

Central Europe Pharma News

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Bulgaria

Market news

Bulgaria's NHIF pays outstanding debts to pharmacies

The Bulgarian National Health Insurance Fund (NHIF) has finally settled its outstanding accounts payable to pharmacies it cooperates with, due for the periods of 15-31 October and 1-15 November 2010. The total amount owed was BGN 33m (€16.9m) and many pharmacies, particularly in the region of Burgas, had declined to sell patients' the most expensive NHIF-reimbursed medicines, until the payments were made. Some individual pharmacies were awaiting delayed payments as high as BGN 200,000 (€102,400) each.

The money comes from NHIF's 2011 budget, in which BGN 100m (€51.2m) has been allocated to settling outstanding debts.

The NHIF management has assured that future payments from the 2011 budget will be made on time.

Medicine prices in Bulgaria increase slightly in December 2010

In December 2010 the prices of medicines available on the Bulgarian pharmaceutical market increased by 0.4% in comparison with the previous month, according to the National Statistics Institute. The price rise reflects the overall monthly inflation in the country. The prices of medical services increased by 0.2% on monthly basis while the prices of dentist services remained unchanged from November.

Pharmaceutical wholesalers reassure cancer patients

The Bulgarian Association of Pharmaceutical Wholesalers (BAPW) has issued a statement that its members are fully prepared to deliver all necessary cancer drugs to hospitals across

the country. As we previously reported in *Central Europe Pharma News*, from 2011 onwards, the National Health Insurance Fund (NHIF) will be responsible for the purchase and management of expensive drugs for conditions such as cancer and HIV/AIDS previously managed by the Health Ministry. The management of tenders for the supply of drugs will be gradually transferred from the Health Ministry to individual hospitals and clinics to reduce costs and to align the model with that which prevails in the European Union.

Patients' organisations had expressed concern in the wake of a Health Ministry decision gradually to devolve tendering to individual hospitals. The Association assured patients that the delivery of life-saving drugs would not be disrupted.

BAPW members deliver approximately 65% of the drugs paid for by public funds.

Company news

Sopharma Trading sales up by almost 15% in 2010

Sopharma Trading, a distribution arm of one of the major pharmaceutical manufacturers in Bulgaria, reported BGN 41m (€21m) sales revenues in December 2010, which represents a 22.8% increase in comparison

to the corresponding period of the previous year. The profit of the company before taxes amounted to BGN 504,000 (€258,280) in that period.

For the whole 2010, the revenue from sales of goods and equipment amounted to BGN 401m (€205m), which is a 14.4% growth compared to the previous year. The total 2010 profit of Sopharma Trading amounted to BGN 7.1m (€3.6m), which is more by 58.6% on a yearly basis.

Sopharma implements first stage of modernisation of its Ukrainian plant

Sopharma, one of Bulgaria's largest pharmaceutical manufacturers, has announced that it has completed the first stage of the modernisation and certification of the production lines at its **Vitamini** plant in Ukraine. The main laboratory of the factory was granted a quality certificate by the Ukrainian authorities, which acknowledged the standard of analysis carried out there.

In early 2008, Sopharma acquired Vitamini, as the transaction complemented its expansion strategy of increasing its share on the Russian, Ukrainian and Polish markets. At present, Sopharma is expanding further through the construction of two new plants – one in Sofia and another in Belgrade (in Serbia).

Russia, Ukraine, Poland, Latvia and Kazakhstan are Sopharma's major export

markets. The company exports 60% of its produce to 28 countries in total.

Citigroup buys 37% stake in Huvepharma

Citi Venture Capital International (CVCI), the private-equity arm of Citigroup, has completed the acquisition of 38% of the shares of **Huvepharma**, a Bulgarian manufacturer of pharmaceuticals for the livestock market, for €75m. Approximately 28% of the shares were purchased from existing shareholders, and the remaining 10% via an increase in the capital of the company.

According to Kiril Domuschiev, the CEO of CVCI, the company is thought to be worth €200m in total as a result of the deal and the increase in capital will be used to acquire competitor companies.

Advance Properties remains Huvepharma's majority shareholder, with a 62% stake.

R&D/medical news

Flu epidemic in 12 Bulgarian regions

Twelve regions in Bulgaria have announced a flu epidemic, with many schools closing and non-urgent medical services such as consultations, immunisations and visits, suspended until further notice. Sofia

was the first to announce an epidemic, on 18 January 2011, and was followed by Blagoevgrad, Dupnica, Rila, Petrich and Kocherinovo on 19 January. Medical officials announced that in Blagoevgrad and Petrich the cause of the epidemic is the seasonal winter flu. On 24 January 2011 six more regions followed the suit, including Burgas, Vratza, Shumen, Blagoevgrad, Veliko Tarnovo, and Kyustendil.

The Health Ministry expects flu rates to reach their peak in the next two weeks. Analysis of the virus at the National Reference Laboratory has demonstrated that the most widespread strain this season is the A(H1N1) flu virus.

Delays in publication of insulin prescription criteria in Bulgaria

The Bulgarian Association of Children with Diabetes (BACD) has complained about the continuing delays in the publication of the national criteria by which endocrinologists need to abide when prescribing insulin to children with diabetes. The criteria were to have been published by the National Health Insurance Fund (NHIF) by 20 January 2011. The BACD has announced that it will organise a protest if the NHIF fails to publish the criteria by 26 January, as they are expected to ensure better and more consistent treatment for diabetes patients. ■

Czech Republic

Market news

Drug manufacturers in lawsuit with Czech Health Ministry

Some 11 pharmaceutical manufacturers in the Czech Republic have taken legal action against the Ministry of Health, claiming that the Czech state authorities have incorrectly calculated the maximum drug prices and re-

imbursements they receive from the public health insurance companies.

Vladimir Srsen, spokesman at the ministry, added that the claims relate to 23 decisions on drug prices and reimbursements. Due to lower reimbursements companies have allegedly lost millions of Czech crowns.

In a public domain, only the Czech manufacturer **Zentiva** confirmed the charges. According to Pavel Kosek of **Teva** another

15-20 companies may plan to sue the ministry. If other 20 companies were successful with their lawsuits, the claims could reach CZK 2bn (€82m).

The primary aim of the pharmaceutical companies is however not to claim the compensations, but to bring about changes in the current drug reimbursement system, which is non-transparent for producers, patients, doctors as well as pharmacists, said Eva Chaloupkova, spokeswoman at Zentiva.

The companies have been encouraged by the successful court case won last year by **Abbott Laboratories**, the American drug manufacturer. As we previously reported in *Central Europe Pharma News*, the Czech State Institute for Drug Control (SUKL) calculated incorrectly reimbursement of its Tarka drug.

Health minister presents core pillars of healthcare reform

The Czech health minister, Leos Heger, has presented the core pillars of the healthcare reform to be implemented in the country by the end of 2012.

