Biweekly News Review

Published by PMR

Central Europe Pharma News

A prime source of market intelligence for pharma professionals

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Biweekly News Review

Issue No. 18 (129) – Wednesday, 3 September 2014
Published by PMR

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Bulgaria

Market news

NHIF has funding for two months only

According to Dr Miroslav Nenkov, the interim health minister, the extra funding provided to the National Health Insurance Fund (NHIF) via the recent budget revision will be sufficient for the next two months only and there will be a funding gap at the end of the year. The previous parliament approved a BGN 225m (€115m) increase in the budget.

According to Dr Nenkov, the healthcare system in the country suffers from a chronic shortage of funding which can be solved only by an increase in healthcare contributions and stricter control over spending. However, these changes cannot be adopted without a working parliament. Parliament was dissolved at the beginning of August during the tenure of the interim government, which will be in power until the next elections, scheduled for 5 October.

Dr Nenkov emphasises that that no hospitals are threatened with closure, although many healthcare providers have run up debts.

Interim minister in Bulgaria suspends tenders worth BGN 30m launched by predecessor

The interim health minister, Dr Miroslav Nenkov, has suspended tenders worth almost BGN 30m (€15.3m) launched by his predecessor, Dr Tanya Andreeva, because of errors and non-compliance with the law.

The largest tender pertains to the establishment of e-health in the country. This is thought to be worth BGN 12m (€6.1m). The technical specifications of the tender contain unclear and inaccurate requirements. For example, the system is required to be run on only 1,000 computers. However, all GPs are supposed to be able to use it, and there are 5,000 GPs.

Furthermore, pharmacies and regional health insurance offices should have access to it also.

Another suspended tender pertains to a BGN 5m (€2.6m) contract for repair work on regional emergency centres. According to Dr Nenkov, these regional centres are located on the premises of municipal hospitals and the ministry cannot carry out work at such hospitals.

Counterfeit pharmaceuticals account for 10% of all medicine in Bulgaria

About 10% of pharmaceutical products in Bulgaria are counterfeit, according to Ivan Savov, the regional director of the international certifying organisation Intertek Moody. By comparison, such medical products account for only 1% in the European Union.

According to Bulgarian Drug Agency data, Bulgarians spent BGN 1.8bn (€917m) on drugs in 2013. The number of packets sold was 249 million. Meanwhile, the State Agency for National Security and the Ministry of the Interior estimate that sales of counterfeit drugs in the country were worth BGN 150m (€76.4m). They enter the country via illegal channels, and the estimates do not include online sales of these drugs.

At present, India accounts for the most substantial proportion of imported counterfeit drugs in Bulgaria.

Pharmaceutical companies spend BGN 76.6m on advertising in H1

The pharmaceutical industry spent BGN 76.6m (€39m) gross on advertising (TV, newspapers and radio) in the first half of 2014, a 12% year-on-year increase, according to data provided by the market research firm GARB. The industry was, therefore, ranked in third place among advertisers, with a 14% share of overall gross advertising spending in the media in question.

Pharmaceutical companies spent BGN 68.3m (€35m) on TV advertisements, a 9% year-on-year increase. The industry was in fourth place with regard to gross TV advertising spending, accounting for 14%. The only pharmaceutical company in the top 15 TV advertisers was **Reckitt Benckiser**, which spent BGN 10.4m (€5.3m), an 8% year-on-year increase.

In print media advertising, the industry was ranked in second place, with a 12% share as a proportion of print media gross advertising spending, and with pharmaceutical advertising representing an investment of BGN 8.3m (€4.2m), a 36% year-on-year increase.

In terms of the amount spent on radio advertising, the pharmaceutical industry was ranked sixth, with BGN 100,000 (€51,000). However, the data pertaining to radio advertising were based on only the two radio stations monitored.

R&D/medical news

Hospitals to receive more NHIF funding in September

The National Health Insurance Fund (NHIF) in Bulgaria will raise hospital budgets for September beyond the August levels. In August, hospitals received amounts which fell 20% short of the July level. The NHIF attributed the cuts to the uncertainties surrounding its 2014 budget revision at the National Assembly.

MPs approved a BGN 225m (€115m) increase in the NHIF budget for this year on 4 August. On 6 August, the NHIF supervisory council decided to reduce hospital funding. Because of this discrepancy, hospital managers suspect the NHIF of trying to channel the extra funding into medicines rather than hospital spending.

When approving the extra funding, parliament consented to the spending of the funds on hospitals and cancer drugs. In response, pharmacies and drug manufacturers have warned that the NHIF will have a BGN 90m (€46m) gap in its spending on drugs. As a result, the NHIF supervisory board is expected to set aside approximately BGN 50m (€25.5m) of the budget increase for medicines.

