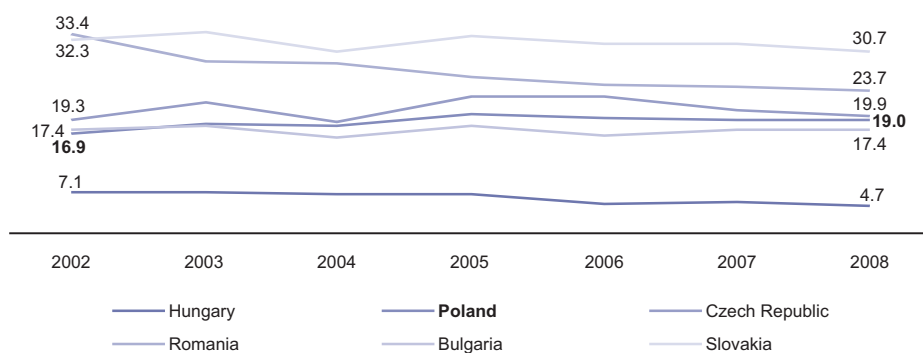
Pneumonia standardised death rate in CEE countries and EU average rate (per 100,000 inhabitants), 2008



Source: Eurostat, 2010

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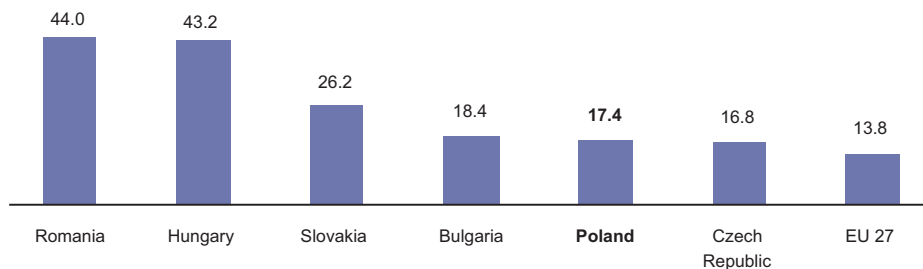
Pneumonia standardised death rate in CEE countries (per 100 000 inhabitants), 2002-2008



Source: Eurostat, 2010

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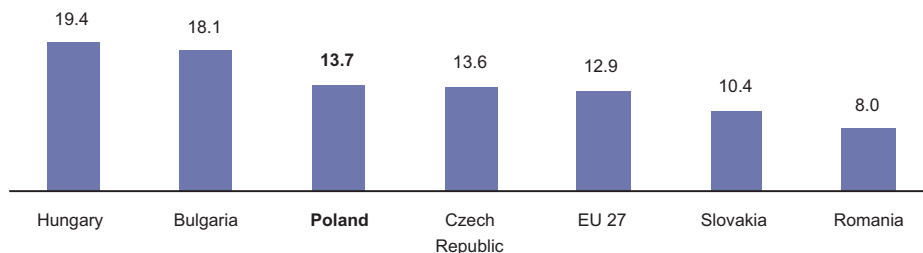
Chronic liver standardised death rate in CEE countries and EU average rate (per 100,000 inhabitants), 2008



Source: Eurostat, 2010

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Diabetes mellitus standardised death rate in CEE countries and EU average rate (per 100,000 inhabitants), 2008



Source: Eurostat, 2010

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The market for NFZ-funded dental care services: a brief overview

Dentistry is the most thoroughly privatised part of the healthcare landscape in Poland, not only in terms of provider ownership but also in terms of the role of state funding. Although the scope of dental treatment that is subject to financing by the National Health Fund (NFZ) is limited, demand for such services is nevertheless substantial. However, this potential is not matched by proportionate NFZ expenditures.

Lower value of NFZ dental care contracts in 2010

In 2010 the aggregate value of contracts signed by the National Health Fund with dental clinics and practices declined by 9% compared with the year before. This came after five years of steady increases, with NFZ expenditures on dental care rising from less than PLN 1bn (€0.25bn) in 2005 to just under PLN 2bn (€0.5bn) in 2009. Even so, throughout the 2005-2009 period dental care accounted for roughly 3-4% of the Fund's annual spending on healthcare services. Only in 2008 did spending on dental care rise sharply, which was made possible by three consecutive years of very strong economic growth. But in 2009, when the global economy was plunged into a crisis and GDP growth in Poland slowed abruptly, expenditures on dental care rose only slightly. Poland's fiscal problems deepened in 2010, which together with the shifting away of the Fund's financing priorities towards other areas was one of the main reasons for the decline in the value of dental care contracts last year.

Limited scope of state-funded dental care

The scope of dental care procedures covered by mandatory health insurance is set forth in the Minister of Health Regulation of 30 June 2009 (Dz.U.09.140.1144). It is limited to procedures aimed at the elimination of a health problem (e.g. through tooth extraction), whereas procedures that improve the patient's comfort or appearance are very restricted.

amalgam, but they have not been proven as yet. A resolution of the Council of European Dentists (CED) of 27 May 2006 stipulates that both the effectiveness and safety of dental amalgam as a material for dental fillings has been demonstrated by years of long usage. Therefore, one should not expect the Health Ministry to change its stance on the issue in the near future.

