

# Central Europe Pharma News

A prime source of market intelligence for pharma professionals

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# Central Europe Pharma News

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## Bulgaria

### Market news

#### Bulgaria's Positive List of reimbursed drugs to be revised

Bulgaria's list of drugs reimbursed by the National Health Insurance Fund (NHIF) and the Health Ministry, known as the Positive List, is to be the subject of revision, Bojidar Naney, the health minister, has announced. The minister explained that the budget suffers monthly losses of around BGN 7-8m (€3.6-4.1m) because of inaccuracies in information pertaining to the medicines on the list. The revision is aimed at bringing about a reduction in NHIF spending on medicines whose prices exceed the required minimum and which are not reimbursed by Bulgaria's reference countries.

#### Bulgarian good distribution practice ordinance revised

The Bulgarian Health Ministry has announced a revised version of Ordinance 39, which covers good practice pertaining to the distribution of pharmaceuticals. The new Ordinance removes the requirement for the stickers which had been placed by wholesal-

ers and retailers on products reimbursed by the National Health Insurance Fund (NHIF). The measure was introduced in 2008 as a way of improving control over NHIF spending but has now been discarded because of its lack of effectiveness.

#### Reduction in fees for opening pharmacies in small towns and villages in Bulgaria

The fee for the right to open pharmacies in villages and towns with populations of fewer than 10,000 in Bulgaria has been reduced from BGN 5,000 (€2,556) to BGN 1,000 (€511), the Bulgarian Health Ministry has announced. This new regulation, included in the Pharmaceuticals Act, approved in December 2009, is designed to encourage the opening of pharmacies in less attractive locations in which access to medicines is inadequate.

#### 380,000 Bulgarians may lose access to healthcare in February

From 1 February onwards, any Bulgarian citizen who has failed to pay three or more

monthly health insurance contributions in the past 36 months will lose the right to state-funded healthcare, in accordance with the newly accepted amendments to the Healthcare Act. This could result in 380,000 Bulgarians losing their access to healthcare. The National Incomes Agency has announced that precise data will be available on 1 February. The self-employed, who pay their own health insurance contributions in full, will have to submit a declaration to the National Incomes Agency or risk being fined BGN 500-1,000 (€256-512).

#### Fees for GP visits updated in Bulgaria

The new Healthcare Act, which comes into force in January 2010, introduces update of fees for a visit to a GP and establishes the health insurance contribution at 8% of an individual's income in Bulgaria in 2010.

In accordance with previous plans (please refer to the news item "New changes to healthcare contributions proposed in Bulgaria" in the October issue of *Central Europe Pharma News*), 60% of the healthcare insurance contribution is paid by the employer and 40% by the employee. The state will pay contributions for children, pensioners and low-income groups.

The fee for a visit to a GP is set at 1% of the minimum wage, or BGN 2.40 (€1.23) but is reduced to BGN 1 (€0.51) for pensioners and waived for some groups, including children, pregnant women and people with disabilities. The fee for hospital care is set at 2% of the minimum wage, or BGN 4.80 (€2.46) per day, to be paid for the first 10 days of hospitalisation.

## Bulgarian Finance Ministry to release funds for healthcare providers

On 5 January, the Bulgarian Finance Ministry announced that it had transferred funds to cover the payments due to healthcare providers working with the National Health Insurance Fund (NHIF). The transferred amount, of BGN 140.5m (€71.8m), is to cover the obligations of the NHIF to doctors, dentists and pharmacies for November 2009. The delay in payment had prompted healthcare providers to threaten industrial action in January.

## Will procedural delays leave Bulgarian patients without immunosuppressants?

The Bulgarian Association of Patients with Kidney Diseases has warned that approximately 300 Bulgarian patients who underwent transplants could be left without their immunosuppressive medicine after 20 January 2010 because of a shortage of state-purchased drugs. The situation has been caused by delays in the tender organised by the Health Ministry in order to purchase the drugs. As the tender process requires around two months, a spokesperson for the Association has called on the Ministry to take immediate

steps to maintain the appropriate healthcare provision for patients after transplants.

## Patients' organisation calls for improvement in treatment of rare diseases in Bulgaria

The National Alliance of People with Rare Diseases, a Bulgarian patients' organisation, has called on the health authorities to provide better healthcare provision for patients suffering from rare diseases. The organisation has demanded an improvement in drug delivery, an increase in the number of reimbursed medicines and the simplification of the procedures for licensing new medicines to allow faster access to new treatments. The demand was prompted by the death of a patient under the age of 18 suffering from mucopolysaccharidosis, which, according to the organisation, was a result of inadequacies in the arrangement of treatment.

## R&D/medical news

### 14% increase in infectious diseases in Bulgaria

Between 14 and 20 December 5,129 cases of acute and infectious diseases were registered

in Bulgaria, 14% more than the 4,487 of the preceding week. 3,878 of this number were cases of flu and acute respiratory diseases, in contrast to 3,395 during the preceding week (a 14% increase). By 20 December there had been 788 confirmed cases of A(H1N1) in the country.

## Two new vaccines to be reimbursed in Bulgaria in 2010

From April 2010 onwards, the Bulgarian National Health Insurance Fund (NHIF) is to reimburse two new vaccines for under-18s. One is for pneumococcal infections, and the other covers five conditions, with a reduced risk of complications in comparison with the currently used vaccine. All vaccines for children and adolescents are to be administered free of charge by the patient's GP.

# Czech Republic

## Market news

### Czech Republic increases VAT on medicines

On 1 January 2010, the Czech Republic increased the VAT rates on a number of goods and services, including medicines. The preferential VAT rate applicable to medicines, among other things, increased from 9% to 10%, whereas the basic VAT rate increased from 19% to 20%. The change was introduced by means of the so called "Janota's

package" adopted in 2009, which brought about a number of amendments to the Czech budget.

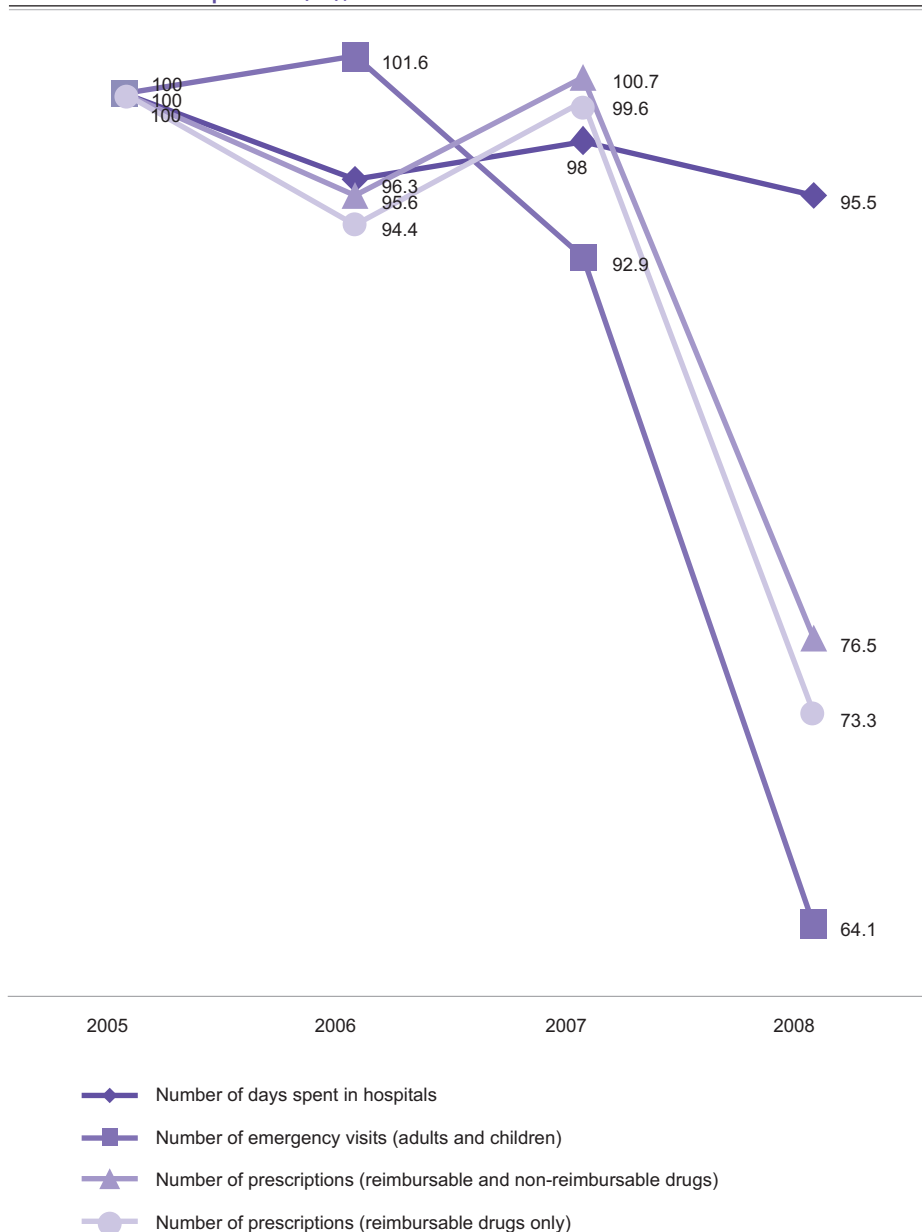
In addition to the changes to the VAT rates, the package – as we have reported on a few occasions in *Central Europe Pharma News* – also reduced the maximum manufacturer's drug prices and reimbursement levels by 7% for a period of one year. The reduction applies to those medicines whose prices were not reviewed by the Czech medicines agency (SUKL) in 2008, when the country introduced a new reimbursement system.