In future, patients will still pay extra for some health services, initially for better materials (e.g. contact lenses or joint replacements) and later also for more expensive treatment. This will be made possible through the definition of standard care, which will be reimbursed by public insurance, and above-standard care which will be extra-paid. The correct treatment procedures for certain illnesses, such as a stroke, will be determined at the same time.

Because, in the past five years, spending on new technologies has grown by 50%, according to the ministry, they will be optimised and regulated by a new technology committee which will decide on the suitability of any given technology for specific treatments or decide whether it is already too expensive. Very expensive technologies will be accepted initially on a trial basis before any decision is taken to use them widely.

The ministry will permit the merger of health insurance funds in order to cut operating costs. It claims that new incentives will be put in place for health insurers to rationalise the healthcare network, as there is an abundance of outpatient specialists but a shortage of hospital doctors.

The proposed drug policy should favour generic drugs, and the drug pricing system should be simplified. Patients will pay CZK 30 (€1.24) for the prescription itself, rather than individual items on prescription, and CZK 100 (€4.12) for a day's hospitalisation, instead of CZK 60 (€2.47), the current fee.

The minister does not expect any opposition within the coalition government, whereas the opposition itself has suggested that the reforms are too general.

National Economic Advisory Board to help with solutions for healthcare sector

Health minister Leos Heger has asked for an expert inquiry from the Government's National Economic Advisory Board (NERV) concerning new solutions for financing the Czech healthcare sector. In response, NERV



of this segment in Poland.

Specifying what is and what is not guaranteed under public mandatory health insurance is crucial for the development of private health insurance, which could provide cover for the part that is above the standard. A similar effort was made by the Health Ministry in Poland more than a year ago. Despite the fact that the scope of guaranteed health care services was defined for the first time, it was too large to create opportunities for private insurers, and in fact it has not contributed to the development

Monika Stefanczyk, Head Pharmaceutical Market Analyst, PMR Publications

has already set up a new healthcare working group that will deal with the economic aspects of healthcare reform.

The group is headed up by economist Miroslav Zamecnik and should meet for the first time in mid-February 2011. It is supposed to analyse future health insurance fees, insurance levels paid by self-employed individuals, and the impacts of potential changes on the labour market. According to Mr. Zamecnik, an analysis of some financing models from abroad should be carried out, including a comparison of costs and benefits.

R&D/medical news

Czech health minister plans to limit over-priced purchases at faculty hospitals

Leos Heger, the Czech health minister, is preparing a plan designed to reduce overpriced purchases of drugs and materials at faculty hospitals. Mr. Heger has already discussed the matter with the directors of all 11 faculty hospitals.

The ministry proposes to implement the so-called positive drug list (in accordance with this hospitals would use drugs on an approved list: these would be procured in bulk and would be cheaper), order purchases in line with reference prices (the usual prices established for individual products to avoid overpriced purchases) or use online auctions.

The ministry is not planning any further legislative changes, as the former changes apply to several procedures only. The plan, which is currently being finalised, could be implemented in a few weeks' time. The money saved could be used to increase the salaries of dissatisfied hospital doctors.

Contracts of Czech faculty hospitals on Internet

Czech faculty hospitals will have to publish their contracts on the Internet, which should eliminate the risk of purchasing overpriced products or services and deliver savings, said Vlastimil Srsen, a spokesman for the Health Ministry. The new requirements, part of the ministry's strategy aimed at cutting corruption in the healthcare sector, shall apply especially to contracts worth more than CZK 50,000 (€2,061). The electronic system should be launched in several weeks.

The hospitals will be guided by a list of common prices at other hospitals in order to assess whether bids submitted in tenders are overpriced or not. Any public contracts at faculty hospitals or the ministry worth over CZK 1m (€41,200) will be approved directly by the health minister. The strategy is currently aimed only at facilities managed by the ministry, but regional governors promised to consider its implementation in the regional hospitals.

According to Transparency International, bribery and corruption accounts for up to 10% of the whole healthcare sector in the Czech Republic, and reached approximately CZK 27bn (€1.11bn) in 2009.

Governors dissatisfied with low payments to regional hospitals

During a recent meeting with the Czech health minister, Leos Heger, the regional governors criticised the low payments for services to regional hospitals (in contrast to the amounts paid to faculty hospitals). The governors justified their statement by claiming that, whereas faculty hospitals receive between CZK 32,000 and CZK 34,000 (€1,300-1,390) from the insurance compa-

nies for medium surgery (e.g. the removal of an appendix), the regional hospitals receive only CZK 20,000 (€820) to cover the patient's entire stay in hospital.

The minister agreed that the current payment mechanism should be improved but said that it is very complex. He also added that the health insurance companies do not publish data on treatment spending per individual policy holder, which would make possible an evaluation of actual spending in the given region. At the same time, he pointed out that the current tariff tables do not include real differences between individual branches of medicine.

Talks continue between ministry and doctors to avoid crisis at Czech hospitals

The Czech health minister, Leos Heger, is now willing to increase funding for hospitals by several hundred thousand Czech crowns and to make up the differences in funding between individual hospitals in order to find a solution to the pressing situation at Czech hospitals, where around 3,800 doctors have threatened to resign on 1 March 2011. Mr Heger intends to hold further talks with the trade unions on 24 January to pro-

pose a solution to the problem of doctors' remuneration.

Meanwhile, the minister has announced that an increase in the salaries of Czech doctors is possible, but not before 2012. In addition, the Czech Prime Minister, Petr Necas, promised that future savings achieved by healthcare reform will be used for the salary increase.

The minister admitted that hospitals had been suffering from a lack of resources for a long time but repeated that it was not a simple matter to allocate money for doctor's salaries. On the television programme TV Prima Mr. Heger claimed that if the hospital doctors do not withdraw their notice within 7-10 days or postpone the protest, a "catastrophic plan" will be needed to ensure the provision of healthcare. Neonatal centres could be the most severely affected – of the 12 centres in the country, 2-5 could be closed as a result of the mass exodus of Czech doctors.

The financial resources for salary increases should be found within the future healthcare reform, which needs to be supported and agreed with the opposition parties in order to last for the duration of several parliaments, irrespective of the nature of the governments. The current Czech government will meet on 26 January to discuss the matter and decide the necessary measures.

Asklepion interested in Cheb hospital

Asklepion, an aesthetic medicine clinic and institute, intends to submit an official offer indicating its interest to operate the Cheb hospital, according to news wire CTK. Roman Smucler, the owner of Asklepion, said that due to free hospital bed capacity in individual departments in Cheb, it would be wise to merge them into bigger one. It would also help to cut operating costs such as heating. Mr. Smucler also added that the company is open to any form of collaboration between the Cheb and Mariánské Lázně hospitals (the latter facility is already operated by Asklepion).

The regional councillor responsible for healthcare, Vaclav Larva, reported that there were more offers on the table, despite the fact that the **Karlovy Vary Regional Hospital** (KKN), which owns Cheb and other two hospitals in Karlovy Vary region, had not published any announcement about the hospital's lease.