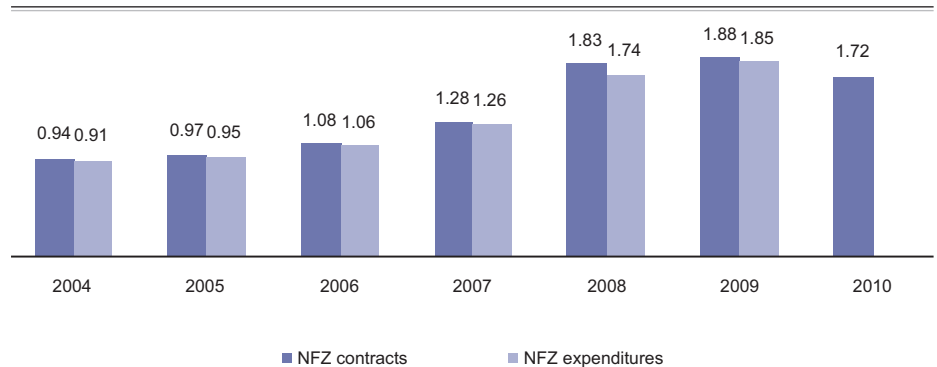
The only dental procedure funded by the state that can be described as an aesthetic one is the orthodontic treatment of malocclusion in children aged up to 12 years.

Benefits of an NFZ contract

In 2008 there were approximately 22,000 dental practices operating in Poland, of which just 8,700, or about 40% of the total, had a contract with the NFZ. The proportion of NFZ contractors among dental clinics varied substantially between voivodships, ranging

The scope of prosthetic dental procedures covered by mandatory insurance includes acrylic prostheses to replace between 5 and 8 missing teeth. State-funded dental fillings are amalgam fillings (mercury mixed with silver, tin, copper, cadmium). Once every few years there are reports about the harmfulness of

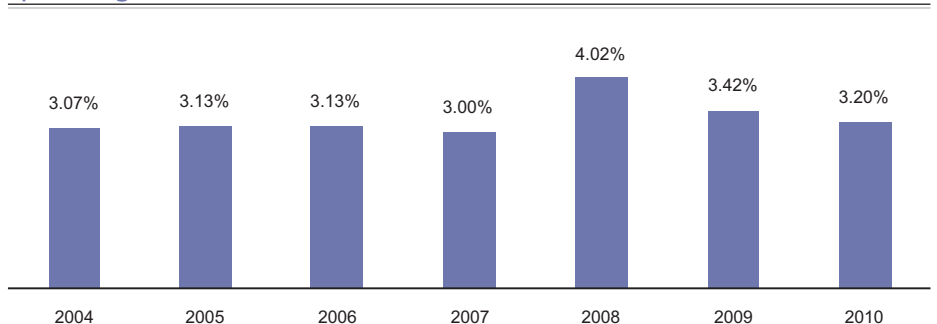
Value of NFZ dental care contracts and expenditures (PLN bn), 2004-2010



Source: NFZ, 2011

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Value of dental care contracts as proportion of NFZ's total planned spending on healthcare services, 2004-2010



Source: own calculation based on NFZ data, 2011

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from just over 20% in Mazowieckie to more than 90% in Kujawsko-Pomorskie.

Despite complaints by dental clinics about highly unfavourable financial terms of NFZ contracts, provider turnover in this category is very limited (analysis shows that the turnover rate was only 3% in 2008-2009 and just 1% in 2009-2010). This suggests that there are other tangible benefits to be derived from NFZ contracts, and confirms that there is demand from patients for NFZ-funded dental care services.

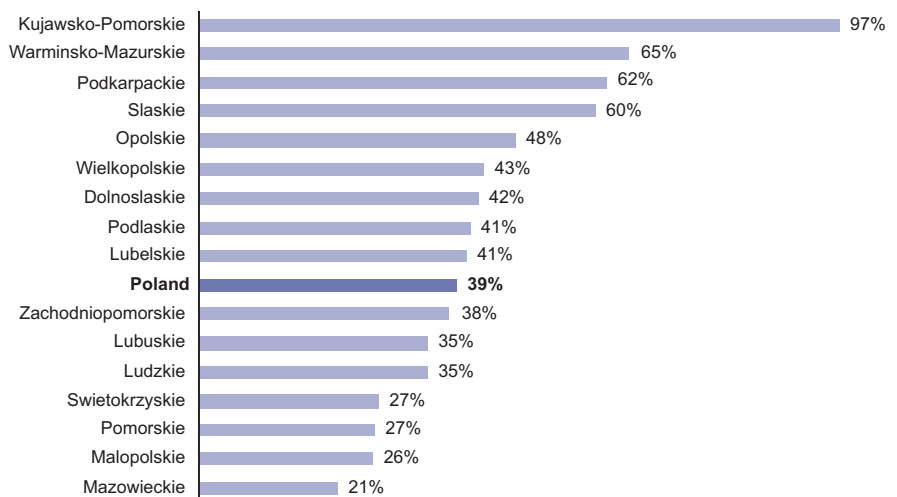
For a dental clinic, the signing of a contract with the Fund provides an additional and steady source of revenue. It also represents an important asset in attracting patients, especially at a time when cuts in state spending are forcing them to pay for treatment out of their own pockets. In such circumstances, any degree of NFZ reimbursement offered by a clinic may be what persuades the patient to choose it over a competitor with no funding from the NFZ.