## Czech patients faced higher level of co-payment for reimbursed drugs in 2009

In 2009 the level of patient co-payment for reimbursable medicines in the Czech Republic increased in comparison with that of 2008, according to the Czech news agency, CTK. By the end of September 2009, the customers of the state health insurance company, **Vseobecná Zdravotná Poistovna (VZP)**, spent CZK 762m (€29m) in the form of drug co-payments. This constitutes 21.41% of all costs related to health care, which also included prescription charges, doctors' visits and hospital stays. In 2008, patient co-payments accounted for 18.32% of healthcare costs – more than 3 p.p. less than the 2009 figure.

The Czech Medical Chamber, the doctors' organisation, believes that the increase in the co-payment level was prompted by increases in the prices of medicines and the disappear-

## Doctors visits, emergency visits, hospital stays and prescriptions in the Czech Republic (%), 2005\*-2008



\*2005=100%  
Source: UZIS, 2009

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ance of cheap drugs from the market. The average price of one packet of medicine has been constantly increasing, and the Chamber believes that the obligatory 7% reduction in manufacturer's prices enforced for some medicines in 2010 might not reverse this trend. This is because the average price increase – which in 2008 came to 17% in comparison with 2007 – greatly exceeds the 2010 reduction. The Chamber believes that – instead of proceeding with the 7% price cut – it would have been better if the Czech State Institute for Drug Control (SUKL) had completed the 2008 drug price revision. This has still not been done.

### Regulatory fees to reduce number of prescriptions and emergency visits in Czech Republic

The introduction of regulatory fees for certain healthcare services in the Czech Republic is thought to be the reason for the significant reduction in the number of prescriptions and emergency visits in 2008, according to the Czech Institute for Health Information and Statistics (UZIS). In 2008 the Czech Republic introduced regulatory fees for doctors' vis-

its, emergency visits, hospital stays and prescriptions. According to the UZIS, in 2008 patients presented 69 million prescriptions in pharmacies – 21 million fewer than any year between 2005 and 2007. Of this number, 59 million prescriptions were for reimbursable medicines, a reduction of more than 25% in comparison with 2007. However, although there was a reduction in the number of reimbursable medicines dispensed at pharmacies, the average reimbursement amount paid by health insurance companies per one packet of medicine increased by 33.2% because doctors were prescribing medicines of superior quality and in larger packets.

The number of emergency visits also fell – in comparison with 2007 – by 41.1% in the case of adults, and by 25% in the case of children. The number of primary care visits in 2008 fell by 17% in comparison with 2007. The reduction in the number of days spent by patients in hospital was marginal. In its analysis, the UZIS emphasised that, although the new fees increased patient co-payment levels, their contribution as a proportion of the healthcare system is still one of the lowest among the OECD countries and constitutes 16.6% of the total spent on healthcare in the country.

### Czech healthcare fees to be re-submitted to Constitutional Court

The Regions Association of the Czech Republic is likely to approach the country's Constitutional Court to ask for a review of regulatory healthcare fees. This was announced by Michal Hasek, the Association's chairman and the governor of the South Moravia region, who was quoted by Czech television.

The discussion about healthcare fees began after the Czech Ministry of Internal Affairs prevented fees from being covered from regional budgets by a number of Czech regional authorities. The Constitutional Court had previously issued a ruling on regulatory fees in 2008, confirming their compliance with the Czech constitution. The regions want the Court to reconsider this matter because they believe that the fees have not had an appropriate regulatory effect on the healthcare system.

The regulatory fees were introduced in 2008. Czech patients pay for visits to surgeries, prescriptions, emergency visits and hospital stays. Health insurance companies reimburse their customers after the amount paid by a given patient has reached CZK 5,000

(€191) per year, or, in the case of children and the elderly, CZK 2,500 (€95) per year.

## Czech patients to pay more for drugs in 2010?

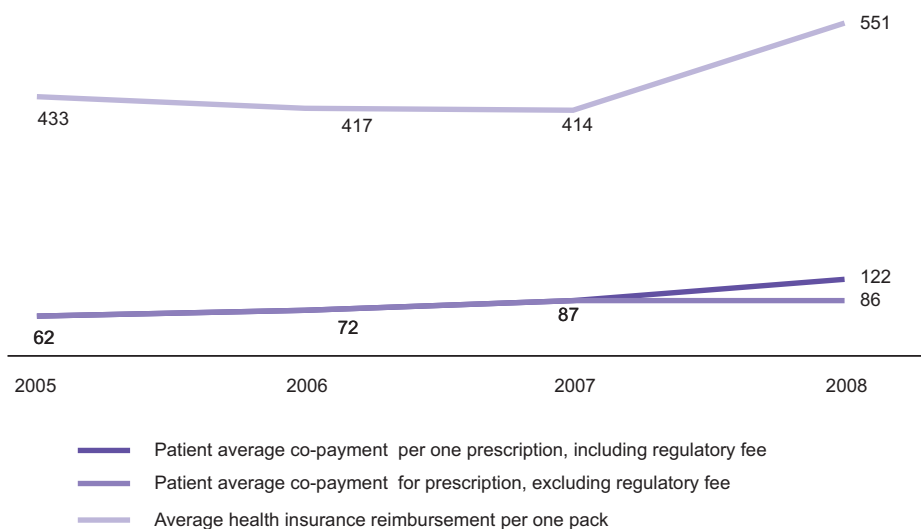
Czech patients may have to pay more for medicines, despite the obligatory 7% manufacturer price cut introduced by the state for some reimbursable drugs. The Czech Chamber of Pharmacists has told the CTK news agency that, in order to make up for the cut, drug manufacturers are preparing to increase the prices of those medicines which are not regulated by the state. Price increases may also be apparent with regard to reimbursable drugs, because, at present, manufacturers sell their products at prices which are lower than the maximum prices registered with the Czech State Institute for Drug Control (SUKL). Furthermore, patient co-payment levels may increase because of the 7% reduction in reimbursement levels which accompanies the obligatory price reduction.

## SUKL to communicate with drug manufacturers by means of public announcements

Since January 2010 all information on administrative procedures pertaining to the establishment of, or changes to, a maximum manufacturer's price for a given medicine in the Czech Republic, along with its reimbursement levels, will not be delivered individually to the manufacturer by post, but will be published on the SUKL website in the form of a public notice, based on the new mode of communication which the Czech State Institute for Drug Control (SUKL) has stipulated for drug manufacturers and marketing authorisation holders. Remote access to public notices will be available via a specially created section of the SUKL website. The notice will be available on the website for 15 days, and after this period it is to be considered by the SUKL as having been delivered.

Through its website the SUKL offers access to all administrative decisions pertaining to the establishment of, or changes to, maximum drug prices and reimbursement levels. They can be accessed by means of the website after a certified, electronically signed application has been submitted.

## Average reimbursement and patient co-payment levels per pack in the Czech Republic (CZK), 2005-2008



Source: UZIS, 2009

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## Obligatory health insurance for non-EU foreigners in Czech Republic

Non-EU long-term residents in the Czech Republic are now obliged to purchase commercial health insurance coverage worth no less than CZK 780,000 (€3,000). The new obligation arises from amendments introduced to Czech legislation on resident foreigners which take effect in January 2010. The regulations apply to non-EU foreigners who are self-employed in the Czech Republic, whereas those employed by Czech companies are included in the public health insurance scheme.