Hungary

Market news

Possible reduction of almost 30% in drug reimbursement spending in 2011

Gyorgy Matolcsy, the government minister for national economic affairs, has said that Hungary's healthcare budget, which will be announced in February 2011, could include drug reimbursement cuts of approximately

€364m, leaving the budget almost 30% smaller than that of 2010. Drug reimbursement is estimated to account for only 20% of total healthcare spending in Hungary, according to the Hungarian public health research centre, GKI-EKI.

As we reported in *Central Europe Pharma News* on a previous occasion, in 2010, the National Health Insurance Fund (OEP) spent HUF 357bn (€1.3bn) on drug reimbursement, which is 5% more than the 2009 figure.

Chamber of Pharmacists approves restrictions on opening and marketing of pharmacies in Hungary

Modifications which affect the opening of new pharmacies in Hungary are designed to improve drug delivery and to encourage the rational use of public funds, according to Zoltan Hango, the vice-president of the Hungarian Chamber of Pharmacists. However, Mr. Hango added that it is necessary to develop a transparent economic environment for the "actual introduction" of ownership regulations.

Dr. Agnes Maria Merczel, the regional president of the Hungarian Chamber of Pharmacists, also expressed her approval for the modification of the restrictions on pharmacy marketing, which she considers a ma-

major step in the transformation of pharmacies from commercial ventures into healthcare institutes.

From January 2011 onwards, pharmacies have been allowed to give only loyalty points for purchases carried out at a pharmacy, and which can be exchanged only for services provided by pharmacists. These include the measuring of blood pressure. In addition to product sales, customers had previously received various benefits (e.g., gifts and exchangeable tickets), which are no longer permitted.

The opening of new pharmacies in Hungary is determined by demographic and geographical conditions (please refer to the news item in the previous edition of *Central Europe Pharma News*: “New demographic and geographical regulations affect opening of new pharmacies”).

Three Hungarian counties join new health association

In accordance with the Semmelweis Plan, three West Hungarian counties (Fejér, Somogy and Veszprem) have decided to establish branches of the Pannon Health Association (PET), which will cooperate with their healthcare institutes. This was prompted by the aims of the Semmelweis Plan, which are: concentration, centralisation, consolidation and the organisation of regional patient care.

The integrated institutes will provide medical care for 1.15 million people in the region, and patient paths can, therefore, readily be organised for such population numbers. Patients can receive adequate treatment for their actual health status on the basis of unified protocols. In addition, PET institutes will have common logistic and procurement procedures and will try jointly to obtain EU funds for development projects.

The members of the PET will have to provide a consolidation plan within 60 days of receiving their share of the HUF 27.5bn (€100m) of OEP financial support, because consolidation was one of the conditions of the aid.

Company news

Skagen increases stake in Gedeon Richter to more than 5%

Skagen, one of the largest investment fund management companies in Norway, an-

nounced on 13 January that it had increased its stake in **Gedeon Richter** from 4.98% to 5.30%. This means that, in addition to **Aberdeen** and **Barclays** and **BlackRock**, Skagen has become the fourth foreign fund with a stake of more than 5% in Gedeon Richter.

Skagen already owned more than 5% of the Gedeon Richter shares, but the number fell below 5% in June 2010.

NanGenex announces chemical validation of new pilot plant reactor

NanGenex, a Budapest-based provider of nanotechnology solutions, announced that it has taken an important step towards developing a new industrial-scale, GMP-compliant pilot plant reactor, after successfully completing the chemical validation of its candidate NanoPilot instrument.

According to the company, the tests have confirmed that the NanoPilot – which is able to produce 2-4 kg actives during a daily shift – guarantees reproducibility, constant quality, dissolution, solubility and bioavailability of the generated nanoparticles.

In the words of CEO Gabor Heltovics, this means that the company not only created an innovative tool for laboratory use but also established a new industrial scale technology.

The success of the validation process is seen as a milestone towards “fulfilling production needs of the clinical development of NanGenex’s NanoActive products”, which are being commercialised by **NanoForm Therapeutics**.

R&D/medical news

Shortage of three-component H1N1 vaccine in Hungary

The National Public Health and Medical Service Agency (ANTSZ) has announced that it cannot fulfil orders from GPs for three-component vaccines against influenza H1N1 (Fluval AB) for several weeks, because of shortfalls in the supply of the vaccine. An official explanation has not yet been given.

Judit Paller, the chief medical officer, has said that, whereas there is a shortage of the three-component vaccine, only 60,000 of the 1.2 million available one-component vaccines have been given to patients, as they

prefer the three-component vaccine, which provides more comprehensive protection and is reimbursed in full by the National Health Insurance Fund (OEP).

Flu epidemic breaks out in Hungary

On 20 January 2011, the Hungarian National Centre for Epidemiology announced that a flu epidemic had erupted in Hungary. The number of people with flu-like symptoms during the week between 10 and 16 January increased by 150%, to 18,400, in comparison with the week before, according to the Public Health and Medical Services Agency (ANTSZ). The majority of patients are between 15 and 34 years of age and live in the county of Pest.

On a nationwide basis, 69 patients were hospitalised: of these, 23 received intensive care and 19 required mechanically assisted breathing.

Almost half of Hungarians suffer from serious illness

Approximately 41% of the Hungarian population of 15 or more years of age suffer from a chronic disease of which they are aware, according to research carried out by GfK HealthCare. At the same time, at least one million people in Hungary have a chronic illness but are not fully aware of their condition. 26% of Hungarians between 15 and 18 suffer from some chronic disease, and the proportion is 84% among those over 60.

Allergic diseases are at their most common in the 15-29 age group (8%) and are followed by anxiety and depression (6% among 20-to-29-year-olds), along with hypertension, which already appears among 6% of this age group.

Most 30-to-39-year-olds mentioned migraine and frequent headaches (9%), in addition to allergies (9%). Hypertension leads the field in terms of diseases among 40-to 49-year-olds (16%) and is followed by arthritis (13%) and migraine (12%).

59% of the over-60s have hypertensive vascular diseases, and one in four suffer from arthritis.

In cases of hypertension and diabetes, 90% of patients are aware that they have the disease; but with regard to chronic obstructive pulmonary disease this proportion is only 50%.

GfK Hungaria canvassed 1,000 persons between 2007 and 2010.

Additional HUF 4-5bn for R&D investments in Hungary due to institutional realignments

The government plans to allocate HUF 4-5bn (€14.5m) to the Research and Technological Innovation Fund, said Minister of State for Strategic Affairs Zoltan Csefalvay. He added that the new resources are the result of “institutional realignments” (see news item “New National Council of Research, Innovation and Science established in Hungary” for more details). At the same time, the Fund will still not receive back the HUF 16bn (€56m), which the government blocked due to budget cuts.

According to Mr. Csefalvay, the new institutions for the management of R&D and innovation will take further steps to find additional financial resources, especially EU funds. Currently, there is HUF 72.7bn (€264m) available for tenders within the New Szechenyi Plan, the Hungarian government’s economic development programme, and that amount is expected to increase to HUF 200bn (€730m) in total by the end of 2013.