Substantial regional disparities in access to NFZ-funded dental care

The value of dental care contracts in each of the country's 16 voivodships is determined by local branches of the NFZ. This leads to local differences in the per patient value of NFZ spending on dental care.

The average annual NFZ per capita spending on dental care is approximately PLN 45 (€11.3). Although differences at the voivodship level are not that significant, at the level of districts they are very substantial. The sums involved range from PLN 298 (€74.7) per patient in the district of Węgorzewo to PLN 1.82 (€0.46) in Warsaw. For many patients this means long trips in search of clinics with NFZ contracts. It also means unused capacity in regions with an oversupply of such clinics.

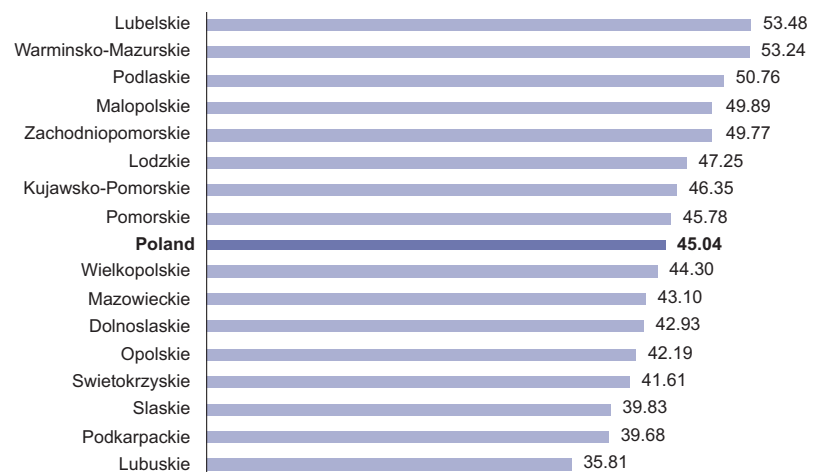
Dental practices with NFZ contracts as proportion of all dental practices in Poland, by voivodship, 2008



Source: own calculation, based on data from the NFZ and the Central Statistical Office (GUS), 2011

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Per capita value of NFZ dental care contracts (PLN) by voivodship, 2010



Source: own calculation based on NFZ and GUS data, 2011

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Per capita value of NFZ dental care contracts (PLN) in selected districts, 2010

Rank	District	Amount per inhabitant
1	Węgorzewo	298.08
2	Brzeziny	246.17
3	Bierun-Ledziny	196.52
4	Ostrow Wielkopolski	135.24
5	Town of Zamosc	123.96
6	Town of Nowy Sacz	114.68
....		
374	Suwalki	15.78
375	Lomza	13.87
376	Piotrkow Trybunalski	12.56
377	Pruszkow	10.82
378	Walbrzych	7.64
379	City of Warsaw	1.82

Source: own calculation based on NFZ and GUS data, 2011

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Central European countries disinclined to boost consumption of innovative drugs

Most pharmaceutical markets in the Central European countries are dominated by generic medicines. No significant increase in the share of innovative medicines is expected in the very near future, because in 2009 and 2010 governments were aiming to boost generic consumption and therefore limit national spending on more expensive innovative medicines. Plans announced for future changes are in step with these prior activities.

Price cuts aimed at healthcare budget savings

In 2010 several actions were taken by Central European governments with the aim of saving money in the healthcare arena.

For example, in Bulgaria a multilateral agreement was signed between the Bulgarian National Health Insurance Fund (NHIF), pharmaceutical manufacturers and wholesalers, and organisations representing doctors and patients, during a meeting held on 30 April 2010. The innovative pharmaceutical manufacturers (24 companies belonging to the Association of Research-Based Pharmaceutical Manufacturers) agreed to offer a 5% discount on all drugs for which the NHIF pays between June and December 2010. If all pharmaceutical manufacturers adhered to this agreement, this would save the NHIF approximately BGN 1.5m (€0.7m) per month.

In October 2010 the Slovak Health Ministry re-introduced the degressive margin on medical supplies to hospitals. The ministry believes that this is an effective instrument for the regulation of drug consumption in Slovakia and for reductions in the costs associated with drug policy. It expects cost savings of approximately €10m per annum.