The new regulations have been introduced because the Czech Foreign Police – the forces of the Ministry of Internal Affairs responsible for dealing with foreigners – were, in the past, accused of accepting fraudulent health insurance cover issued by companies which were unlicensed in the Czech Republic. This had unfortunate consequences for Czech hospitals, as they were not paid for treating foreign citizens, and this led to significant losses every year.

Czech human rights organisations believe, however, that the amended law discriminates against foreigners, as the insurance they have to purchase, estimated to cost CZK 5,000 (€200) per year, is much more expensive than the treatment costs incurred by health insurance funds. The organisations believe that if foreign self-employed people were insured

under the same conditions as Czech citizens they would pay approximately CZK 400m (€15.24m) into the public health insurance system.

## Company news

### Czech Health Ministry to proceed with order for swine flu vaccine

The Czech Health Ministry has no intention of cancelling its swine flu vaccine order, according to the Czech news agency, the CTK.

The cancellation of the 800,000 outstanding doses of vaccine of the million which had been ordered in 2009 from **Novartis** had been suggested by Milan Kubek, the President of the Czech Medical Chamber, who believed that the country would not use all of the vaccine.

Discussion in the country has been heating up, as other EU countries, including France, have been selling surplus stocks of ordered vaccines. The Czech Health Ministry argues that the country based its order on conservative estimates and that the entire amount will, therefore, be used, particularly given that a second wave of the swine flu pandemic is expected later in 2010.

The total cost of the vaccines ordered by the country came to CZK 220m (€8.4m). The amount ordered is sufficient to inocu-

late 10% of the Czech population, particularly as it has now been established that only one dose of the vaccine is needed for the patient to build up immunity. According to the Czech Vaccination Society, 25% of the delivered vaccines have been used so far.

## R&D/medical news

### Czech Republic records 97 cases of adverse reactions to swine flu vaccine

The Czech medicines agency (SUKL) has, so far, recorded 97 cases of suspected adverse drug reactions associated with the swine flu vaccine Pandemrix, since the beginning of the inoculation campaign on 23 November 2009. The most frequent adverse reactions

were flu-like symptoms (44 cases) and localised skin reaction to the vaccination – 34 cases reported since the beginning of the vaccination programme.

According to the European Medicines Agency (EMA), 26 million people in the EU have, so far, been vaccinated with three EU-wide authorised vaccines: Pandemrix (**GlaxoSmithKline**), Celvapan (**Baxter**) and Focetria (**Novartis**).

### Record number of HIV infections in the Czech Republic in 2009?

By the end of November 2009, 136 new cases of HIV infection were reported in the Czech Republic, according to the CTK news agency. Miroslav Hlavaty of the Czech AIDS association claims that in 2008 there were 142 new

cases of HIV infection and that the number of new HIV cases for 2009 as a whole might be even higher. The rate at which new cases appear has been accelerating in recent years, and since 2007 their number has exceeded 100 new cases per year. Since 1986, the Czech authorities have recorded 1,325 cases of HIV infection, and 288 patients have developed AIDS. Of these, 153 people have died.

The increase in the number of HIV afflicted patients might be a result of cuts in the Czech budget, which have affected the HIV/AIDS prevention programmes in particular, according to Beatriz Cebolla, the director of the Health Consumer Powerhouse, which prepared the 2009 Euro HIV Index. These have led to shortages of personnel and the closure of some volunteer counselling and testing points in the country. ■

## Hungary

### Market news

#### Hungarian hospitals which fail to meet minimum requirements face closure

Hungarian hospitals will have six months to adhere to the minimum quality of treatment requirements. If any hospital departments fail to do so the National Health Insurance Fund (OEP) might refuse to sign the contract, and this will result in the closure of the hospital. This stems from an amended ordinance on hospital operation recently adopted by the Hungarian government. From 2011 onwards any Hungarian hospitals which do not meet the minimum requirements will not be able to function with temporary permission, as they can at the moment. Hospitals have until June 2010 to prepare.

At present there are over 70 hospital departments in Hungary which do not meet

the minimum level of the terms required. However, they can operate with a temporary licence.

#### Hungary's Health Ministry to delay support for hospitals

The Hungarian Health Ministry postponed extra aid of HUF 6bn (€22.2m) for hospitals, originally planned for December 2009, until January 2010. The decision has been criticised by hospital directors, as the financial support is to cover the HUF 60-70bn (€222-260m) debt of Hungarian hospitals. The Ministry agreed to grant extra money after demonstrations and strained talks with hospital directors held in October 2009. The hospital directors initially demanded HUF 25.5bn (€94.4m) in total. During the first round the government offered HUF 4.5bn (€16.6m) but finally agreed to grant extra aid of HUF 6bn

(€22.2m) to be paid in December 2009, in addition to further support of HUF 38bn (€140.7m).

#### Most flu vaccination points in Hungary to be closed

164 of more than 200 flu vaccine points in Hungary were to have been closed on 22 December 2009. From 4 January 2010 onwards the number of vaccine points is to be reduced to 40, mainly those operating under the aegis of the Public Health and Medical Services Agency (ANTSZ).

The vaccine points carried out well over 3,000 inoculations per day, and 2.5 million people were vaccinated in total.

After the successful inoculation programme against the A(H1N1) virus, which covered more than 25% of the country's population, Hungary is placed in third position in Europe behind Sweden and the Netherlands in terms of number of people inoculated.

#### Hungarian Health Ministry expresses pride in its 2009 performance

The Hungarian Health Ministry performed well in 2009: by the end of the year HUF 294bn

(€1.1bn) of the HUF 369bn (€1.4bn) available for investments between 2007 and 2010 was spent on tenders, Tamas Szekely, the health minister, stated. Most of the developments carried out at each level of national health services were a result of the efficient use of EU funding.

With regard to legislation, the Ministry ratified three acts and passed 16 government regulations and 46 ministerial regulations in 2009, but the most important achievement was, allegedly, the introduction of seven new, innovative medicines, including four cancer treatments, to the healthcare reimbursement system.

According to the minister, the financial system of the Hungarian healthcare industry needs to be modified further. One step toward this goal was taken when, in October 2009, the Ministry, along with hospital representatives, agreed to provide extra benefits worth HUF 6bn (€22.2m) for health institutes.

## Company news

### Egis to open new R&D base in Hungary in 2010

**Egis Hungary**, a Hungarian drug manufacturer, intends to modernise its production capabilities and to open a new research and development facility in 2010, Istvan Hodasz, the new CEO of Egis has told *Korhaz* magazine.

The new R&D base will contain a 3,500 m<sup>2</sup> pharmaceutical laboratory and a production testing facility and will employ 200 people. According to Mr. Hodasz, the base will enable Egis to introduce more generic drugs on the market than in previous years and to focus on new therapeutic areas, including oncology and OTC.

As we reported on a previous occasion in *Central Europe Pharma News*, the firm was planning to invest HUF 3.76bn (€13.6m) in the new base. This was supported by a grant of HUF 200m (€0.7m) from the Hungarian Investment and Trade Development Agency.

### GSK Godollo plant to start production for US market?

**GlaxoSmithKline** (GSK) Hungary Godollo plant might start production for the US market in 2010, Gyorgy Leitner, the GSK CEO, has said in an interview for *Korhaz* magazine. He stated that company expects the final audit by the US Food and Drug Administration (FDA), to be carried out in 2010, to confirm the plant's eligibility for manufacturing vaccines in accordance with the standards required in the US. GSK's application is in tandem with an investment of HUF 274m (€1m) in the Godollo production base earlier in 2009.

## R&D/medical news

### Bekescsaba hospital wins HUF 456m for development

The Rethy Pal hospital in Bekescsaba, in Hungary, has obtained HUF 456m (€1.85m) for renovation and development within the framework of the Social Infrastructure Operational Programme. The local authorities will provide 10% of the total budget of the project. Developments will include the remodelling of the emergency department, improvements in accessibility, the replacement of the computer tomography machine and the harmonisation of the IT system.

### Mezotur hospital to pay debts accumulated by former operator

The Mezotur hospital has been granted a loan from the local authorities to cover its current expenditures and debts left by **Medisyst**, its former operator. The hospital will have to pay off an additional HUF 74m (€0.27m) associated with Medisyst investments.