The amount of public spending on R&D in Hungary is currently less than 1% of the country’s GDP, while the EU average is 1.9%, according to data quoted by Mr. Csefalvay. The government announced that it plans to increase the amount to 1.8% of GDP by 2020.

New National Council of Research, Innovation and Science established in Hungary

The Hungarian government established the National Council of Research, Innovation

and Science in December 2010, which is now the main decision-making body regarding scientific research, research and development, and innovation-related strategic issues. The Council consists of the ministers of the four main ministries (Ministry of Public Administration and Justice, Ministry of National Development, Ministry for National Economy and Ministry of National Resources) and the president of the Hungarian Academy of Sciences, together with representatives of professional interests, universities, and the business sector. Before the change, the National Office for Research and Technology (NORT; whose name was changed into National Innovation Office since January 2011) was responsible for the development of R&D policy and the use of financial resources, including the procurement process, which according to minister of state for strategic affairs Zoltan Csefalvay, resulted in the inefficient use of resources. Due to the division of responsibilities, NORT is now responsible only for establishing a connection between R&D and innovation, helping access EU funds, and professional evaluation and supervision. Finally, the Research and Technological Innovation Fund now operates under the jurisdiction of the Ministry of National Resources (it previously operated under NORT), whose main task is the management of the tenders.

More financial support for National Ambulance Service upgrade

The National Ambulance Service (OMSZ) has received an additional HUF 520m (€1.9m) from the Ministry of National Resources for the purchase of ambulances, which means that the total amount for the OM has been increased to HUF 850m (€3.08m). The tender has already been announced. The OMSZ

will also be able to spend an additional HUF 1.75bn (€6.34m), provided by the ministry, on upgrades, in 2011.

Cross-border healthcare could boost Hungarian medical tourism

According to Janos Ader, a member of the European Parliament and the European People’s Party, the directive on cross-border healthcare in the European Union is particularly favourable for Hungary because it establishes a framework within which the country can effectively use its national resources for medical tourism. Mr. Ader also added that approval of the directive could lead to a situation in which Hungary becomes the target country for several medical treatments, including balneotherapy, speleotherapy, rehabilitation and physiotherapy.

On 19 January 2011 the European Parliament approved a draft directive on cross-border healthcare in the European Union, designed to make it easier for EU citizens to obtain medical treatment in another member state. The costs of the treatment would be reimbursed by the healthcare system to the extent to which the treatment would cost the patients in their own countries. The new regulations are expected to be take effect in 2013.

Poland

Market news

Employers and unions in Poland join forces to urge changes in Reimbursement Act

Leading employer organisations and trade union federations represented in the Tripartite Commission of government, business and labour – including PKPP Lewiatan, Business Centre Club, Pracodawcy RP, Solidarnosc, and OPZZ – have issued a joint statement about the draft Reimbursement Act being considered by the Sejm. While welcoming a number of its provisions, the signatories nevertheless believe some proposals to be harmful both to the country's pharma industry and to patients, and have therefore called on the government and MPs to give the law fresh consideration, and specifically to drop several proposals and introduce changes.

First, the law should not cap the National Health Fund (NFZ)'s annual spending on drug reimbursement at 17% of its budget; instead, the budget on reimbursement should be based on epidemiological, demographic and economic data (regarding the costs of pharmacotherapy), and should be at least equal to the figure for the previous fiscal year. Second, the proposed payback mechanism should be replaced by individual agreements between the Fund and drug makers that allow for risk-sharing. Third, the proposed new tax should be set at 3% of marketing expenditures related to reimbursed medicines, rather than 3% of sales from reimbursed medicines, with proceeds used to supplant the reimbursement budget. Fourth, the law should make tax-deductible investments in R&D, so as to support the domestic pharma industry. Finally, the signatories would like the fixed price on reimbursed medicines to remain at PLN 3.2 (€0.8), rather than be tied to the minimum wage as proposed in the new law, as such a change would mean higher contributions from patients.

GPs warn of reimbursed prescriptions shortage in Poland

The failure by regional branches of the National Health Fund (NFZ) to finalise new agreements with GP clinics from the Porozumienie Zielonogorskie (PZ) alliance of GPs – despite having reached preliminary agreement with PZ on new terms late last year – could lead to patients in many parts of the country being unable to claim reimbursed prices on medicines, PZ's Jacek Krajewski has warned in a radio interview. He explained that in the absence of new contracts, PZ doctors are unable to obtain new NFZ-approved prescription forms and may only use old ones, which are quickly running out. This means that their patients may soon have to pay the full price for their medicines.

The problem is reportedly particularly acute in Opolskie and Podkarpackie.

Therefore the alliance has called on the Health Ministry to put pressure on the Fund to finalise new agreements. Deputy health minister Jakub Szulc asked NFZ director Jacek Paszkiewicz for information about the delay, adding that the problem should be solved "within days". The NFZ itself meanwhile said that its officials were acting "as quickly as possible" to approve the new agreements.

Changes to rheumatic diseases programmes in Poland

The Health Ministry and National Health Fund (NFZ) on 20 January 2011 announced important changes to National Health Fund (NFZ) therapeutic programmes on rheumatic diseases, i.e. treatment of aggressive rheumatoid arthritis (RA) and juvenile idiopathic arthritis (JIRA), and treatment of severe, active ankylosing spondylitis (AS) using TNF-alpha inhibitors.

Thus, etanercept (Enbrel, **Pfizer**) is the new first-line therapy in the RA programme, and the indicated therapy in the AS programme. Rituximab (Mabthera, **Roche**) is the new second-line therapy in the RA programme. In the JIRA programme, etanercept (Enbrel, Pfizer) is the indicated therapy for patients aged 13 and over, while there is no indicated therapy for those aged below 13.

Also, the Health Ministry has defined first-line therapy in the RA/JIRA programme as the least costly therapy "taking into account the real cost of the therapy in case it continues for more than a year", to be determined every six months. Furthermore, it extended to six months from one month the period of low activity or remission after which therapy is to be ended.

At the same time, a change to the AS programme will spare patients whose therapy was discontinued (due to low activity or remission state extending for at least six months) the need to undergo the full qualification procedure again in order to reenter the programme, after relapse.

Multiple sclerosis therapeutic programmes to be enlarged in Poland

There is strong chance that the National Health Fund (NFZ)'s therapeutic programme for multiple sclerosis (MS) will soon be significantly expanded, Prof. Danuta Ryglewicz, the country's chief neurologist, revealed during a press conference on 18 January 2011. Meanwhile, work is underway to create a second MS programme involving natalizumab, an experimental monoclonal antibody, Wojciech Matuszewicz, director of the Health Technology Assessment Agency (AOTM) said during the same event.

A new version of the existing programme has already been drafted and should be submitted to for approval later this month, Ms. Ryglewicz said. Under it, the maximum duration of immunomodulating therapy (interferone-beta or glatiramer acetate) funded by the programme would be extended to 60 months from 36 months, for patients displaying positive reaction; and there would no longer be any lower or upper age limits for eligibility (currently set at 16 years and 39 years, respectively). The changes fall some-

what short of the proposal submitted in June 2010 by the Polish Multiple Sclerosis Society (PTSR), which called for the abolition of the temporal limit as well.