In the Czech Republic in 2009 the State Institute for Drug Control (SUKL) concentrated on changes to ex-factory prices for reimbursement medicines, which were started ex officio in 2008. In 2009, maximum prices were reduced for 390 SUKL codes (by 29% on average), and increased for 190 SUKL codes (by 84% on average). The SUKL expected to save CZK 2.4bn (€94.9m) by means of the

revision of the prices of 1,270 reimbursed drugs introduced on 1 April 2010. As a result of this, health insurance companies would pay the same amount for drugs with the same active ingredient, adjusted to the price of the cheapest alternative.

Poland: will legal regulations hamper innovation?

As clinical trials are one of the main modes of access to the most innovative medicines for Polish patients, it is quite easy to recruit clinical trial participants in Poland, in comparison with other countries. The potential of clinical trials in Poland is, however, not used to the full, as a similar number of trials (450-500 per annum) are carried out in, for example, Hungary and the Czech Republic, countries with smaller populations. One of the reasons for this is the ambiguous legislation, which, according to the results of a survey carried out by PMR specifically for the purposes of the *Clinical trials in Poland 2010* report is the second most obstructive obstacle to the development of companies operating on the Polish clinical trials market: this was indicated by 37% of respondents.

There is no single legal act in force in Poland, which would regulate the clinical research market comprehensively. The relevant provisions pertaining to the clinical trials market are contained in various legal acts of various categories, including those relating solely to the pharmaceutical market (e.g. the Pharmaceutical Law), but also the Civil Code and the Penal Code. It is also worthy of note that provisions of various acts are frequent-

ly inconsistent with each other. In December 2009 the Ministry of Health published the assumptions underlying the Clinical Trials Act, but the act still has not come into force.

Another problem is VAT applied on clinical trials. In these area Poland has still not harmonised its legislation with the European Union directives. Pursuant to the so-called VI EU Directive, expert services, including clinical research, should be subject to taxation only in the country of the client; nevertheless, most companies operating in Poland pay 22% VAT (23% VAT rate from 2011) as the monitoring of clinical trials, according to the effective statistical classification can be classified into four different groups of services and which group it is categorised under depends on the civil servant's interpretation.

A client from an EU member state or Switzerland commissioning the organisation of a clinical trial in Poland can request to be reimbursed for the tax; however, the reimbursement is very time-consuming. The situation is even more difficult in the case of firms headquartered in the United States where there is no such thing as VAT. For them the 22% VAT comprises an additional cost. Thus, these firms most often decide to conduct clinical trials in countries other than Poland.

Improvement in these areas would not only lead to an increase in the number of clinical trials conducted by international concerns in Poland (which would improve patient access to innovations) but could also encourage domestic manufacturers to invest in innovative medicines. This could, in the longer term, prompt an increase in the share of innovative medicines as a proportion of the Polish pharmaceutical market, which is one of the less substantial in Central Europe.

Hungary: R&D expenditures no longer tax-deductible

A Hungarian government proposal suggests that drug manufacturers in Hungary will no longer be able to deduct their R&D expenses from the fee of the medical sales representative and the 12% tax on revenues from reimbursed drugs paid to the National Health Insurance Fund (OEP). The legislative changes could constitute a burden for some of the largest drug manufacturers on the Hungarian pharmaceutical market. These include Egis and Gedeon Richter, which paid HUF 1.8bn (€648m) and HUF 2.1bn (€756m) respectively to the OEP in 2009. This could also adversely affect manufacturers of innovative

drugs, which may, as a result, reduce their R&D spending. The deduction was introduced in 2009, when 20% of the R&D costs could have been subtracted from the expenditures, and this was increased to 100% in 2010.

The Hungarian government is also planning to change the existing system which involves obligatory courses for doctors who allegedly prescribe excessively expensive medicines. It hopes, instead, to convince doctors to prescribe cheaper generic drugs, thus saving public money by establishing an incentive system. It is estimated that HUF 3-4bn (€11-14m) could be saved every year if the doctors used the system. Furthermore, pharmacists would also be involved and rewarded when they replace a prescribed medicine with the product with the lowest reimbursement level.

Slovakia: reimbursement reform to boost generic consumption

After an allegation that the Categorisation Committee lacked transparency, the Slovak Health Ministry has decided to make drug

policy more open and the individual steps within the categorisation process of drug reimbursement more transparent. Several regulations pertaining to the drug reimbursement system could come into force in Slovakia in 2011.

The proposed changes in the area of generic and innovative medicines include the earlier appearance of generics and conditional drug categorisation, along with the introduction of API prescription by doctors.

The proposed changes will allow the submission of applications for the categorisation of new drugs before a decision on their registration has been made. As a result, the assessment of applications for registration and categorisation will be carried out simultaneously. The ministry believes that this move will accelerate the arrival of cheaper generics on the market and save about €5m per annum.