Since 1 January 2010 the Mezotur hospital has been operated by the local authorities, because Medisyst, a Hungarian private healthcare company, withdrew in November

2009. The company explained that the shortage of funds in the Hungarian healthcare system over the past few years had made it impossible for the company to run the business in such an environment.

### Flu on the wane in Hungary

The number of flu cases reached 36,600 in Hungary between 14 and 20 December, 20% fewer than during the previous week, according to data based on the reports of Hungarian doctors involved in the observation service. During this period 553 patients in all were treated in hospitals with flu or flu-like illnesses, and 39% of these were children.

During the week which ended on 31 December 2009 the number of flu cases in Hungary fell again by 58% in comparison with the previous week. The number of patients with flu symptoms reached 15,200. In all, 360 patients were treated in hospital with flu or flu-like illnesses, one-third fewer than the figure during the previous week. The National Public Health and Medical Officer's Service (ANTSZ) reported that to the end of 2009 65 Hungarians died as a result of the flu epidemic, including seven A(H1N1) patients during the final week of 2009.

According to Tamas Szekely, the Hungarian health minister, the A(H1N1) inoculation programme, which covered more than 25% of the population, is expected to emerge as the reason for the fall in the number of flu cases.

A second flu wave is expected in Hungary in March/April 2010, and a third is predicted for next winter by Ferenc Falus, the country's chief medical officer.

# Poland

## Market news

### Wholesale drug sales up by 10.8% in 2009 despite weaker December

The value of wholesale sales of medicines to pharmacies rose by 5% y-o-y in December 2009 and amounted to PLN 1.6bn (€390m), according to latest data from IMS Health. This represents a sharp slowing of market growth after a 27% y-o-y surge in November. In monthly terms the market declined by more than 20%.

The weaker result reflected both a typical seasonal drop that tends to occur in December – a consequence of fewer working days – but also a steep decline in flu and other respiratory infections, which had soared to record levels in November and drove up sales. (The number of confirmed and suspected flu cases fell to 23,427 in the last week of December 2009 from a peak of 133,970 in the eight days to 30 November, according to the National Institute of Hygiene).

Even so, in 2009 as a whole the market grew by a solid 10.8% y-o-y – a better result than in 2008 and 2007 – and was worth PLN 21.4bn (€5.2bn).

### No disruption to dietary supplements market in early 2010

Concerns that drug retailers might stop stocking dietary supplements whose legal status became uncertain following the transposition of an EU directive as of 1 January have so far proven unfounded, *Rzeczpospolita* reported. According to the newspaper, pharmaceutical firms and pharmacies in Poland fielded many calls from patients in the last days of 2009 who were worried about such a scenario, but there are no signs that it actually materialised.

The controversy centres around new rules for the classification of products as medicines vs. dietary supplements, which could force

makers of supplements to either withdraw “borderline” products or reclassify them as medicines, a costly and time-consuming procedure. This could paralyse the market for dietary supplements, the industry had warned.

Jaroslav Lichodziejewski, vice president of the Polish Council for Supplements and Nutritional Foods (KRSiO) – which brings together 45 companies – told the newspaper that it was monitoring the situation and that if drug retailers were to block the sales of certain products due to their supposedly uncertain status, the Chamber would consider suing them for compensation.

The KRSiO has vowed to take legal action as far as the European Court of Justice if makers are forced to reclassify existing products.

### Relaxed pharmacy-ownership rules to help PGF, Farmacol

**Polska Grupa Farmaceutyczna** (PGF) would be the main beneficiary of the Economy Ministry proposal to relax anti-concentration laws for pharmacy chains, but **Farmacol** also stands to benefit, as a string of recent acquisitions left the company with more than 1% of pharmacies in three voivodships, according to *Parkiet*.

Under a law passed in 2004, a single company is not allowed to own more than 1% of pharmacies in a voivodship. However, the limit can be – and probably is – side-stepped by means of various legal arrangements, and the number and share of chain pharmacies is rising steadily. The Health Ministry has vowed to tighten the regulations, but the Economy Ministry proposal goes in the opposite direction and would facilitate faster network expansion.

Although it is PGF that has put expansion of pharmacy network at the heart of its growth strategy, Farmacol has also built up a sizeable network through the acquisition of several former state-owned Cefarm drug wholesalers. According to the newspaper, the company currently owns more than 1% of all pharmacies in the voivodships of Zachodniopomorskie, Dolnoslaskie,

and Swietokrzyskie. And its 2009 takeover of **Cefarm Bialystok** involved the acquisition of 50 pharmacies in Podlaskie and Warminsko-Mazurskie.

In the draft legislative proposal sent out for consultation last month, the Economy Ministry argues that existing restrictions on pharmacy ownership in Poland find no basis in European law and may constitute a violation of the constitutionally-enshrined freedom of enterprise.

### Apothecary Chamber opposes liberalisation of drug distribution laws

The chairman of the National Apothecary Chamber (NIA) has strongly criticised the Economy Ministry’s proposal to relax anti-concentration and permit rules for drug distribution. In a letter, Dr. Grzegorz Kucharewicz described the proposed changes as “highly dangerous” for the Polish pharmaceutical market.

The Chamber opposes both the idea to scrap licenses for drug wholesaling operations (with companies required only to register with the Main Pharmaceutical Inspectorate); as well as the proposal to remove the cap on the number of pharmacies that can be owned by a single company in a voivodship.

See the news item “Relaxed pharmacy-ownership rules to help PGF, Farmacol”.

### Pharmaceutical inspector supports ban on price promotions

Zofia Ulz, the main pharmaceutical inspector, has written to the Health Ministry backing demands for a total ban on price promotions by pharmacies and pharmacy points. She also urged the adoption of laws regulating loyalty programmes.

According to Ulz, aggressive price promotions, such as “medicine for PLN 0.01”, discount vouchers, or gifts, encourage excessive purchasing and consumption of medicinal products. She added that although promotional leaflets typically mention only OTC drugs, these special offers extend to prescription medicines as well, and pharmaceutical inspectors lack effective tools to combat such practices.

Furthermore, Ms. Ulz noted that loyalty schemes run by drug distributors also offered

various material incentives in return for regular purchases of medicines in a given pharmacy chain, and that the Pharmaceutical Act should be urgently amended to help tackle such arrangements.

In the opinion of Ulz, pharmacists are a profession with a special claim to public trust, and pharmacies should not be governed in their operation entirely by the market logic.

## URPL faces stark choice over flawed syringe needles

A large-scale examination of disposable syringe needles available on the Polish market has revealed a disturbingly high proportion of permeable packagings, *Dziennik Gazeta Prawna* has learnt. URPL, the medicines registration office, which commissioned the tests, is reportedly at a loss over whether to order mass product withdrawals, fearing that this might create supply problems and restrict access to life-saving injections.

In June, **Mifam**, a Polish maker of syringe needles, informed the URPL that during in-house comparative tests, it discovered that many of the needle packagings of German firms **KDM** and **Henke Sass Wolf** – market leaders which between them control about 50% of the Polish market – were permeable. Subsequent URPL tests – the largest ever to be conducted in Poland – have led to the withdrawal of a total of 14 batches, with even up to 10% of all packagings in a batch found to be less-than-bacteria-proof. More withdrawal orders could follow, as the problem is most probably due to a flaw in the production process. Furthermore, URPL also asked for a sample of Mifam's products to have them examined, and they too were found to be less than perfect.

According to Leszek Borkowski, former URPL chief, quoted by the newspaper, the Office should suspend sales of all batches to protect public health. Other experts are divided over the seriousness of the threat.

## Government rules out purchase of swine flu vaccines, Poles unperturbed

The Health Ministry is no longer in talks with pharma companies about the purchase of A/H1N1 vaccines, after they refused to accept its demands regarding stronger safety

assurances and wider distribution, *Dziennik Gazeta Prawna* reported. Meanwhile, the ministry spokesman categorically denied that authorities were contemplating the purchase of surplus vaccines from countries known to be considering selling off their excess stocks, such as the United Kingdom or Italy.

At the same time, a TNS OBOP poll found that Poles were far from panicky about swine flu, with 63% of respondents declaring that they had no special concerns about the virus, against 33% who said that they did. As regards coping strategies, 30% said they were taking various flu medicines and vitamins, while 7% said they got a flu vaccine. Interestingly, only 9% admitted that they had caught flu or a severe cold this autumn but not the year before, whereas 19% experienced such conditions both in 2009 and 2008.