About 200 Bulgarians receive medical care for ALS

According to Professor Ivaylo Tarnev, of the Neurology Clinic of the Aleksandrovska Hospital, approximately 200 Bulgarians currently receive medical care for amyotrophic lateral sclerosis (ALS). Professor Tarnev adds that the exact number of people with the disease is unknown. In fact, the total number is difficult to calculate as there are many people who are at an advanced stage of the disease, cannot leave their homes and do not, therefore, receive any treatment.

The Aleksandrovska Hospital has treated more than 500 people diagnosed with ALS over the past 10 years.

Czech Republic

Market news

Health Ministry to get more money from 2015 budget to finance investments

After consultations with the Ministry of Finance, the Czech Health Ministry will get CZK 1.2bn (€43.2m) more from the state budget in 2015 to carry out its planned investments, news portal E15 reported.

As PMR previously reported, the ministry wanted CZK 1.4bn (€50.5m), but the health minister Svatopluk Nemecek said that he is satisfied with the smaller sum.

The agreement with the Finance Ministry will allow the Ministry of Health all key points of its agenda net year. The ministry wants to use the funds to invest into public hospitals and improve oversight over public health insurance companies.

In line with the previous proposal, the Ministry of Finance allocated CZK 5.7bn (€205.4m) to the healthcare sector from the state budget, a sum lower by CZK 636m (€22.9m) compared with 2014.

Abolishment of CZK 30 prescription fees could be compensated by pharmacy margin increase

Czech health minister Svatopluk Nemecek believes that the negative effects of cancellation of CZK 30 (€1.1) prescription fees in pharmacies as of 2015 could be offset by a slight increase of pharmacy margins, news agency CTK reported.

Czech pharmacies claim that their revenues from prescription fees amounted to around CZK 1.7bn (€61.2m) last year, but many of them do not collect the fees or return them back to customers, so the actual figure is closer to CZK 800m (€28.8m) and this the sum that the Czech government is taking into account when preparing to compensate pharmacies for the abolished fees.

The health minister also said that the margin increase would not raise the prices of medicines for patients, as the cost of increased margins will be covered by public health insurance providers.

Medical franchises grow popular in Czech Republic

Czech entrepreneurs, who want to open a franchise business, are increasingly investing in non-traditional ideas and products, including the sale of alternative medicines or provision of healthcare services, *Hospodarske Noviny* reported.

Last year was very successful for a franchise chain **Konopna Lekarna**, which offers various products, including hemp ointments, and already operate 14 franchised branches around the country. It costs around CZK 300,000 (€11,000) to open a franchise unit under Konopna Lekarna brand, with regular franchise and marketing fees to be paid to the company amounting to 6% of the profit obtained by a given branch.

A franchise network called **Novodoba sanitka**, which provides rapid hospital transportation for patients who are not eligible for free transportation by an ambulance, has managed to open 25 branches and sell over 30 franchise licenses since last May.

Novodoba sanitka says that it already obtained expressions of interest in its services from Slovakia and Poland and could also expand into Hungary, *Hospodarske Noviny* noted. The initial investment to open a Novodoba sanitka franchise amounts to CZK 100,000 (€3,600), while a monthly fee to be paid out to the company is set in the area of between CZK 1,500 (€54) and CZK 3,000 (€108).

Czech Republic not eager to fine pharma companies for corrupting doctors

The Czech state practically stopped imposing penalties on pharmaceutical companies for offering over-generous incentives to doctors for prescribing their medications, news website Medical Tribute reported after Czech TV broadcaster Ceska televize.

The country's State Institute for Drug Control (SUKL) penalised just one pharmaceutical company within the last three years, with two financial penalties worth the total of CZK 300,000 (€10,800) imposed on **Abbott Laboratories**. The company decided not to appeal the fines.

However, the SUKL is now looking into three new cases, in which pharmaceutical companies could have bribed a doctor. The authority did not release the names of the companies, saying that they will be made public if fines are imposed on the firms.

Most Czech patients support reimbursement of alternative medicine

As many as 85% of Czechs would like to see some of the methods of alternative medicine to be officially recognised as a supplement to conventional medical treatment and covered from the public health insurance system, news agency CTK reported citing a survey carried out by market research company STEM/MARK.

Around 50% of the survey respondents said that public health insurance providers could cover the costs of acupuncture, acupressure and herbal products, while one third of them pointed to homeopathy and chiropractic treatment.