The Health Ministry is also considering the introduction of new regulations which will stipulate that doctors in Slovakia should prescribe only the active pharmaceutical ingredient (API) instead of the specific drug name. A pharmacist would then advise patients on the drugs available, particularly those which

carry the lowest co-payments, and patients would take the final decision. The new system would not cover all drugs – cancer and psychiatric medication would still be a matter for the doctor. At the moment, the schedule for the introduction of the new prescription system is not clear.

More information on the generic and innovative drug market in Central Europe, along with the reimbursement policies of individual countries, can be found in the PMR report entitled “Generic and innovative drug market in Central Europe 2011. Comparative analysis, reimbursement policies and development forecasts 2011-2013”.

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A D V E R T I S I N G

Drug withholds, withdrawals and relaunches in Poland, December 2010

	Date	Marketing authorisation holder	Product	Pharmaceutical form	Pack size	Series
Withholds	3 December 2010	Pfizer Europe MA EEIG	Carboplatin Pfizer 10 mg/ml	Injection solution	1 phial 450 mg/45 ml	EL17D
	7 December 2010	Teva Pharmaceuticals Polska Sp. z o.o.	Metformax 1,000	Coated tablets	30 tablets 1,000 mg	21M095
	9 December 2010	Omega Rex J. Jablczynski, K. Dobrowolski S.J.	Grypostop	Coated tablets	325 mg + 30 mg + 15 mg	0710239
	10 December 2010	Omega Rex J. Jablczynski, K. Dobrowolski S.J.	Grypostop	Coated tablets	12 tablets 325 mg + 30 mg + 15 mg 24 tablets 325 mg + 30 mg + 15 mg	0110239, 0109230, 0211239
Withdrawals	13 December 2010	Omega Rex J. Jablczynski, K. Dobrowolski S.J.	Grypostop	Coated tablets	12 tablets 325 mg + 30 mg + 15 mg 24 tablets 325 mg + 30 mg + 15 mg	0610239, 0411239, 0109239, 0209239, 0210239, 0310239, 0410239, 0510239, 0111239, 0311239, 0301230, 0401230, 0501230, 0601230
	23 December 2010	GlaxoSmithKline Export Ltd.	Poetra (Quetiapinum)	Coated tablets	30 tablets 25 mg	F20265
	23 December 2010	Bio-Trends Polska Sp. z o.o.	Intim-X, Intim-Y	Capsules	-	0011209, 009.210, Y010309
Relaunches	17 December 2010	+Pharma Arzneimittel GmbH	Limeral	Tablets	30 tablets 1 mg 30 tablets 2 mg 30 tablets 3 mg 30 tablets 4 mg	F14852, F14843, F14900, F14934
	20 December 2010	Ebewe Pharma GmbH Nfg KG	Cisplatin-Ebewe 0.5 mg/ml	-	1 phial 10 mg/20 ml 1 phial 50mg/100ml	95477912, 95511704