By 30 December swine flu had claimed 135 lives in Poland, out of 2,301 confirmed flu cases.

## Company news

### GSK moves more production to Poland

**GlaxoSmithKline** (GSK) will shift some of the production of Avodart, an urology drug, from France to its Polish factory in Poznan in a project worth PLN 70m (€17m), the company has informed. The medicine is reportedly one of the company's most profitable products.

According to Jerzy Toczyski, CEO of GSK's Polish unit, the move reflects cost considerations, but also the factory's reputation as one of the most efficient GSK plants in Europe. The Poznan facility is to ultimately supply the medicine to about 80 markets worldwide. GSK is planning substantial investments in upgrading and expanding the factory, so that it has the capacity to put out approximately 600,000 capsules of the drug per year.

GSK has already invested PLN 417m (€102m) in the Poznan plant since acquiring the then-Polfa Poznan from the state in 1998, making it one of the most modern factories in Central and Eastern Europe. Over this period the factory has introduced more than 100 new medicines. Mr. Toczyski stressed that the company was also investing in its logistics infrastructure for serving foreign markets, as well as in clinical trials. Poznan is also home to GSK's global IT centre and its R&D unit participates in multinational research projects.

## Adamed buys Polfa Pabianice

**Polski Holding Farmaceutyczny** (PHF) has signed an initial agreement about selling **Polfa Pabianice** (PP), the state-owned drug maker, to **Adamed**. The decision clears the way for Adamed to negotiate a social package with PP employees, the last hurdle to completing the deal.

Artur Wozniak, CEO of the state pharma holding company, said that he was pleased with the outcome of the talks and that PHF managed to negotiate a "fair price" for Polfa Pabianice, although he stopped short of revealing the agreed value of the transaction.

Adamed, a major domestic drug maker, was granted exclusivity for talks about the privatisation of PP after trumping rival offers from Italy's **Recordati** and two fellow domestic pharma firms: **Polpharma** and **Polfarmex**.

Polfa Pabianice is one of three state-owned drug makers slated for privatisation in 2009/2010. Adamed, which is eyeing various possibilities for M&A deals to bolster its manufacturing and R&D base, is known to be contemplating bids also for the other two, i.e. **Polfa Tarchomin** and **Polfa Warszawa**.

In the first half of 2009 Polfa Pabianice reported a 0.3% y-o-y increase in sales turnover to PLN 84.6m (€20.2m), and a 18.5% y-o-y jump in net profit to PLN 14.1m (€3.4m).

## Ciech invites bids for Ciech Polfa

**Ciech**, the listed chemicals group, announced that it is looking for a buyer for **Polfa** (former Ciech Polfa), its pharmaceutical arm. The deadline for the submission of offers has been set at 25 January. According to Ciech, several pharma companies and investment funds have already confirmed interest in acquiring the business and signed confidentiality agreements with the group.

All previous attempts to sell the unit – of which there were at least three – have been unsuccessful.

Polfa specialises in exports and imports of medicines, active pharmaceutical ingredients and packagings for the pharmaceutical industry, and has a particularly strong presence in Central and Eastern Europe and former Soviet Union and Eastern Bloc countries. It has operations in, e.g. Russia, Czech Republic, Hungary, Ukraine, Bulgaria, Belarus, as well as Kazakhstan, Kyrgyzstan or Vietnam. Its main asset is a well-recognisable brand with trademark protection in 39 markets.

## Polfa Warszawa sale attracts five bidders

Five companies have submitted initial offers in the privatisation of **Polfa Warszawa** (PW), **Polski Holding Farmaceutyczny** (PHF) announced. The deadline for the submission of bids expired on 6 January 2010. A short-list of investors invited for advanced-stage talks is to be announced around 20 January.

The state pharma holding firm stopped short of revealing the names of the potential buyers, but said that it was satisfied with the response, as all the suitors were “renowned domestic and foreign pharma companies”. This, according to PHF CEO Artur Wozniak, “bodes well for the privatisation process”.

Among companies known to be contemplating a bid for Polfa Warszawa were e.g. **Adamed** and **Teva**.

According to PHF, PW’s key assets are a broad portfolio of Rx and OTC drugs and extensive manufacturing capacity that also includes two subsidiaries, **Sanfarm**, a maker of drugs and dietary supplements, and **Ipochem**, a maker of active pharmaceutical ingredients.

## Rehabilitation equipment maker invests in LSSE

**LIW care technology**, a Polish maker of innovative rehabilitation equipment for disabled persons, will invest at least PLN 5m (€1.2m) to build a factory in Nowy Jozefow near Lodz, in the Lodz Special Economic Zone (LSSE). The company pledged to create at least 12 jobs at the new facility.

LIW’s flagship products are standing seats for people with abnormal curvature of the spine and muscle dysfunction. They are distributed through partner stores across the country and are subject to reimbursement by the National Health Fund (NFZ) and district family support centres (PCPR). The company is currently in the process of expanding its distribution network.

## HTL-Strefa to build new production line of insulin pen needles in Ozorkow

**HTL Strefa**, the listed maker of capillary blood microsampling devices, will invest PLN 40m (€9.7m) to build a new production line of insulin pen needles at its factory in

Ozorkow (Lodzkie voivodship), in the Lodz Special Economic Zone (LSSE). The project will result in the creation of 18 new jobs.

So far, HTL-Strefa has invested a total of PLN 116m (€28.1m) in the LSSE. It has two plants in the zone, in Ozorkow and Leczyca, which currently employ 100 people between them.

HTL-Strefa is in the process of being acquired by Swedish private-equity group EQT.

## Court rejects €1m compensation suit against Optopol

A court in Czestochowa has struck down a lawsuit against **Optopol Technology**, the listed maker of ophthalmic diagnostic equipment, filed by its former distribution partner in the United States. The ruling is subject to appeal.

In the suit, **Reichert**, a US maker of ophthalmic and analytical instruments, demanded compensation of \$1.3m (€0.3m) and €0.7m from Optopol for terminating a distribution agreement signed by the two parties in February 2007. The court sided with Optopol in concluding that the claim was baseless.

Optopol’s current exclusive distributor in the US is **Canon**, which in December launched a takeover bid for the Polish company. The Japanese firm aims to buy 90% of shares in Optopol for about PLN 248m (€59m) and delist it from the Warsaw Stock Exchange.

Optopol CEO Adam Bogdani praised the deal as a friendly transaction that would protect R&D and production activities in Poland and give the Polish firm an important role within a major global company.

## R&D/medical news

### Platinum to invest PLN 115m in Warsaw hospital

**Platinum Hospitals** will spend PLN 115m (€30.1m) to revamp and expand the former Elizabethan Nuns’ Hospital in Warsaw’s Mokotow district, *Zycie Warszawy* has learnt. This is significantly more than the previously estimated PLN 90m (€21.7m). The company also revealed some more details about the timetable of the project and the anticipated profile of the transformed hospital, which is scheduled to admit first patients in two years’ time.

The investment is divided into two phases. In April, remodeling work will start at the existing five-storey hospital building, and a new underground area will be constructed. The remodeling is to be completed in April 2011. The revamped building will have 7,000 m<sup>2</sup> and 170 beds. Interestingly, it will not be rigidly divided into separate wards, but will have one “specialist ward” with services including e.g. general and vascular surgery, orthopaedics, laryngology, gastroenterology, urology & nephrology, cardiology and internal neurology, with beds allocated according to need. There will also be a one-day surgery ward with four treatment rooms, a dialysis station, a diagnostic lab and a specialist clinic. As a second step, in 2012 the company will start the construction of a new, 5,000 m<sup>2</sup>, four-storey wing that will house an operating block consisting of six operating rooms.

Platinum wants the hospital to provide services both on a commercial basis and under contracts with the National Health Fund (NFZ).

## Krakow biotech cluster takes off

The first facility of **LifeScience Park**, a project of the Jagiellonian University that will offer high quality, fully-equipped R&D space for the life science industry (and especially for biotech companies), was due to begin operations in Krakow on 1 January.

The 6,000 m<sup>2</sup> building contains facilities designed for large companies engaged in long-running and expensive research programmes. Planning work is underway for a second building of a similar type, as well as for Bioincubator, which will provide R&D facilities for start-up companies.