Around 45% respondents said that when applied as addition to conventional treatment, alternative medicine services should only be provided by doctors, while 40% said they could be carried out by a doctor or a healer with a relevant certificate.

The market research agency conducted the survey in August on a sample of 500 people aged 15-59 years.

Company news

Czech court confirms advertising fine for Green-Swan Pharmaceuticals

The Czech Supreme Administrative Court confirmed in July a CZK 400,000 (€14,000) fine imposed on **Green-Swan Pharmaceuticals** in relation to the advertising of its dietary supplement GS Condro Forte, news website Apatykar reported.

The court said that the advertisement contained statements on therapeutic effects of the dietary supplement in relation to the problems and diseases of the musculoskeletal system.

The advertising message was further supported by noting that the product is recommended by a company offering medicinal products used in the treatment of pain caused by arthrosis, which could have mislead the viewers by assigning the product properties related to prevention, treatment or cure of the disease.

R&D/medical news

Czech Republic mulls merger of public health insurance providers

The Czech government began to plan a merger of state-owned public health insurance providers **Vseobecna Zdravotni Pojistovna** (VZP), **Vojenska Zdravotni Pojistovna** (VoZP) and **Zdravotni pojistovna ministerstva vnitra** (ZPMV), *Lidove Noviny* reported, adding that the plan to merge the three insurers is enshrined in the government's coalition agreement.

The merged insurer would have an 80% share on the market and the Czech Association of Health Insurance Funds is worried that the public health insurance market would become monopolised, with the remaining small insurers disappearing from it within a few years.

Ruling parties CSSD and ANO believe that the merger of the three state insurers would bring tens of millions of Czech crowns in savings, but the critics of the idea, such as Czech pharmacoeconomist Tomas Dolezal, are concerned that the move would have a negative effect on patients' wallets. The newspaper pointed to Poland and Hungary, where the public health insurance model is based on just one insurance provider, and where the level of patient co-payment in the public healthcare system is one of the highest in the OECD.

Proton cancer treatment to be covered from public health insurance in Czech Republic?

The Czech Ministry of Health plans to add photon and proton cancer treatment to the list of medical procedures covered from the public health insurance system, which means that the treatment could soon be financed by all Czech public health insurance providers, *Mlada Fronta Dnes* reported on its website Idnes.cz.

The ministry says that the treatment would be covered from public health insurance only after a prior recommendation issued by one of 13 Czech oncology centres. An amendment to the public health insurance law that would give the centres the power to do so is already being prepared and could be introduced next year. After that, the ministry will amend the list of procedures covered from public health insurance by adding proton/photon cancer treatment.

The Prague Proton Centre, which is currently the only Czech facility providing this treatment, welcomed the move of the Ministry of Health. The cost of proton cancer treatment provided by the Prague centre amounts to around CZK 740,000 (€27,000) per patient, while the price charged by a proton centre in Munich is about 10% lower, according to Czech insurer **Vseobecna Zdravotni Pojistovna**, which covered the costs of the treatment for a number of patients on an individual basis.

AIFP points to problem of harmful drug interactions by launching new information website

The Czech Republic's Association of Innovative Pharmaceutical Industry (AIFP) launched in June this year a new website called "I know my drugs" which provides patients with advice on the correct use of medicines and potential risks stemming from drug interaction. The website was launched in cooperation with the company **Infopharm**, the main aim of which is to gradually build up a central database of information about drugs and their interactions.

A total of 750 patients visited the website since the launch of the pilot project in June. During this time, almost 150 potentially problematic drug interactions have been identified, as well as 40 cases, where patients have been taking the same drug under two different brand names.

The AIFP points out that interactions stemming from combining various medicines or mixing drugs with otherwise harmless food products constitutes a serious problem. A survey conducted at the request of the AIFP by agency STEM/MARK showed that around 10% of 560 survey respondents ignore doctor's instructions or information leaflets inserted in drug packages, when taking medicines.

The association also estimates that around CZK 1bn (€35.8m) per year is spent by the Czech healthcare system on the treatment of complications resulting from drug interactions and harmful combination of drugs, with estimated 889 patients dying from the complications. The data was obtained by extrapolation of research carried out in a UK-based Merseyside hospital and published in 2004.

The AIFP noted that the problem of adverse drug interactions and incorrect medicines prescription could be eliminated to a large extend by the computerization of the healthcare system.

Brno-based hospital upgrades cerebrovascular centre

University Hospital Brno modernised its cerebrovascular centre, spending on the project CZK 70m (€2.5m), news agency CTK reported, adding that the aim of the modernisation was to improve care over stroke patients.