Meanwhile, Mr. Matuszewicz said that although the AOTM previously issued a negative advice for the state reimbursement of natalizumab due to safety concerns, he himself was in favour of such a therapeutic programme provided that the drug's price was brought down to improve its cost effectiveness profile.

Company news

Alliance between Boehringer Ingelheim and Eli Lilly may result in new insulin analogue in Poland

Boehringer Ingelheim, a German drug manufacturer, has signed a global agreement with **Eli Lilly** for the joint development and commercialisation of a portfolio of diabetes compounds currently at the medium or late stages of development, and at least one of them will be introduced onto the Polish market, Wojciech Gryta of Boehringer Ingelheim has told *Pharma Poland News*.

This involves Boehringer Ingelheim's two oral diabetes agents – linagliptin and BI10773 – in addition to Lilly's two basal insulin analogues – LY2605541 and LY2963016. There is also an option to co-develop and co-commercialise Lilly's anti-TGF-beta monoclonal antibody. Linagliptin, in the form of an oral, once-daily, tablet for the treatment of Type 2 diabetes, is currently being reviewed by the European Medicines Agency (the application was filed in Q3 2010), and a decision is expected in July 2011.

Mr. Gryta added that the launch of three other compounds is possible, but not certain, at this stage.

Abbott to introduce bioresorbable vascular scaffold to Polish market in 2012

Abbott Laboratories, a global pharmaceutical and medical products manufacturer, plans to introduce the world's first drug eluting bioresorbable vascular scaffold (BVS) onto the Polish market.

The product (named Absorb) is used for treatment of coronary artery disease.

Kathleen Rinehart from Abbott told *Pharma Poland News* that the full commercial launch is planned in Poland and other CEE countries (Czech Republic, Slovakia, Bulgaria, Romania and Hungary) by the end of 2012. Because Absorb represents a new therapy, the company is focused on building the market in the near term. Over the next few years it expects modest revenue in CEE countries as it is building the market and clinical data and experience, she added.

Abbott recently received the CE (EU consumer safety) approval mark for the BVS device. In 2011, it also plans to initiate a randomised, controlled clinical trial in Europe, which will provide additional data to support European commercialisation and reimbursement activities.

Bioton and GSK in talks about new collaboration agreements

Bioton, the Polish biopharmaceutical manufacturer, announced that it has signed a letter of intent with **GlaxoSmithKline** (GSK) to negotiate collaboration agreements for the commercialisation by GSK of the Polish firm's insulin products in a number of foreign markets, mainly developing and emerging ones.

The document grants GSK exclusivity until 28 February to negotiate with Bioton the terms of supply, licensing and other agreements involving the Polish firm's insulin products, including insulin analogs and insulin pens, on the following markets: the Commonwealth of Independent States (CIS) countries, Asia and the Pacific (excluding Japan and China), the Middle East, Latin America and Africa.

The news comes less than a month after Bioton signed an agreement with GSK giving the global pharma firm exclusive rights to the marketing, distribution and sale of Gensulin, its flagship human insulin product, and Gensupen, its insulin pen, on the Russian market, for a period of 15 years.

Bioton is also in talks about similar agreements with **Actavis**.

Genefar terminates Ravenex distribution deal with Bioton

Genefar, the Netherlands-based a capital group connected with Jerzy Starak and the owner of **Polpharma**, has unilaterally terminated its agreement with **BioPartners**,

Bioton's Swiss affiliate, for the exclusive distribution of Ravenex (ribavirin), BioPartners' hepatitis C drug, in the markets of the European Union, Central and Eastern Europe, Turkey, the Commonwealth of Independent States (CIS) countries, and Japan. The reasons for the decision were not disclosed.

Bioton commented that the development might actually speed up the launch of Ravenex on EU markets, and that it was in talks with other potential partners.

The agreement with Genefar was signed in 2009 as part of wider collaboration between Polpharma and Bioton. The two firms also agreed to collaborate on the development of new biotech products, and **Medana Pharma**, a unit of Polpharma, bought a stake in Bioton. The termination of the agreement over Ravenex will raise questions about the future of these other projects as well.

Mavit cedes control to private-equity fund

Resource Partners (RP), a Polish private equity firm with a focus on healthcare (among other sectors), has acquired majority control over **Mavit**, the healthcare provider with operations in Katowice and Warsaw.

In a deal that came just over two months after RP bought a minority stake in Mavit, the fund more than doubled its holding in the company to 66%, by buying 36% of shares held by one of Mavit's private shareholders. The value of the transaction was not disclosed.

The fund pledged to invest PLN 15m (€3.9m) in Mavit to support an ongoing investment programme that among other things envisages the opening of an ophthalmology ward at its 24/7 specialist hospital in Katowice in 2011.

Mavit was founded in 2000. It operates two ophthalmology clinics in Warsaw and a 24/7 specialist hospital in Katowice focused on laryngology and face & jaw surgery.

Established in June 2010, Resource Partners has raised €300m from its backers (which include the EBRD, Rabobank and Axa) for investments in mid-sized companies from the healthcare, FMCG, financial services and retail sectors. It aims to complete up to 12 investments worth €4-4.5m each over the next 3-5 years in firms with EBITDA of at least €2.5m, with half of the deals in Poland and the other half in Romania, the Baltic states or in other countries of Central Europe. RP is not interested

in restructuring and cost-cutting, but in supporting growth at its portfolio companies.

R&D/medical news

Medical cluster to be launched in Poland

The Wielkopolski Capital Club (WKK) and the Polish Chamber of Importers and Exporters (PZIEK) have created Wielkopolski Klaster Medyczny (WKM), a healthcare cluster designed to foster collaboration between companies from healthcare-related sectors, research institutions, academia, and local authorities in the region. Applications will be accepted until the end of January. The number of participating entities is expected to be around 50. So far, expressions of interest have been received from hospitals, medical and business schools, and a maker of healthcare furniture. Among the backers are reportedly two private healthcare providers, **Lux Med** and **Med Polonia**.

Dr. Grzegorz Bigaj, coordinator of the WKM project, said that by joining the cluster, companies will be able to pool resources, better adapt their offerings to market needs,

and get better access to local authorities and the National Health Fund (NFZ).

Polish Bialystok Tech's new spin off to work on healthcare projects

The Bialystok Technical University (PB) in Poland has created a spin-off that will be responsible for the development and commercialisation of new devices and technologies for healthcare (and other sectors). The name of the unit is **IIT**, short for Institute of Innovation and Technology.

Jerzy Muszynski, chief executive of IIT, identified healthcare, and especially diagnostic technologies, as the area where new projects are likely to come from. For instance, the Institute will work on the commercialisation of new software for the interpretation of X-ray images. First projects will be in IT, though.