Source: Main Pharmaceutical Inspectorate (GIF), 2011

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A D V E R T I S I N G

Drugs approved for trading in Poland, November 2010

No	Drug name	Commonly used drug name	Pharmaceutical form	Dose	Pack size	Availability category	Marketing authorisation holder	Manufacturer	Country of manufacturer
1	Allopurinol Teva	Allopurinolu m	Tablets	100, 200, 300 mg	30, 50, 100 tablets	Rx	Teva Pharmaceuticals Polska Sp. z o.o.	Teva Sante SA Teva UK Ltd. Teva Pharmaceutical Works Private Limited Company Pharmachemie B.V.	France Great Britain Hungary Netherlands
2	Alizepil ODT	Donepezili hyd rochloridum	Orodispersible tablets	5, 10 mg	28, 30, 50, 56, 60, 98, 120 tablets	Rx	Egis Pharmaceuticals PLC	Genepharm S.A.	Greece
3	Amoclan BID	Amoxicillinum + Acidum clavulanicum	Oral suspension powder	(400 mg + 57 mg)/50 ml	1 bottle 6.75, 13.51 g	Rx	Hikma Pharmaceutica S.A.	Hikma Pharmaceutica S.A.	Portugal
4	Amoxicillin/Ciavulanic acid Aurobindo	Amoxicillinum + Acidum clavulanicum	Coated tablets	500 mg + 125 mg, 875 mg + 125 mg	4, 5, 6, 7, 8, 10, 12, 14, 15, 16, 20, 21, 25, 30, 35, 40, 50, 100, 500 tablets	Rx	Aurobindo Pharma Limited	Milpharm Limited APL Swift Services Ltd.	Great Britain Malta
5	Artizin	Cetirizini dihydrochloridum	Coated tablets	10 mg	10, 20 tablets	Rx	Tabuk Poland Sp. z o.o.	Medana Pharma S.A.	Poland
6	Ascalin Plus o smaku malinowym	Acidum acetylsalicylicum + Acidum ascorbicum + Calcium	Effervescent powder	500 mg + 300 mg + 200 mg	6, 10, 14, 20, 28 sachets	OTC	Zakłady Polfa-Lodz S.A.	Zakłady Farmaceutyczne Polfa-Lodz S.A.	Poland
7	Atorvastatin -1A Pharma	Atorvastatinum	Coated tablets	10, 20, 40, 80 mg	30, 60, 90 tablets	Rx	1A Pharma GmbH	Salutas Pharma GmbH Lek S.A. Lek Pharmaceuticals d.d.	Germany Poland Slovenia
8	Atosener	Atorvastatinum	Coated tablets	10, 20, 40, 80 mg	30, 50, 100 tablets	Rx	Sandoz GmbH	Salutas Pharma GmbH Lek S.A. Lek Pharmaceuticals d.d.	Germany Poland Slovenia
9	Bisfozen	Acidum alendronicum	Tablets	70 mg	4, 8, 12 tablets	Rx	Zentiva k.s.	Zentiva k.s.	Czech Republic
10	Carbomedac	Carboplatinum	Infusion solution concentrate	10 mg/ml	1 phial 5, 15, 4 5, 60, 100 ml	Lz	medac Gesellschaft für klinische Spezialpräparate mbH	medac Gesellschaft für klinische Spezialpräparate mbH	Germany
11	Circlet	Etonogestrelum + Ethinylestradiolum	Therapeutic vaginal system	(0.120 mg + 0.015 mg)/24 h	1, 3 sachets	Rx	N.V. Organon	Organon Ireland Ltd. N.V. Organon	Ireland Netherlands
12	Ciazistada	Gliclazidum	Modified release tablets	30 mg	10, 20, 28, 56, 60, 90, 98, 120 tablets 30, 100, 180 tablets in blisters 30, 100, 180 tablets in a bottle	Rx	Stada Arzneimittel AG	Stada Arzneimittel GesmbH Sanico N.V. Eurogenerics N.V. Stada Arzneimittel AG PharmaCoDane ApS, Lamp Sp Prospero Sp.A Clonmel Healthcare Ltd. Actavis hf. Centrafarm Services B.V.	Austria Belgium Germany Denmark Italy Ireland Iceland Netherlands
13	Contexine	Ropinirolum	Coated tablets	0.25, 0.5, 1, 2, 5 mg	21, 84 tablets	Rx	Ranbaxy (Poland) Sp. z o.o.	Centre Specialites Pharmaceutiques (CSP) Ranbaxy Ireland Limited Terapia S.A.	France Ireland Romania