Ultimately, the complex is to house 500 researchers, engaged in research work using latest-generation equipment for biotech and physico-chemical analysis. According to the Jagiellonian Centre for Innovation (JCI), the special-purpose company that manages the complex, it will be the first facility of this type in the entire Central and Eastern Europe region.

The Park belongs to the Krakow Special Economic Zone and is located near the Jagiellonian University’s 3<sup>rd</sup> Campus. The project has received EU funding worth PLN 125m (€30m).

## Lux Med to maintain double-digit growth in 2010 thanks to new clinics and hospital

**Lux Med Group**, Poland's number one private healthcare provider, expects to achieve 11-12% revenue growth in 2010, thanks to a broader service offering, organic expansion of its clinic network, and the opening of

a one day surgery hospital in Warsaw in the summer, CEO Anna Rulkiewicz-Kaczynska told *Puls Biznesu*. At the same time, the group estimates that 2009 sales grew by about 15-16%.

According to Rulkiewicz-Kaczynska, the projected rate of sales growth is high given the tough market environment. Lux Med generates approximately 70% of its revenues

from corporate benefit plans, and job cuts are having a direct negative impact on its patient base.

At the moment the group boasts one million patients served by 69 retail clinics, 26 corporate clinics and about 1,000 partnership clinics. ■

## Romania

### Market news

#### Wholesale drug sales in Romania up by 3.6% in euro terms in Jan-Oct 2009

In the first ten months of 2009, the value of wholesale sales of medicines to pharmacies in Romania climbed by 3.6% y-o-y and amounted to the equivalent of €1.7bn, according to latest data from IMS Health. In October, the Romanian market grew by 6.8% y-o-y in value terms to €179m, whereas in volume terms it edged up by 0.6% y-o-y.

According to Corin Ciolan, CEO of IMS Romania, quoted by *Ziarul Financiar*, the situation on the market is difficult and could deteriorate significantly in the coming months if the underfunding of the healthcare system continues, leading to even later payments.

#### Romanian lei devaluation expected to inflate pharmaceutical market in 2010

The Romanian pharmaceutical market is expected to grow by up to 10% in Romanian lei, whereas a further decline in volume and euro value is expected in 2010.

The problem became worse in 2009, as we reported previously in *Central Europe*

*Pharma News*, resulting in a 12.8% year-on-year increase in lei between January and October and a 2.8% reduction to €1.5bn in euro.

The main challenge for market players remains the lack of liquidity as pharmacies continue to sell reimbursed drugs while suffering delays in reimbursement from the health budget. The problem pertains, in particular, to local independent pharmacies and manufacturers. Large importers and distributors are expected to be in better shape as a result of external financing, and are, therefore, expected to strengthen their market positions and increase their market shares.

#### Romania abandons plan to buy vaccines from France

Romania has pulled out of talks with France about buying the latter country's surplus of A(H1N1) vaccines, French newspaper *Le Parisien* has learnt. The negotiations reportedly went on for two months.

The government of Bulgaria likewise rejected an offer to buy some of France's surplus. France is one of several countries which have been left with excess stocks of the swine flu vaccine, the others being Switzerland, Germany or Spain. The country is looking for a buyer for several million doses of the vaccine, out of 94 million of doses purchased.

### Company news

#### Plafar begins rebranding to avoid insolvency

**Plafar**, a Romanian state-owned manufacturer of plant and herbal medicines, has announced that in 2010 it intends to launch a rebranding campaign as part of a company restructuring plan, according to a report in *Corporate News*. Plafar began to restructure its business after it found itself on the verge of insolvency in March 2009.

The company has changed the product and corporate image and has launched an advertising campaign through its new website and the local media.

#### New operations manager for Sensiblu

In January 2009 Robert Popescu, the CEO of **A&D Pharma**, will take over the position of operations manager of **Sensiblu**, the largest Romanian pharmacy chain, after the contract with Claudiu Opran, the previous Sensiblu manager has expired. Claudiu Grosu will be appointed sales manager.

A&D Pharma is the main shareholder of Sensiblu, which operates 220 pharmacies in the country. The revenues of the chain reached RON 573.7m (€135.7m) in the first nine months of 2009.

See also the news item "Government rules out purchase of swine flu vaccines, Poles unperturbed".

## R&D/medical news

### Romania to attract drug production investment of RON 870m

An unnamed US firm is planning to invest RON 870m (€209m) in the construction of a drug production plant in the Tetarom Industrial Park, in the region of Cluj. The investor has applied to Tetarom's management to obtain 35-40 ha of land for the project.

The investor has not been identified, but there has been speculation that it might be the entity which bought Procter&Gamble's Rx drug division in 2009. The new factory could produce medicines for of the Eastern European markets, Ukraine, Russia and Turkey.

### Turkish Mediana to expand into Romania and Bulgaria

**Medicana Hospital**, a Turkish private healthcare firm, is in advanced plans to en-

ter the markets of Romania and Bulgaria, its chairman Huseyin Bozkurt told Turkish daily *Zaman*. The company aims to capture the growth opportunities offered by the rapidly expanding healthcare tourism traffic within the European Union, as well as free movement of healthcare professionals inside the EU.

Bozkurt indicated that Mediana's strategy in foreign markets was centred around the transfer of technology and expertise rather than direct investments.

At the moment Mediana operates five hospitals in Turkey. It has plans to extend its operations to regions such as the Balkans, the Middle East, Central Asia or North Africa.

### Euromedic Romania says sales will rise 30% in 2010

The Romanian unit of **Euromedic**, the pan-European medical services provider, expects to achieve 30% revenue growth in 2010, up from over RON 80m (€19m) that it estimates to have generated last year, Anca Petca, chairman of Euromedic Romania, told *Ziarul Financiar*. Petca added that the company

would concentrate on consolidating its existing network of dialysis and diagnostic centres and equipment upgrades in 2010, although new clinic openings could not be ruled out in the latter part of the year.

This is in contrast to 2009, when revenue growth was driven in large part by new centre openings. Euromedic Romania opened one diagnosis centre (in Focsani) and three dialysis centres (in Baia Mare, Botosani and Piatra-Neamt) last year. Total capital spending – which also included purchases of equipment for existing centres – exceeded the equivalent of €8m. The new openings contributed to the revenue of RON 75.6m (€18m) generated in January-November 2009. ■

## Slovakia

### Market news

#### Slovak Health Ministry updates reimbursement list

The Slovak Health Ministry has unveiled an updated reimbursement list which became valid in January 2010 and will remain so for the next three months. According to the Slovak news agency, SITA, the new list includes 5,167 medicines – 120 more than the previous list, which was valid be-

tween October and December 2009. Of this amount, 53% of medicines will be covered in full from the obligatory health insurance scheme or will require just a nominal patient co-payment of up to €1. This constitutes a slight increase in comparison with 51% for the previous reimbursement list. The Health Ministry says that the patient co-payment level would increase only for those medicines for which clinical studies pertaining to efficacy in the treatment of a given disease had not been completed.

### Financial assistance scheme for Slovak hospitals set in motion

Slovak hospitals have signed agreements with the government pertaining to long-term loans, according to the Slovak news agency, TASR. The hospitals signed the agreements on the very last day of 2009 – just as the legal protection against their creditors was about to expire. The eight-month protection period was introduced by the Slovak parliament in April 2009.

As we reported in *Central Europe Pharma News*, 25 state hospitals have been included in the financial aid programme, which will offer loans of €130.2m in total. The hospitals will have 15 years to pay off these government loans.

The Health Ministry hopes that the loans will help hospitals to reduce their debts and lead to a reduction in the prices of goods sold to hospitals, as current prices depend largely on the amount a given hospital owes to its suppliers.

## Slovakia modifies its patient waiting list system

Slovakia is to create a single, more centralised, waiting list system for patients who are waiting for treatment. A Health Ministry ordinance which took effect on 1 January 2010 unifies the entire system, laying down common criteria for the creation and maintenance of the waiting lists. Until that moment, because of the lack of appropriate legislation, waiting lists had been formed by each health insurance provider in accordance with its own, individual criteria.

The new regulations stipulate that a patient cannot be placed on more than one waiting list for the same treatment or procedure. In addition, in order to shorten the waiting period, the insurer will be able to offer the patient the treatment at a different healthcare facility from that originally scheduled. If the patient changes his/her health insurance provider during the waiting period, the new insurer will place him or her at the bottom of its waiting list.