The Institute will serve both academia and business, by helping to commercialise inventions, conducting development work and pilot production, and providing advisory services (such as e.g. assistance with patent applications).

Poland's first customised implants lab opens in Lodz

The Lodz Regional Science and Technology Park (Technopark) on 14 January launched a Laboratory of Custom-Made Medical Implants, the first facility of this type in Poland.

The lab will make customised implants using a proprietary method developed by researchers from the Lodz Medical University and the Lodz University of Technology, which involves the creation of 3D anatomic models of limbs based on computed tomography scans. Initially it will focus on making implants of the facial cranium. According to deputy health minister Adam Fronczak, who attended the lab's official inauguration, the method's potential application goes beyond skull and facial surgery and ophthalmology and could well extend to neurosurgery, orthopedics, or dental care.

Technopark is co-owned by the Lodz city government, the University of Lodz, the Lodz Medical University and the Lodz University of Technology. ■

Romania

Market news

17% increase in Romanian pharmaceutical market in first 11 months of 2010

In the first 11 months of 2010 the pharmaceutical market in Romania grew by 16.9% year on year, to RON 9.3bn (€2.2bn), according to IMS Health.

In terms of volume, between January and November 2010 alone, drug consumption in Romania increased by only 1.6% year on

year, which means that the main driver of market development was price increases. The average prices of drugs in Romania increased during the period in question by 6% year on year. Another factor which influenced the market in 2010 was an increase in the market share of expensive drugs in comparison with cheaper pharmaceuticals.

It is expected that in 2010 the pharmaceutical market in Romania will boast a 17% increase on a yearly basis (in lei terms), in comparison with the 10% predicted at the beginning of 2010.

Romanian drug exports triple between Q1 and Q3 2010

In the first nine months of 2010, Romanian exports of pharmaceutical products were worth €420m, almost three times those of the corresponding period of the previous year, according to data from the National Institute of Statistics. Higher prices and the prompt collection of money are the main factors which make export sales attractive for Romanian manufacturers, who are planning to expand international sales further in 2011 and beyond.

One of the reasons for such a high growth of medicine exports last year could have also been parallel exports, i.e. medicines bought in Romania and resold in countries where prices are higher. According to Cegedim Romania, parallel exports was the main driver of the Romanian pharmaceutical market growth last year, which reached 15% of total

drug sales in the country. Cegedim estimated that the total drug sales in Romania could hit RON 8.8bn (€2bn) last year.

Drugs account for approximately 25% of the total value of exports, and the remainder are other pharmaceutical products. The main export markets for Romania are the EU member states.

Romanian drug manufacturers to insure commercial loans

Romanian drug manufacturers are attempting to insure the risk of payment defaults, as they are expecting more insolvencies in the arena of drug distribution in the wake of the **Montero** and **Relad International** cases, two drug distributors which petitioned for insolvency, according to a report in *Ziarul Financiar*. The practice of payment insurance is followed by, for example, **Sanofi-Aventis** one of the leading drug manufacturers in the country, and by **Antibiotice Iasi** with regard to its export sales.

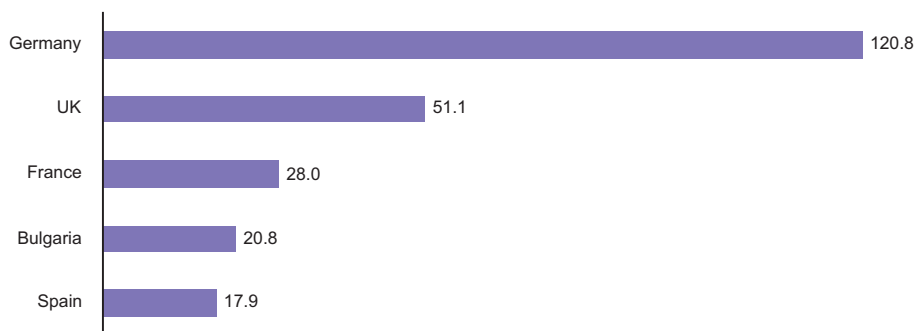
Commercial credit insurance services in Romania are provided by several companies, including Coface and Euler Hermes. The cost of a policy varies between 0.2% and 0.9% of the value of the contract, depending on additional factors such as the payment period, and guarantees up to 80% of the payment. The costs of policies increase significantly at times of crisis, when the risk is greater. In fact, it is very difficult to obtain such a contract at present, according to Ioan Nani, the general director of Antibiotice Iasi, quoted by the newspaper.

Approximately 2-3% of companies use this system. The insurance described is not used for public purchases.

Number of public hospitals in Romania to be reduced by 200

In 2011, the number of public hospitals under the decentralisation process (managed by local authorities) is expected to be reduced by 200, from 370, as the Romanian Health Ministry continues to implement cost cutting measures. In 2011 hospitals are also able to spend no more than 70% of their total funds on salaries. Furthermore, the calculation of the salaries of family doctors will be based on the volume of medical services actually delivered (50%) and the number of patients

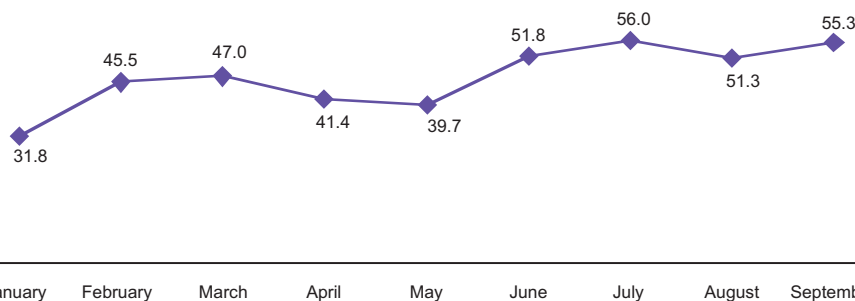
Value of Romanian pharmaceutical export to the main EU countries (€ m), January -September 2010



Source: National Institute of Statistics, 2010

www.pmrpublications.com

Pharmaceutical products export from Romania (€ m), January-September 2010



Source: National Institute of Statistics, 2010

www.pmrpublications.com

per capita (50%). In the past, the figures were 30% and 70% respectively.

From 2011 onwards, the Romanian Health Insurance House (CNAS) will also allocate 60% of the funds received in each province to finance the healthcare spending of this province.

As we reported in *Central Europe Pharma News* on a previous occasion, in 2011 Romania will spend €230 per capita overall on public healthcare services, or 5% of the country's GDP in comparison with the €275 allocated in 2010. A budget of RON 4.4bn (€1bn) has been approved for the Romanian Health Ministry, and RON 16.5bn (€4bn) for the CNAS.

Algocalmin to be sold as Rx drug from February onwards

The National Drug Agency of Romania has banned the sale of algocalmin (produced by **Zentiva**, which is currently in the hands of **Sanofi-Aventis**), one of the most popular analgesics in Romania, along with 13 other met-

amizol-based drugs, without a prescription. Recent research proves that uncontrolled use of these medicines can cause a number of serious illnesses. The rule will take effect in February 2011.