14	Donepezil Bluefish	Donepezil hydrochloridum	Coated tablets	5, 10 mg	28, 56, 98, 100 tablets	Rx	Bluefish Pharmaceuticals AB	Sweden
15	Euroclast	Atorvastatinum	Coated tablets	10, 20, 40, 80 mg	30, 50, 100 tablets	Rx	Salutas Pharma GmbH Lek S.A. Lek Pharmaceuticals d.d.	Germany Poland Slovenia
16	Finasteride Eurogenus	Finasteridum	Coated tablets	5 mg	28 tablets	Rx	Eurogenus Farmaceutica Sociedade Unipessoal Lda	Italy Portugal
17	Flavamed	Ambroxoli hydroch loridum	Effervescent tablets	60 mg	10, 20 tablets 10, 20, 28, 56, 60, 90, 98,	Rx	Berlin-Chemie AG	Germany
18	Gliclazide Gentian Generics	Gliclazidum	Modified release tablets	30 mg	120 tablets 30, 100, 180 tablets in blisters 30, 100, 180 tablets in container	Rx	Gentian Generics Limited	Iceland
19	Gluscan PL	Fludeoxyglucosum [18 F]	Injection solution	500 MBq	1 phial	Rx	Advanced Accelerator Applicati Advanced Accelerator Applicati Applications	France Italy
20	Haepcard	Atorvastatinum	Coated tablets	10, 20, 40, 80 mg	30, 50, 100 tablets	Rx	Sandoz GmbH	Germany Poland Slovenia
21	Kalium chloratum 15% Kabi	Kalii chloridum	Concentrate for infusion solution	150 mg/ml	20 ampoules 5, 10, 20 ml 50 ampoules 5, 10 ml	Rx	Fresenius Kabi Polska Sp. z o.o.	Spain
22	Lorista HL	Losartanum kalicum + Hydrochlorothiazidum	Coated tablets	100 mg + 12.5 mg	28, 56 tablets	Rx	Krika d.d., Novo mesto	Slovenia
23	Methadone Hydrochloride Molteni	Methadoni hydrochloridum	Syrup	5 mg/ml	1 bottle 20, 1,000 ml	Rpw	L.Molteni & C. dei F.lli Alitti Societa di Esercizio S.p.A.	Italy
24	Montelukast Sunfarm	Montelukastum	Chewable tablets	4, 5 mg	14, 28, 98 tablets	Rx	Sun-Farm Sp. z o.o.	Portugal
25	Montelukast Sunfarm	Montelukastum	Coated tablets	10 mg	14, 28, 98 tablets	Rx	Sun-Farm Sp. z o.o.	Portugal
26	Montexal	Montelukastum	Chewable tablets	4, 5 mg	14, 20, 28, 30, 50, 98, 100 tablets	Rx	ICN Polfa Rzeszow S.A.	Portugal
27	Montexal	Montelukastum	Coated tablets	10 mg	14, 20, 28, 30, 50, 98, 100 tablets	Rx	ICN Polfa Rzeszow S.A.	Portugal
28	Nasic Kids	Xylometazolini hydrochloridum + Dexpanthenolum	Nasal spray, solution	(0.05 mg + 5 mg)/dose	1 bottle 10 ml	OTC	JPZ Firma Doradcza Joanna Pleszczynska-Zawisza	Germany
29	Nicorette Icy White Gum	Nicotinum	Chewing gum, medicated	2, 4 mg	10, 12, 15, 30, 105, 210 pieces	OTC	McNeil AB	Sweden
30	Ondansetron Pfizer	Ondansetronum	Orodispersible tablets	8 mg	6, 10, 30, 50, 100 tablets	Rx	Pfizer Europe MA EEIG Pfizer Italia S.r.l.	Belgium Italy
31	Orocal D3 Lemon Plus	Calcium + Cholecalciferolum	Chewable tablets	500 mg + 800 IU	30, 60 tablets	Rx	Nycomed Pharma Sp. z o.o.	Estonia Norway
32	Orocal D3 Orange Plus	Calcium + Cholecalciferolum	Chewable tablets	500 mg + 800 IU	30, 60 tablets	Rx	Nycomed Pharma Sp. z o.o.	Estonia Norway
33	Oxycodon Acino	Oxycodoni hydrochloridum	Extended release tablets	5, 10, 20, 40, 80 mg	20, 50, 100 tablets	Rpw	Acino AG	Germany
34	Palandra	Drosiprenonum + Ethinyloestradiolum	Coated tablets	3 mg + 0.03 mg	21, 63, 126 tablets	Rx	Bayer Schering Pharma AG	Germany