The facility spent around CZK 20m (€716,000) of its own resources on reconstruction works in the centre, which is based at the hospital's neurology clinic. The cost of new medical equipment amounted to CZK 50m (€1.8m), with 80% of the sum covered from EU subsidies. The facility acquired new beds, ultrasound equipment, instruments to monitor patients' vital signs and other equipment.

Around 1,000 patients with cerebrovascular condition were hospitalised in the hospital last year, a number similar compared with 2012, the news agency said.

Bulovka Hospital eyes construction of clinic for patients with highly infectious diseases

A new clinic for highly infectious diseases could be set up within the next two years at Prague-based Hospital Bulovka, next to the facility's a national centre for the treatment of dangerous infections, news agency CTK reported.

The hospital says that the Czech state needs to be prepared for various epidemics and the appearance of highly infectious diseases, with these types of risks increasing the globalised world. The operating costs of the clinic are estimated at around CZK 15m (€539,000) per year.

The Czech Ministry of Health will contribute CZK 65m (€2.3m) to the construction of the clinic, while the remaining costs will be covered by the hospital itself. The total cost to set up the clinic is estimated at CZK 80m (€2.9m), according to Czech TV station Nova.

The current national centre for the treatment of dangerous infections includes two Biobox chambers, eight isolation beds and two beds in the intensive care unit, while the new clinic would have 12 specialised beds. Patients with high-risk infectious diseases would be admitted to the clinic, but in the meantime it could be used by regular patients, Czech media reported.

■

Hungary

Market news

Increase in sales of OTC products in H1 2014

In Hungary, retail sales of OTC products were worth HUF 77bn (€245.4m) in the first six months of 2014, a 7% increase in comparison with the corresponding period of the previous year, according to the market research company Nielsen. The most substantial increases were in sales of probiotics (22%), infant nutrition products (18%) and antiflatulents (17%). In the 25 best-selling product categories, there was an increase in 19, a reduction in five and stagnation in one.

Vitamins and dietary supplements remained the most popular OTC category, with a 30% market share, and analgesics were in second place, with 16%. These were followed by cough medicines (7%), products for the treatment of varicose veins (5%), nasal congestion products (5%), antiflatulents (4%) and antidiarrhoeal products (4%).

Manufacturers spent HUF 75bn (€239m) on advertising in list prices in the first half of the year, 35% more than a year earlier. 19% of television advertising costs involved anti-flu products, whereas vitamins and analgesics represented the second and third most substantial shares as a proportion of TV advertising, with figures of 12% and 11% respectively.

Ministry of Justice and Public Administration may supervise GYEMSZI

Istvan Gyorgy, the government commissioner for Budapest, has told *Info Radio* that, in accordance with a new structural change currently being prepared, the National Institute for Quality & Organisational Development in Healthcare & Medicine (GYEMSZI), might, along with other state institutions, be taken under the wing of governmental bureaux (regional administrative institutions under the Ministry of Justice and Public Administration). He added that the aim of the possible change is to make administration more effective.

Possible Russian sanctions on medicine exports from Hungary

Mihaly Varga, the Minister for the National Economy, has told the state-run radio station in an interview that Hungarian pharmaceutical exports are among those products which could be subject to Russian sanctions in the future. According to Mr Varga, the Russian embargo measures must be monitored to ensure that losses to the Hungarian economy are minimised. He also said that the government must closely monitor the product categories which are is affected because the effects could damage the whole Hungarian economy.

Weak forint causes difficulties for medical equipment manufacturers

Hungarian medical equipment manufacturers may be forced to make people redundant and to stop marketing certain products unless the government helps the industry to fend off the negative effects of the weak forint, according to a letter sent by four professional associations to Gabor Zombor, the health secretary, according to a report in the daily business publication *Vilaggazdasag*. The Association of Medical Device Manufacturers, the Dealers' Alliance for Health, the Orthopaedic Shoe Makers' Association and the Hungarian Orthopaedic Guild argue that their member companies should be allowed to raise their prices. Those products which are reimbursed have fixed prices, determined by the National Health Insurance Fund (OEP), and with a few exceptions these prices have not been changed since 2003. In 2003 one euro was worth 245 forints, but the euro is now work well over 300 forints. Since most medical devices are either imported or manufactured with the use of imported material, the weakening of the forint has recently reduced margins to a minimum.

R&D/medical news

Increase in number of healthcare fund members in Hungary in Q2 2014

The total asset value of the 12 private healthcare funds – the members of the Stabilitas Hungarian Association of Pension and Health Funds, which encompasses 70% of Hungarian private healthcare funds – was HUF 42bn (€134m) at the end of the second quarter of 2014, according to a report in *Vilaggazdasag*. This represents a 1.4% increase in comparison with the previous quarter.