According to IMS Health, there were 18.6 million packets of metamizol-based drugs sold in Romania in 2010, 13% fewer in comparison with 2009. Last year these drugs were thought to be worth €20.5m.

Company news

A&D Pharma borrows €150m for debt refinancing

A&D Pharma, one of the largest drug distributors and retailers on the Romanian pharmaceutical market, took out a €150m loan at the end of December 2010 from a consortium of local banks which includes Erste Group, BCR and Unicredit. The money will be used to repay a €100m loan taken out by the company in 2009 and to fund other company projects.

As we reported in *Central Europe Pharma News* on a previous occasion, **Fildas**, another drug distributor in Romania, has applied for a €71m loan to pay off its debts.

For the first nine months of 2010, A&D Pharma reported consolidated sales worth RON 2bn (€482.2m), a 32% increase (in euro terms) in comparison with the corresponding period of last year.

At the end of 2010 the company also decided to withdraw from the London Stock Exchange, believing that the cost of being publicly traded exceeds the benefits for its management and shareholders.

Antibiotice Iasi expects sales revenues of RON 294m in 2011

Antibiotice Iasi, one of the leading Romanian drug manufacturers, is planning to achieve sales worth RON 294m (€69m) and to make a gross profit of RON 22.4m (€5.2m) in 2011, according to *Wall-street*. The company's target for this year exceeds the sales figure expected for 2010 by approximately 20%. The main drivers of business growth in 2011 are expected to be exports and the launch of 10 new medicines for cancer treatment in Romania scheduled for April this year.

Antibiotice has not yet announced its financial results for 2010, but in mid-December 2010 the company's management estimated that revenue in 2010 would reach RON 242m (€57m), and that the company's gross profit should reach RON 20m (€5m).

R&D/medical news

Romanian private medical services market to be worth €500m in 2011

The Romanian private medical services market is expected to grow by 20% year on

year in 2011, to €500m, according to *Ziarul Financiar*. This growth rate will fall short of that of previous years because of the declining purchasing power of the country's population.

According to **Medsana**, a chain of private clinics in Romania, in 2010 the corporate sector cut its spending on healthcare services for employees, and private customers are now the main driver of demand for medical services. However, in 2010 the average private patient spent only €35 on medical treatment, in comparison with €40 in 2009.

Medsana hopes for 35% increase in sales in 2011

Medsana, a Romanian network of medical diagnostic and treatment centres, expects a 35% increase in sales in 2011, if it relaunches an investment programme frozen last year which involves the opening of paediatric clinics and two new medical centres in Bucharest, along with the construction of a 200 bed hospital. If the management takes the decision to postpone its investments in 2011 also, the increase will be a mere 15%.

In 2010 Medsana reported sales revenues of €6.2m. The company served approximately 170,000 patients at the three clinics which it operates. Corporate subscriptions accounted for approximately 40% of revenue, slightly less than the 2009 figure. At present the company employs 175 doctors and medical staff.

MedLife expects revenue of €53m in 2011

MedLife, one of the leading Romanian private healthcare service providers, is hoping that its revenue will reach €53m in 2011: this would represent a 33% increase in comparison with that reported by the company in 2010. This forecast is supported by the fact

that in the first weeks of 2011 MedLife had already registered a 40% increase in the average daily number of patients, to 4,000.

In 2011 MedLife also plans to spend €25m on the expansion of its network of clinics. Furthermore, the company expects the sales of its pharmacy chain **PharmaLife** to increase to €2-3m this year.

CMU borrows €18.3m to fund business growth

Centrul Medical Unirea (CMU), one of the leading Romanian private healthcare operators, has taken out three loans worth €18.3m in total from Raiffeisen Bank Romania to finance the further development of the business. In 2011 the company plans to open a new hospital and three clinics and intends to develop new medical services, including interventional imaging, urology, transplants and other surgery.

In 2010, CMU reported revenue of €30m and plans to double this figure over the next 2-3 years. The company employs approximately 1,000 people and wants to increase the number of its employees to 2,000 by the end of 2011.

At the moment, CMU operates four hospitals in Bucharest and one in Brasov. The chain also includes 23 clinics. In 2010 CMU acquired **Euroclinic**, another private Romanian provider of healthcare services. ■

Slovakia

Market news

OECD: Slovakia should limit spending on drugs

The Organisation for Economic Co-operation and Development (OECD) recommends that the country should cut spending on drugs, particularly by using generic equivalents. At present, spending on pharmaceuticals, as a proportion of total health spending, stands at 28% (in comparison with the OECD average, of 17%). Spending on drugs constitutes 2.2% of GDP in Slovakia, whereas the OECD average is 1.8%.

The OECD therefore encourages the introduction of an upper limit on out-of-pocket payment, which could help to bring down total drug spending, as low co-payments encourage the consumption of expensive drugs. The organisation also advised that the remuneration of doctors be increased, as their salaries are well below the OECD average.

Furthermore, the OECD identifies several other areas of concern, such as substantial direct payments in the healthcare system, low incentives for general practitioners and hospital workers and limited competition on the health insurance market.

The organisation therefore encourages an increase in competition among insurance funds, thus reducing barriers to entry, allowing selective contracting with providers and allowing contributions to vary. The OECD also suggests the splitting or partial privatisation of the state-owned **Vseobecna Zdravotna Poistovna**.

In general, the OECD observes that the Slovak healthcare system is less efficient than those of many other OECD countries, particularly in terms of translating substantial increases in expenditures into better health-related outcomes.

OECD included the recommendation in its overview of the economic situation in Slovakia published in November 2010.

VsZP and small hospitals fail to conclude deal

The state-run **Vseobecna Zdravotna Poistovna** (VsZP) and the Association of Slovak Hospitals (ANS) have failed to reach agreement on existing hospital contracts. The association, which represents smaller, private hospitals, is opposed to the amendment, mainly because of the proposed cuts in funding for hospitals (a reduced figure has been established for individual hospitals and ranges between 3 and 6%). The talks are likely to continue.

At the same time, the parties also failed to agree whether the amendments should become valid on 1 January 2011 or 1 April, as suggested by the Slovak Insurance Association.

Marian Petko, the head of the ANS, claims that hospital budgets are stretched to their limits. On January 2011, the minimum wage was increased and, in addition, the trade unions demanded a salary increase of 5% for both medical and non-medical staff. Mr. Petko claimed that such demands are unrealistic, given the likely reduction in payments.

SaS will not support cancellation of health insurance contributions

Richard Sulik, the leader of Liberty and Solidarity (SaS), one of the coalition parties in the Slovak government, has announced that the party will not support the cancellation of health insurance contributions, as this measure was not in the government's manifesto. The Slovak media has reported that this cancellation could be one of the possible alternatives of the planned fiscal reform. If so, the government would raise taxes, and health insurance companies would receive the money directly from the state.