35	Pantoprazole Olinka	Pantoprazolum	Intestinal tablets	20, 40 mg	14, 28, 100 tablets in blisters 14, 28, 100 tablets in a bottle	Rx	Olinka (UK) Limited	Laboratorios Belmac S.A.	Spain
36	Pantoprazole Phargem	Pantoprazolum	Intestinal tablets	20, 40, mg	14, 15, 28, 30, 60, 100 tablets	Rx	Phargem Sp. z o.o.	Laboratorios Belmac S.A.	Spain
37	Primacor	Lercanidipini hydrochloridum	Coated tablets	20 mg	7, 14, 28, 35, 42, 50, 56, 98, 100 tablets	Rx	Berlin-Chemie AG	Berlin-Chemie AG (Menarini Group) Recordati Industria Chimica e Farmaceutica S.p.A.	Germany Italy
38	Reprifax	Naratriptanum	Coated tablets	2.5 mg	2, 6 tablets	Rx	Sandoz GmbH	Salutas Pharma GmbH Lek S.A. S.C. Sandoz S.R.L. Lek Pharmaceuticals d.o. Lek Pharmaceuticals d.o.	Germany Poland Romania Slovenia
39	Risperidon Stada	Risperidonum	Orodispersible tablets	1, 2 mg	20 tablets	Rx	Stada Arzneimittel AG	Stada Arzneimittel GmbH Eurogenerics N.V. Stada Arzneimittel AG Laboratorio Stada S.L. Lamp San Prospero Sp.A Centrafarm Services B.V. Krika, d.o., Novo mesto Slovenia	Austria Belgium Germany Spain Italy Netherlands Slovenia
40	Rivastigmine Mylan	Rivastigminum	Hard capsules	1.5, 3, 4.5, 6 mg	10, 28, 30, 56, 60, 90, 112, 250, 500 capsules in blisters 10, 28, 30, 56, 60, 90, 112, 250, 500 capsules in a bottle	Rx	Mylan S.A.S.	Laboratorio Merck Farma y Quimica S.L. Pharma-Pack Kft. McDermott Laboratories t/a Gerard Laboratories	Spain Hungary Ireland
41	Sentor	Losartanum kalicum	Coated tablets	25, 50, 100 mg	30 tablets	Rx	Gedeon Richter Polska Sp. z o.o.	Gedeon Richter Plc. Gedeon Richter Po lska Sp. z o.o.	Hungary Poland
42	Sentor HCT	Losartanum kalicum + Hydrochlorothiazidum	Coated tablets	50 mg + 12.5 mg, 100 mg + 25 mg	30 tablets	Rx	Gedeon Richter Polska Sp. z o.o.	Gedeon Richter Plc. Gedeon Richter Polska Sp. z o.o.	Hungary Poland
43	Servenon	Escitalopramum	Coated tablets	10, 15, 20 mg	28, 56 tablets	Rx	Glenmark Pharmaceuticals s.r.o.	Glenmark Pharmaceuticals s.r.o. Synthon Hispania S.L. Synthon B.V.	Czech Republic Spain Netherlands
44	Sonirem	Zolpidemi tartras	Oral drops, solution	10 m g/ml	1 bottle 30 ml	Rx	ITF Pharma Kereskedelmi es Szogaltato Kft.	Italfarmaco S.A.	Spain
45	Sortis 5	Atorvastatinum	Chewable tablets	5 mg	30 tablets	Rx	Parke Davis GmbH	Godecke GmbH	Germany
46	Sortis 10	Atorvastatinum	Chewable tablets	10 mg	30 tablets	Rx	Parke Davis GmbH	Godecke GmbH	Germany
47	Sortis 20	Atorvastatinum	Chewable tablets	20 mg	30 tablets	Rx	Parke Davis GmbH	Godecke GmbH	Germany
48	Sortis 40	Atorvastatinum	Chewable tablets	40 mg	30 tablets	Rx	Parke Davis GmbH	Godecke GmbH	Germany
49	Soya Meno	Soyae seminis extractum siccum	Tablets	150 mg	30, 60 tablets	Rx	Medana Pharma S.A.	Medana Pharma S.A.	Poland
50	Tadroxil	Cefadroxilum	Oral suspension powder	125 mg/5 ml, 250 mg/ 5 ml, 500 mg/5 ml	1 bottle 60, 100 ml	Rx	Tarchominskie Zaklady Farmaceutyczne Polfa S.A.	Tarchominskie Zaklady Farmaceutyczne Polfa S.A.	Poland
51	Terпамid SR	Indapamidum	Extended release tablets	1.5 mg	30, 50, 100 tablets	Rx	Przedsiębiorstwo Farmaceutyczne Lek-Am Sp. z o.o.	Przedsiębiorstwo Farmaceutyczne Lek-Am Sp. z o.o.	Poland
52	Tezeo	Telmisartanum	Tablets	40, 80 mg	28, 30, 90 tablets	Rx	Zentiva k.s.	Zentiva k.s. Zentiva S.A. Zentiva a.s.	Czech Republic Romania Slovakia
53	Valsartan Teva	Valsartanum	Hard gelatin capsules	40 mg	14, 28, 56, 84, 90, 98 capsules	Rx	Teva Pharmaceuticals Polska Sp. z o.o.	Teva Czech Industries Teva Sante SA Teva UK Ltd. Teva Pharmaceutical Works Private Limited Company	Czech Republic France Great Britain Hungary

54	Valsartan Teva	Valsartanum	Hard gelatin capsules	80, 160 mg	14, 28, 30, 56, 84, 90, 98, 100 capsules	Rx	Teva Pharmaceuticals Polska Sp. z o.o.	Teva Czech Industries s.r.o. Teva Sante SA Teva UK Ltd. Teva Pharmaceutical Works Private Limited Company	Czech Republic France Great Britain Hungary
55	Velastina	Rivastigminum	Hard capsules	1.5 mg	28 capsules	Rx	Pabianickie Zakłady Farmaceutyczne Polfa S.A.	Pabianickie Zakłady Farmaceutyczne Polfa S.A.	Poland
56	Velastina	Rivastigminum	Hard capsules	3, 4.5, 6 mg	28, 56 capsules	Rx	Pabianickie Zakłady Farmaceutyczne Polfa S.A.	Pabianickie Zakłady Farmaceutyczne Polfa S.A.	Poland
57	Vicks TriActin Complete Cytrynowy	Paracetamolum + Guaifenesinum + Phenylephrini Hydrochloridum	Powder for oral solution	500 mg + 200 mg + 10 mg	5, 10 sachets	OTC	WICK Pharma Zweigniederlassung der Procter & Gamble GmbH	Wraifon Laboratories Ltd.	Great Britain
58	Xamiol	Calcipotriolum + Betamethasonum	Gel	(50 mcg + 0.5 mg)/g	1 bottle 15 g	Rx	Leo Pharmaceutical Products Ltd. A/S	Leo Pharmaceutical Products Ltd. A/S Leo Laboratoires Ltd.	Denmark Ireland

LZ – hospital use

Rpw – available on special prescription only (e.g. narcotics)

Source: Office for the Registration of Medicinal Products, Medical Devices and Biocides (URPL), 2011

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Annual Registration Summit 2011 - MOVIDA Conferences Izabella Kiriczok i Wspolnicy sp.k.

Warsaw 2-4 February 2011

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fax: 22 626 81 38
email: jkolodzinska@movida.com.pl
www: www.movida.com.pl

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