The market leaders among these 12 are OTP, with 10.2bn (€32.6m) worth of assets, MKB, with HUF 9.8bn (€31.3m), and Premium (previously known as AXA), with HUF 6.2bn (€19.8m). OTP has 213,000 members, MKB 171,000 and Premium 139,000.

The total number of members of these 12 private healthcare funds rose significantly in comparison with the previous quarter and reached 725,500, 5,000 more than in the first quarter of 2014. The assets of the average healthcare fund member were worth HUF 58,400 (€186), slightly less than the figure at the end of the previous year: 60,300 (€192).

Healthcare fund members spent HUF 9.5bn (€30.3m) between them in the second quarter, mostly on OTC and

Rx medicines, but much less on healthcare services and medical aids. Members used their healthcare fund savings 1.8 million times in the second quarter of 2014, and the average amount spent was HUF 5,263 (€16.8), 2.2% more than that of the previous quarter.

Hungarian innovative 3D dental implant system to be launched

A consortium consisting of **Medimetal**, a Hungarian developer and manufacturer of trauma implants and other medical products, **Smart Dental Solutions**, a company which develops, produces and sells innovative dental and surgical technologies, and the University of Szeged is planning to introduce a new 3D dental implant system on the market, to be personalised for individual patients, according to the Medimetal's website.

The project began to use a HUF 330m (€1.1m) EU subsidy in 2012. It provides software which analyses CT images of the patient's jaw, to plan the most suitable operation techniques and implants, and uses the images to create an individual three-dimensional model with 3D printing – instead of traditional dental technology – to produce a tailor-made implant. It also provides a specific surgical toolset for the operation.

After the surgery, the dentist can use the software to compare the 3D image of the planned implant and the CT images of the patient's jaw after the operation.

Renovation and expansion of Tapolca hospital begins

The cornerstone was laid in mid-August 2014 marking the start of Jeno Deak Hospital's renovation and expansion in Tapolca. The undertaking will cost HUF 2bn (€6.4m), for which the municipality of Tapolca is receiving HUF 760m (€2.4m) in EU funding.

The project comprises, among others, the renovation of the pulmonary department and the respiratory rehabilitation centre. The renovation also involves the development of more modern facilities and reconstruction of the building's interior, which will involve creating 20 two-bed hospital rooms and 30 new rooms for chronically ill patients. The expansion is comprised of building a new cardiac care centre, which will be located in a separate, adjoined 130,000-m² building. The building will also house an indoor training facility for patients. Completion is scheduled for mid-2015.

Cardiology centre construction begins in Zalaegerszeg

Construction of the Cardiology Centre at Zala County Hospital began in mid-August 2014 in Zalaegerszeg. The investor is the National Institute for Quality and Organisational Development in Healthcare and Medicines (GYEMSZI). The undertaking will cost HUF 5.5bn (€17.5m), for which the investor is receiving 100% EU funding.

The project comprises the construction of a new building for the cardiology department. The building will also house several other departments that will be relocated from the health complex external sites. HUF 1bn (€3.2m) will be invested in purchasing new machinery and developing the reception and patient management system. Completion is planned for March 2015.

HUF 7.4bn development of Hetenyi Hospital commences in Szolnok

The cornerstone was laid in August 2014 marking the start of Hetenyi Hospital's expansion and development in Szolnok. The investor is Jasz-Nagykun-Szolnok Megyei Hetenyi Geza Korhaz-Rendelointezet, the hospital's owner and operator. The cost of the undertaking is HUF 7.4bn (€23.8m), for which the investor is receiving 90% EU and 10% state funding. The general contractor is **Swietelsky Magyarorszag**.

The undertaking involves the construction of several new building units. The new buildings will house the central hospital department and waiting areas, the obstetrics and gynaecology departments, the maternal and paediatrics medicine departments, as well as the department of ophthalmology.

Poland

Market news

Polish Health Ministry unveils new changes to reimbursement list

The Health Ministry on 19 August published for consultation a draft update of the list of reimbursed medicines, due to come into effect on 1 September.

A total of 63 new products are to be added to the pharmacy medicines list including, for the first time, a medicine (one EAN code) containing glycopyrronium bromide. It will be reimbursed as maintenance therapy for adult patients suffering from chronic obstructive pulmonary disease (COPD), thus increasing the available therapeutic options for COPD patients. Furthermore, in the case of three active ingredients (four EAN codes) already on the list, namely denosumab, vigabatrin, and posaconazole, the range of reimbursed indications will be expanded to include new ones (three off-label uses in the case of pozaconazole).