Such a reform could take place in 2011, with effect from January 2012. Iveta Radicova, the

Slovak Prime Minister, has said that the aim is not to cancel health insurance contributions as such, but to decide on alternatives – support an increase in direct taxes and eliminate burdens for employers or *vice versa*. Public consultation should follow.

Company news

Slovak Health Ministry suspected of cronyism with Pfizer

The Slovak Ministry of Health was accused by the *SME* daily of favouring **Pfizer Slovensko** as its Prevenar 13-valent vaccine was included in the categorisation list under a shortened procedure.

As Eva Kaszasova from Pfizer told *Central Europe Pharma News*, the company categorically rejects accusations of cronyism and breaches of legislation. Mrs. Kaszasova explained that firstly, Prevenar 13 is not a new vaccine in Slovak vaccination scheme – since January 2009 was the only vaccine approved for mandatory vaccination of children against pneumococcal diseases (first as 7-valent conjugate vaccine Prevenar, and later since July 2010 as a 13-valent conjugate vaccine Prevenar 13). Moreover, with regards to the new categorisation of medicines effective as of 1 January 2011, and due to the fact that second reimbursed vaccine Synflorix from **GlaxoSmithKline** was categorised as a new vaccine for mandatory vaccination of children against pneumococcal diseases, Pfizer was asked by the Healthcare Ministry of the Slovak Republic to hold price negotiations with the aim to eliminate the extra charge for Prevenar 13 (mandatory vaccination must be fully-covered by the health insurance). Several remarks and amendments of experts were raised in the interdepartmental review, resulting in further changes in the categorisation process.

Slovak media however states that other pharmaceuticals need about 100 days to undergo the categorisation process and have to be approved at least by the Categorisation Committee, while Pfizer's drug was not. Moreover, the media pointed out that that the minister had worked for Pfizer between 1996 and 2003 and his brother still works there.

The issue is now being investigated by the Attorney General.

Dovera in rush to review hospital contracts

Dovera, the Slovak private health insurer, intends, in February 2011, to enter into talks with hospitals about new contracts for this year. The negotiation schedule should result in a change to the date on which new contracts take effect, from 1 July to 1 April 2011, whereas the policyholders will be provided with services continuously. The changes should be agreed individually based on the evaluation of the effectiveness and quality of each hospital. Dovera has already contacted all 80 hospitals and made it clear that it does not intend to renege on any contracts.

As we reported in *Central Europe Pharma News* on a previous occasion, Dovera predicts that its total revenues in 2011 will be €925.9m (excluding reallocated premiums), which represents a reduction of 1.7% in comparison with the estimated revenues of 2010. Conversely, its drug spending will increase by few percentage points in 2011, which means fewer resources for healthcare services and stays in hospital. The talks with the hospitals will, therefore, focus on adjusting prices.

New contracts at Magellan in Slovakia in 2010

Preliminary figures published by **Magellan**, the Polish provider of financing services for healthcare providers and suppliers, show that the company maintained its rapid growth in Q4 and can look to an equally strong 2011.

Thus, in 2010 Magellan signed new contracts with customers in Poland, the Czech Republic and Slovakia with combined value of nearly PLN 918.6m (€238.6m), which represents an increase of 54% compared with the year before. Of this, so-called off-balance sheet agreements (i.e. framework and conditional agreements) climbed 14% y-o-y to just over PLN 209.4m (€54.4m), whereas new balance-sheet agreements, a more immediate pointer to sales performance, surged 71% y-o-y and exceeded PLN 709.3m (€184.2m).

In the fourth quarter, off-balance sheet agreements almost doubled to PLN 53.4m (€13.9m), whereas new balance-sheet agreements jumped by 20% y-o-y to PLN 243.9m (€63.3m) contributing 34% of the full-year figure.

According to Magellan, the strong rise in new contracts provides a solid foundation for continued dynamic expansion going forward.

Slovak Association of Generic Drug Manufacturers appoints new management

The Association of Generic Drug Manufacturers (GENAS) appointed in December 2010 Karol Poloni, business director at **Krka Slovensko** as the new director of the association. The appointment was the result of personnel changes within the individual member companies. The association also appointed new deputy directors and heads of working groups.

Founded in 2000, GENAS currently has 20 member companies.

R&D/medical news

Implementation of eHealth in Slovakia suspended

The implementation of the electronic healthcare system known as eHealth in Slovakia is suspended, according to information published by news agency SITA. The Ministry of Health is currently carrying out an audit in order to ensure that future benefits of the eHealth system are maximised and any possible risks are identified. The ministry has not disclosed its plans for 2011 or amount of money it has already invested into the project.

As we previously reported in *Central Europe Pharma News*, former health minister, Richard Rasi, pointed out eHealth, should be launched in early 2013, and its implementation costs should reach €252m.

The system shall include a new electronic healthcare book and electronic prescriptions and will allow patients to book a doctor's appointment electronically.

One-third of Slovak hospitals fail to report cases of nosocomial infection

In 2010 there were some 5,000 cases of nosocomial infection reported in Slovakia, but the Public Health Institute (UVZ), which monitors the prevalence of infection in Slovakia, quoted by the SITA news agency, has claimed that at least one-third of Slovak hospitals did not report a single case.

One of the reasons for failing to report such cases is the financial condition of the hospitals and a declining emphasis on prevention,

according to Lenka Sramkova, a spokeswoman for the UVZ. Another problem is insufficient bed capacity for the isolation of patients. According to the Health Ministry, a substantial administrative burden contributes to the very low number of reports submitted. As a result, health insurance companies do not include such infections in their evaluation criteria, mainly because only a small number of facilities carry out their reporting duties in full.

The ministry plans to introduce a number of legislative changes which would result in audits of healthcare facilities and quality indicators.

In the past, in the developed countries 5-8% of hospitalised patients, on average, have fallen victim to nosocomial infection, whereas in Slovakia in 2009 the figure was 0.5%. Slovak legislation stipulates that the heads of hospital departments should report each case of nosocomial infection to the regional UVZ office within 48 hours.

Slovak dentists dissatisfied with minimum network

Jan Gasic, the president of the Slovak Chamber of Dentists (SKZL) has said that dentists in Slovakia are not satisfied with the current minimum network of dental service centres. According to SKZL data, each Slovak dentist looks after 2,600 patients, which is the most substantial number among the Visegrad group countries. Whereas in Bratislava the number is approximately 1,000 patients per dentist, in Velky Krtis it stands at 4,500, which proves that dentists are concentrated in the larger cities and more prosperous regions, with villages being poorly covered or served by retired dentists.

Another serious problem is the shortage of young medics. In Slovakia, 44% of all dentists are more than 56 years old, according to the SITA news agency. Mr Gasic called on the Health Ministry to improve the education framework at the medical schools, which do not deal with enough patients, one result being the fact that their graduates have insufficient experience. There is also shortages of personnel and medical equipment. With regard to emergency dental service centres, these are poorly equipped and their doctors badly paid. The SKZL has proposed a reduction in the network of emergency centres, from 46 to 14.

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 frequently 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 areas 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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