The waiting periods and waiting lists do not apply to acute health problems, and if the patient's condition requires it, a given medical procedure will be carried out immediately.

## Company news

### Slovak Biotika to expand its product portfolio and employ more people

**Biotika**, the prominent Slovak pharmaceutical manufacturer, is planning, in March 2010, to begin the production of a new pharmaceutical substance, according to the Slovak news agency, TASR. In order to cope with the new production the company has decided to take on 17 new employees by the end of January 2010 and another 13 by the end of March 2010. The company expects to add up to ten new products to its manufacturing portfolio in 2010.

Biotika was established in 1953. It manufactures antibiotics, active substances used in human and veterinary medicines and feed additives for breeding farm animals. In 2005 the firm was acquired by **Sanitas**, the Lithuanian drug producer. In 2009 Biotika employed 467 people.

## Slovakia's Union health insurance fund expects to end 2009 with a loss

The Slovak health insurance company **Union** expects to end 2009 with a significant loss, according to the SITA news agency. The loss will reflect a reduction in income from obligatory health insurance premiums in 2009, the higher costs of healthcare services and the unfavourable system of premium redistribution among health insurance companies. The Slovak state redistributes the premiums among insurers to compensate for the differences and to avoid preferential treatment for affluent and healthy clients at the expense of the poor and ill. The current premium redistribution criteria include the age and the gender of customers insured by a given company. However, from 2010 onwards the redistribution criteria will be broadened and will also include the number of customers insured by a given fund. Union believes that the changes in the redistribution mechanism will have a positive effect on the company's condition and will enable it to break even in 2010, when both the fund's estimated intakes and expenses are expected to reach €204m.

Union was founded in 2006. Its shareholder is a Dutch investment company, Eureko. In 2008 the company suffered a financial loss of €10.8 m.

## R&D/medical news

### Bratislava children's faculty hospital plans further modernisation

The children's faculty hospital in Bratislava is planning to continue the modernisation which it commenced in 2009. It intends to construct a unit for bone marrow transplants, modernise its maternity ward and continue the construction of an oncology and physiotherapy ward. It also intends to increase the number of beds in the intensive care unit at its maternity ward and to purchase an MRI scanner, according to the SITA.

Last year the hospital succeeded in refurbishing its polyclinic premises and purchasing new equipment. In addition, it began the construction of a hostel for nurses, which will also offer rooms for parents whose children

are staying at the hospital. The construction work is due to be completed by April 2010. The hospital has also succeeded in modernising its emergency rooms and purchasing a new operating table, a lung ventilator, an amino-acid analyser and an infant incubator. The money for the reconstruction came from the Health Ministry, the hospital's sponsors and the sale of surplus hospital property.

The children's faculty hospital in Bratislava is the largest specialised hospital for children in Slovakia. In 2008 there were 16,000 patients hospitalised at its facilities, and it is estimated that in 2009 the number increased by 1,000.

## Controversial Slovak law on non-profit healthcare organisations comes into force

From February 2010 onwards the Slovak government will have a significant say in the composition of the management boards of healthcare facilities set up in the form of not-for-profit organisations, based on the amended Act on Non-profit Organisations, signed by the Slovak president at the end of December 2009. The Act will allow the Health Ministry to nominate more than half of the management board members if public funds account for more than 50% of the organisation's initial founding capital.

The initiators of the amendments to the Act have claimed that their aim is to act in the best interests of the state and to protect government money invested in non-profit healthcare facilities. However, as we reported in a previous edition of *Central Europe Pharma News*, the amendments prompted a great deal of controversy, as some Slovak politicians believed that the changes would limit the independence of non-profit organisations and could result in the facilities being taken over by the state. ■

# CEE countries bring up the rear in Europe in access to innovative MS treatments

Access to innovative multiple sclerosis (MS) treatments in Central and Eastern European (CEE) countries is significantly more limited than it is in the “old” European Union countries. Access to innovative drugs and the percentage of patients treated in 2008 in Western Europe greatly surpassed the CEE region, reflecting the latter’s generally inferior economic status and the weaker condition of its healthcare systems.

## Access to innovative MS drugs in CEE countries a burden on healthcare systems

The *Access to innovative treatments for multiple sclerosis in Europe* report, recently published by the EFPIA, estimated that the percentage of MS patients on immunomodulating treatment in Western Europe (the “old” EU + 3) was 40-50%, and in CEE (the “new” EU) countries only 5-25%. The disparity in access to disease-modifying MS treatment

lished by the EFPIA, estimated that the percentage of MS patients on immunomodulating treatment in Western Europe (the “old” EU + 3) was 40-50%, and in CEE (the “new” EU) countries only 5-25%. The disparity in access to disease-modifying MS treatment

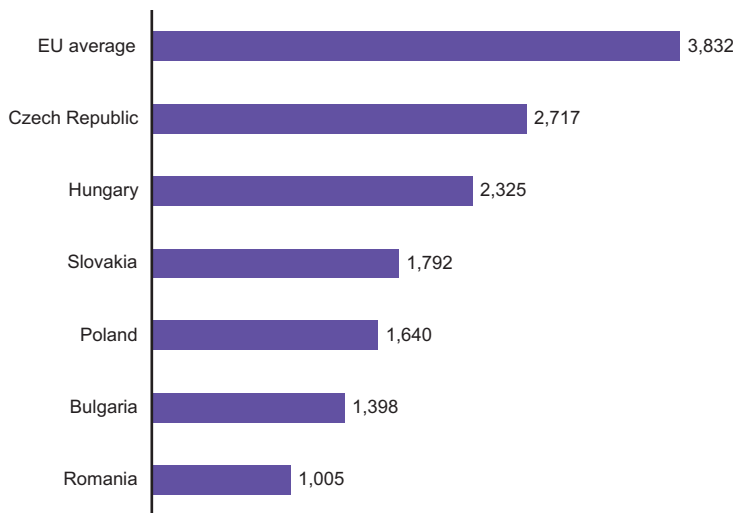
(DMT) in Europe is mainly a result of two conditions: macroeconomic indicators, reflecting a country’s wealth, and thus the affordability of DMTs, and reimbursement policies which place restrictions on expensive medicines. The price level factor finally appeared not to have a significant impact on access to MS treatment. Whereas the general price level in the “new” EU countries is somewhat lower than that of the “old” EU, as a consequence of the lower prices established in the former countries prior to EU accession, the differences are not particularly substantial. This is because of the policy of manufacturers, fearing the effect of parallel trade, of keeping global drug prices fixed. The average annual cost of the disease per patient was estimated in the report to be €11,950 in the Western EU countries and €9,830 in the CEE countries.

However, the lower price levels in the CEE countries seem not to influence drug uptake. The reason is not always the affordability of the treatment in individual countries, but, rather, specific conditions governing the rules of distribution of DMTs in a given country. On the markets on which these drugs are not subject to the official approval of the payer, such as Germany, prices are at their highest, whereas on the highly-regulated markets for these treatments, e.g. Poland, where they are subject to the so-called therapeutic programme and are available only within the closed hospital distribution system, prices are much lower for patients, and manufacturers are not afraid of parallel trade. Furthermore, there are also significant MS treatment price variations among the CEE countries. The price in Slovakia is relatively close to that of Germany, and yet this is one of the countries which treats the highest number of patients. Conversely, the Czech Republic, where the price is lower than that of Slovakia, treats fewer patients. Price does, however, explain the low rate of usage in Romania, where it is the same as that of most Western European countries, and the affordability about one-third that of Germany.

The disparities in access to immunomodulative MS treatments across Europe are, in most cases, correlated with the condition of healthcare, as expensive treatments have a significant impact on the healthcare budget.