The remaining additions to the pharmacy list are equivalents of products already reimbursed.

At the same time, 25 products are to be removed from the list, either at the request of manufacturers or due to the expiry of reimbursement decisions.

The official selling prices of 77 products (35 active ingredients or types of foods for particular nutritional uses or types of medical devices) will be reduced, by between PLN 116.1 (€27.7) and PLN 0.01, whereas the selling prices of five products (two active ingredients) will be raised, by between PLN 0.54 (€0.13) and PLN 86.23 (€20.59).

The gross retail prices of 565 products (583 items of the list) will decrease as of 1 September, by between PLN 121.91 (€29.11) and PLN 0.01, while the retail prices of 29 products (30 items) will increase, by between PLN 0.01 and PLN 91.73 (€21.91).

Patient co-payment will decrease for 133 products (136 items), by between PLN 119.60 (€28.56) and PLN 0.01, and increase for 506 products (519 items), by between PLN 0.02 and PLN 15.90 (€3.80).

There are also a number of changes on the hospital list. For example, a new programme will be created titled "Treatment of primary immunodeficiency in adult patients" that will pay for the cost of several medicines (eight EAN codes) containing human immunoglobulin. There is already a similar programme for patients aged up to 18 years.). Also, new medicines will be included in existing programmes, e.g. "Upper limb spasticity in post-stroke patients using Type A botulin toxin" (one EAN code) or "Treatment of soft tissue sarcoma" (sunitinib, two EAN codes), among other changes.

As of 1 September, the official selling prices of 16 medicines (7 active ingredients) used in chemotherapy and drug programmes will be reduced, by between PLN 1,922.40 (€459) and PLN 0.01. Also, the reimbursement ceilings for medicines containing imatinib and bosentan will change.

Drugs with highest share in National Health Fund (NFZ) expenditures on drug reimbursement in Poland, 2013

Drug	Manufacturer	Share in NFZ's budget for reimbursement (%)
Clexane	Sanofi	2.90
Neulasta	Amgen	1.80
AccuChek Active	Roche	1.45
Abilify	Lundbeck	1.37
Spiriva	Boehringer Ingelheim	1.29

Source: NFZ quoted by Puls Biznesu, 2014 www.pmrpublications.com

The biggest beneficiary of National Health Fund (NFZ) reimbursement expenditures on pharmacy medicines in Poland, 2013

Company	Reimbursement costs (PLN m)	Share in NFZ's budget for reimbursement (%)
Polpharma	343	4.78
Novo Nordisk	286	3.99
GlaxoSmithKline	257	3.58
Sanofi	246	3.42
Adamed	240	3.34
Sandoz	218	3.04

Source: NFZ quoted by Puls Biznesu, 2014 www.pmrpublications.com

NFZ: Clexane accounted for nearly 3% of drug reimbursement spending in 2013

Sanofi's anti-coagulant Clexane captured the highest share in the National Health Fund (NFZ) expenditures on drug reimbursement in 2013, accounting for 2.9% of the total, the Fund's 2013 report shows obtained by *Puls Biznesu*.

Amgen's white blood cell booster Neulasta came second with 1.8%, followed by **Roche**'s AccuChek Active blood glucose monitoring system (1.45%), Abilify, a schizophrenia drug from **Ludbeck** (1.37%) and Spiriva, a drug made by **Boehringer Ingelheim** used to treat chronic obstructive pulmonary disease.

Polpharma headed list of pharmacy reimbursement beneficiaries in 2013

Polpharma was the biggest beneficiary of National Health Fund (NFZ) reimbursement expenditures on pharmacy medicines in 2013 with the Fund spending a combined PLN 343m (€81.5m) on the company's outpatient drugs last year, according to an NFZ report obtained by *Puls Biznesu*. Compared with 2011, i.e. the last year before the Reimbursement Act, Polpharma's share in the NFZ's pharmacy-drug reimbursement expenditures increased to 4.78% by 0.5 p.p., from 4.27%, allowing it to overtake **Sanofi** and **GlaxoSmithKline** (GSK). Yet, NFZ spending on Polpharma's outpatient medicines declined by 9% during this period, from PLN 377m (€90m) in 2011.

Polpharma was able to largely compensate for price reductions thanks to higher sales volumes and new product launches, and the acquisition of Polfa Warszawa, Magdalena Rzeszotalska, a spokeswoman for the Polpharma group, told the paper.

Novo Nordisk also moved up two places to second, accounting for PLN 286m (€67.9m). Next came GSK, the market leader in 2011, with PLN 257m or €61m (3.58%), down from PLN 481m or €114.2m (5.46%) in 2011.

Novo's high ranking comes as a surprise for the company, even despite its near-50% share of the diabetes management market, its spokesman Radek Popiel told the paper. Novo estimates its ranking at 9th or 10th, with the difference possibly stemming from the fact that the NFZ figures do not include hospital medicines, and may not take into account all subsidiaries (Sanofi alone has three marketing authorisation holders in Poland).

Jerzy Toczyski, the CEO of GSK, noted that the NFZ spent more on his company's oncology and other specialist hospital medicines, but that this was not sufficient to offset lower revenues in the pharmacy market, with the group's overall sales in Poland declining as a result.

Euler Hermes: A third of pharmacies could go bust within five years

Even up to 30% of pharmacies could be closed down over the next five years, as traditional independent stores find it increasingly hard to compete with chain pharmacies in what is an overcrowded market, according to Euler Hermes, the global provider of credit management solutions.

The company calculates that the average period of payment to wholesalers in the independent pharmacy segment has increased in comparison with 2013, indicating deteriorating financial performance. On the other hand, wholesalers are serving as a positive buffer, accepting later payment and absorbing the delays instead of passing them on to drug manufacturers, said Michal Modrzewski, head of sector analysis at Euler Hermes. This allows them to negotiate more attractive prices for medications, thus increasing the price competitiveness of their own pharmacy chains. The independent stores, meanwhile, are able to retain sales levels. But they are also being encouraged to join wholesalers' systems to benefit from lower prices and marketing support. However, the market is overly saturated and there are set to be closures among independent retailers, although the scale of the process will depend on wholesalers' preparedness to accept the costs, according to Grzegorz Hylewicz, head of debt collection at Euler Hermes.

NIA asks URPL to intervene over four pharma firms' distribution policy

Polish Pharmaceutical Chamber (NIA) president Grzegorz Kucharewicz has sent a letter to the Office for Registration of Medicinal Products, Medical Devices and Biocides (URPL), complaining about the practice of research-based drug manufacturers distributing their products to pharmacies only through a handful of select wholesalers, and asking URPL to examine its legality under Article 36 of the Pharmaceutical Law.

The letter, which was sent in late June but whose text was made public only late last month, mentions four specific medicines from four companies, namely **AstraZeneca Polska**'s Pulmicort, which the NIA has established is distributed exclusively by Pelion and Neuca; **Boehringer Ingelheim**'s Pradaxa, distributed only by Farmacol and Neuca; **Sanofi**' Clexane, distributed by ACP Pharma, Farmacol, Neuca, Polska Grupa Farmaceutyczna (PGF), and Prosper; and **GlaxoSmithKline**'s Fraxiparine, Seretide, distributed by Farmacol, Neuca, and PGF.

According to the Chamber, by refusing to allow other wholesalers to distribute these products, the companies are restricting supplies to the pharmacy market, thus making it impossible for drug retailers to fulfill their statutory duty of ensuring universal availability of medicinal products for patients. The practice violates provisions of Article 36 of the Pharmaceutical Law and fulfills the conditions specified in Article 33 for revoking marketing authorisations, the NIA president concludes, asking the URPL to take necessary steps to eradicate the "pathology".

According to the manufacturers, the system complies with existing law and is designed to prevent parallel exports.

Company news

Pelion reports higher wholesale sales, lower pharmacy sales in Q2

Second quarter sales at **Pelion** amounted to PLN 1.85bn (€441m) and were 4.4% higher than in the equivalent period of 2013, while the group's net profit slumped by 87.6% y-o-y to PLN 2.7m (€0.6m), due among other things to an unfavorable court ruling in Lithuania and an impairment charge on its pharmacy business.

Revenues from wholesale operations (excluding intragroup transactions) rose 6.6% y-o-y in Q2 to almost PLN 1.37bn (€327m), whereas revenues from pharmacy operations (excluding intragroup transactions) decreased by 2.4% y-o-y to PLN 468.8m (€111.8m).

Cumulatively in January-June 2014 Pelion had revenues of nearly PLN 3.8bn (€906m), up 2.7% y-o-y, and a net profit of PLN 28m (€6.7m), down 52% y-o-y.

Revenues from wholesale operations totalled PLN 2.81bn (€670m) in H1 2014, up 4.8% y-o-y. Revenues from pharmacy operations came to PLN 965.4m (€230.2m), down 3.8% y-o-y.

By way of comparison, the Polish pharmaceutical wholesale market grew by 3% y-o-y over this period and the Lithuanian market by 1.7% y-o-y.

Pelion forecasts that in 2014 as a whole the market will grow by 3-6%.