We believe, therefore, that the most important factor which affects access to innovative MS treatment is the ability of the national reimbursement systems to carry the cost of refunding such expensive therapies. Access to medicines at such prices is considered to

## Health expenditure per capita in Europe (PPP €), 2005

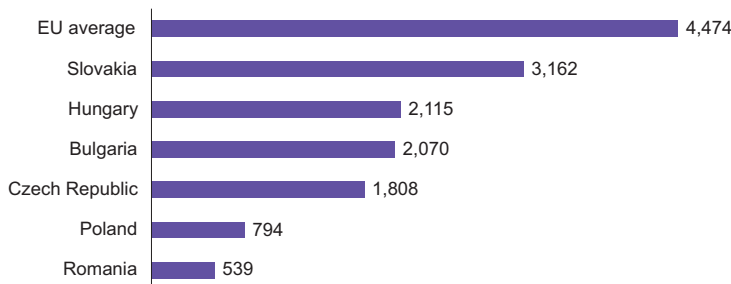


PPP – Purchasing Power Parity

Source: WHO, Eurostat, quoted in *Access to innovative treatments for multiple sclerosis in Europe report, 2009*

www.pmrpublications.com

## Mean annual costs of MS biologics per patient in Europe (€), 2008



Source: *Access to innovative treatments for multiple sclerosis in Europe report, 2009*

www.pmrpublications.com

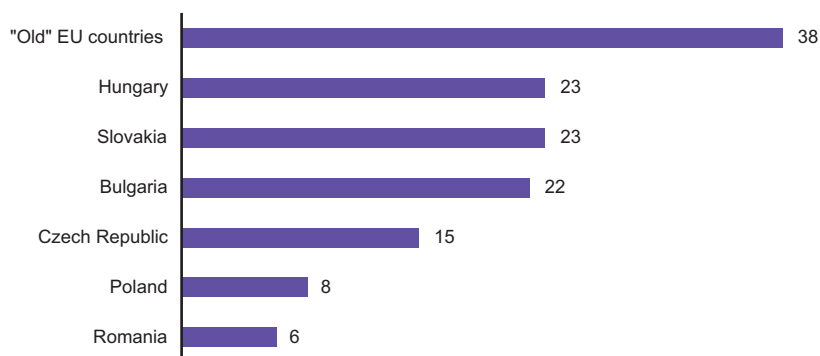
## Mean annual total MS cost per patient in Europe (€), 2008

|                             | Total (€) | Direct medical (excl. biol) (€) | Biologics (€) |
|-----------------------------|-----------|---------------------------------|---------------|
| <b>Western EU countries</b> | 39,326    | 7,665                           | 4,905         |
| <b>EU average</b>           | 35,877    | 7,114                           | 4,474         |
| <b>Czech Republic</b>       | 15,610    | 4,517                           | 1,808         |
| <b>Hungary</b>              | 14,410    | 3,877                           | 2,115         |
| <b>Slovakia</b>             | 12,622    | 2,892                           | 3,162         |
| <b>Eastern EU countries</b> | 11,632    | 3,243                           | 1,443         |
| <b>Poland</b>               | 11,340    | 3,361                           | 794           |
| <b>Bulgaria</b>             | 6,590     | 2,238                           | 2,070         |
| <b>Romania</b>              | 5,677     | 1,603                           | 538           |

Source: Access to innovative treatments for multiple sclerosis in Europe report, 2009

www.pmrpublications.com

## Estimated proportion of MS patients being treated in CEE and 13 "old" EU countries (%), 2008



Source: Access to innovative treatments for multiple sclerosis in Europe report, 2009

www.pmrpublications.com

have a significant impact on the healthcare budgets of the CEE countries. As proof of this the Polish Health Technology Assessment Agency (AOTM), in its analysis of immunomodulatory MS treatments, stated that the cost-effectiveness threshold<sup>1</sup> of this group of

medicines is much higher than that recommended by the WHO, i.e. it is three times per capita GDP, which is regarded by the Agency as the ceiling at or below which it recommends the therapy for reimbursement.

## Disparities in access to MS innovative treatments match variations in MS-related costs across Europe

The total cost of MS, defined in the EFPIA report as the proportional combined costs of healthcare, non-medical costs, production losses and informal care costs in Europe, was estimated to be €15bn. The bulk of this (€14bn) was accounted for by the old EU countries, with the estimated number of treated patients being 165,000-170,000 of a diagnosed group of 412,000 MS patients, and €650m in the CEE countries, with 59,000 diagnosed patients, where affordability remains an issue despite the lower prices. The average cost per patient was estimated in the report to be €36,000, which shows a discrepancy between Western Europe (€39,000) and the CEE countries, with an annual cost of €11,600 per patient.

The analysis of cost distribution shows the dominance of the costs which lie outside the healthcare market (i.e. production losses, informal care and non-medical costs). In the Western EU countries these constitute two-thirds of all costs, whereas biologics in both EU regions represent 12% of the total cost of MS.

## Conditional reimbursement a solution for CEE countries

In most European countries a health technology assessment is introduced as part of the decision making process in the introduction of innovative drugs. The quality-adjusted life-year (QUALY) cost of MS immunomodulating drugs is relatively high and, because of this, most countries have decided to restrict access to this treatment. The health authorities allocate a separate budget to reimburse the expensive drugs and organise tenders to maintain direct control over purchase and distribution for patients.

In Poland, for example, immunomodulatory MS drugs are available within a therapeutic programme open only to patients who meet specified criteria. The programme is carried out by specialist centres, with drug prices specified in tenders, and the number of patients and costs are, therefore, strictly con-



The therapeutic programmes of the National Health Fund (NFZ) are very restrictive. They contain eligibility criteria which are extra-medical in character. For example, under these criteria, a patient under 40 years of age stands a better chance of being eligible for treatment than a person who is a little older. The time limit of three years for the duration of therapy is equally inappropriate. In line with current medical knowledge, therapy should continue for as long as it is effective. The discontinuation of

therapy could even lead to a deterioration in the patient's condition. The Polish Multiple Sclerosis Society (PTSR) plans to report one such documented case to the European Court of Human Rights in Strasbourg. The highly restrictive character of the eligibility criteria leads to the percentage of MS patients in Poland in receipt of immunomodulating drugs being monstrously low. A mere 3% of patients in Poland have access to such therapies, and this is the lowest rate in Europe.

Izabela Czarnecka

President of the Polish Multiple Sclerosis Society

<sup>1</sup> Cost effectiveness threshold per one year of living gained (LYG).

trolled. As a result of this, the number of patients treated with interferon beta1 and beta2 rose from 500 of the 50,000-60,000 diagnosed to 2,602 in H2 2009. However, the programme provides treatment for three years only. The local MS patients' organisation has, therefore, approached the Health Ministry in the hope of having some of the restrictions eased and access extended to 15,000-16,000 patients who react positively to treatment or at least to those 5,000-6,000, who require immediate intervention.

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*Methodology note:*

*The report Access to innovative treatments for multiple sclerosis in Europe, published in October 2009, analysed 30 European countries (27 EU member states, in addition to Iceland, Norway, Switzerland and Turkey).*

*The MS drugs included in the report were Avonex (interferon-β-1a), Betaferon (interferon-β-1b), Copaxone (glatiramer acetate), Rebif 22/44 (interferon-β-1a), Tysabri (natalizumab), based on IMS data.*

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| <b>DATES:</b>     | 20-21 January 2010<br>Jacob Fleming Conferences<br>Phone: + 420 257 222 800  |
| <b>ORGANISER:</b> | E-mail: david.polak@jacobfleming.com<br>URL: <a href="http://www.jacobfleming.com/conferences/life-science/5th-pricing-reimbursement-market-access-in-pharma-medical-devices-1">http://www.jacobfleming.com/conferences/life-science/5th-pricing-reimbursement-market-access-in-pharma-medical-devices-1</a> |
| <b>EVENT:</b>     | <b>13th Annual Competitive Intelligence in Pharma</b>  |
| <b>VENUE:</b>     | Nice, France   |
| <b>DATES:</b>     | 27-28 January 2010<br>Arena International<br>Phone: +44 207 936 6672   |
| <b>ORGANISER:</b> | fax: +44 207 915 9773<br>email: emanhauari@arena-international.com<br>www: <a href="http://www.ciinpharma-events.com">www. www.ciinpharma-events.com</a>   |
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| <b>VENUE:</b>     | Papp Laszlo Budapest Sports Arena, Budapest  |
| <b>DATES:</b>     | 17-18 February 2010<br>Marcus Evans<br>Phone: +357 22 849 321  |
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| <b>EVENT:</b>     | <b>BioForum 2010</b>   |
| <b>VENUE:</b>     | New Business Centre Manufaktura, Lodz, Poland  |
| <b>DATES:</b>     | 19-21 May 2010<br>Bio-Tech Consulting /Ltd.<br>Phone: +48 42 299 60 83   |
| <b>ORGANISER:</b> | fax: +48 42 678 01 28<br>email: <a href="mailto:bioforum@bioforum.pl">bioforum@bioforum.pl</a><br>UR: <a href="http://www.cebioforum.com">www.cebioforum.com</a>   |



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