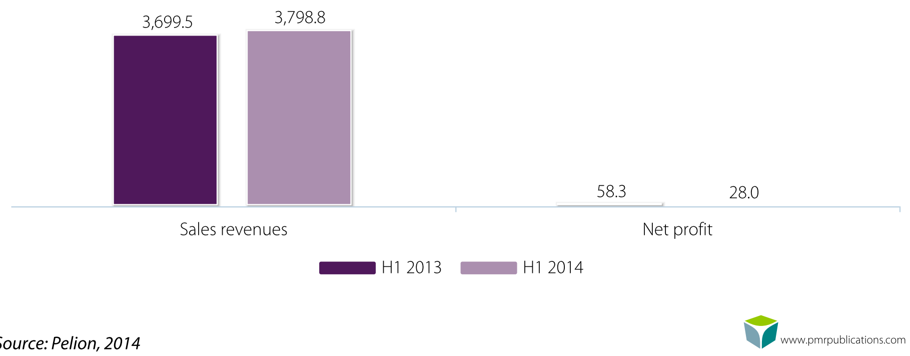
Pelion acquires Natura drugstore chain

CEPD NV, the subsidiary of **Pelion**, on 26 August entered into a conditional agreement to buy 100% of shares in **Polbita**, the operator of 258 drugstores under **Natura** brand, from Alior Bank and Erste Bank, the pharmaceutical distribution group announced on 27 August.

The value of the transaction was not disclosed. The deal is subject to anti-trust clearance.

Under the terms of the agreement, CEPD NV has undertaken to inject PLN 10m (€2.4m) of fresh capital into Polbita, while Alior and Erste Group have undertaken to

Pelion financial results (PLN m) in H1, 2013-2014



Source: Pelion, 2014

provide long-term financing in the amount of PLN 150m (€36m) for Polbita's development and for the refinancing of its debt, Pelion revealed.

The acquisition will be funded from the group's own resources. In 2013 Polbita had consolidated sales revenues of over PLN 420m (€100.3m).

Neuca posts 10% sales rise in Q2 helped by ACP Pharma

In the second quarter of 2014 **Neuca** recorded consolidated sales revenues of nearly PLN 1.56bn (€372m), an increase of 9.7% y-o-y in comparison with the same period of 2013. The result, boosted by the consolidation of the wholesale business of **ACP Pharma** as of May, marked a sharp reversal from the 2.3% y-o-y sales dip reported by the group in Q1 and means that in January-June 2014 Neuca had revenues up 3.5% y-o-y to over PLN 3.05bn (€727m).

Revenues from its core wholesale pharmaceutical distribution operations amounted to almost PLN 3.05bn in H1 2014, up 5.3% y-o-y.

This is better than the market as a whole, which grew by just under 3% y-o-y during this period. As a result, Neuca's average share in wholesale sales to pharmacies rose to 29.8% in Q2 from 26.5% a year earlier.

The group's pharmaceuticals business (Synoptis Pharma) had another excellent period, with revenues from the sale of own brands up 76.3% y-o-y in H1 2014, to PLN 26.3m (€6.3m), helped by a steady stream of product launches. The segment also reported a more than doubling of its net profit to PLN 6.5m (€1.6m).

The group as a whole experienced a sharp decline in its Q2 net profit, which almost halved to PLN 10.8m (€2.6m) due to the cost of integrating ACP Pharma and the consolidation of that company's negative net result, as well as due to the reduction in the official margin on reimbursed medicines. Neuca's net profit for January-June declined by 9.3% y-o-y to PLN 47.1m (€11.2m). However, the group expects a rise in net profit for 2014 as a whole.

The integration of ACP Pharma also had a negative impact on sales margins as the company commands lower margins than Neuca.

Neuca expects big benefits from ACP Pharma deal in H2 and to grow drug portfolio to 400

Neuca anticipates a "dramatic" improvement in its financial results in the second half of 2014 thanks to the **ACP Pharma** acquisition, while it plans to broaden its drug portfolio by more than 50% during this period to reach 400 products, CEO Piotr Sucharski told a news conference on 28 August. The group also expects to complete more acquisitions of ambulatory clinics in the rest of 2014 than it has concluded so far this year (i.e. two).

The group estimates that in 2014 as a whole, the financial benefits from the integration of ACP Pharma will total PLN 30m (€7.1m), for example owing to the fact that ACP's wholesale units will purchase medicines on terms negotiated by Neuca. In H1 2014, by contrast, the acquisition had a negative overall impact on Neuca's profits, as the advisory, restructuring and other costs related to the deal amounted to PLN 18m (€4.3m) while the benefits totalled PLN 3m (€0.7m).

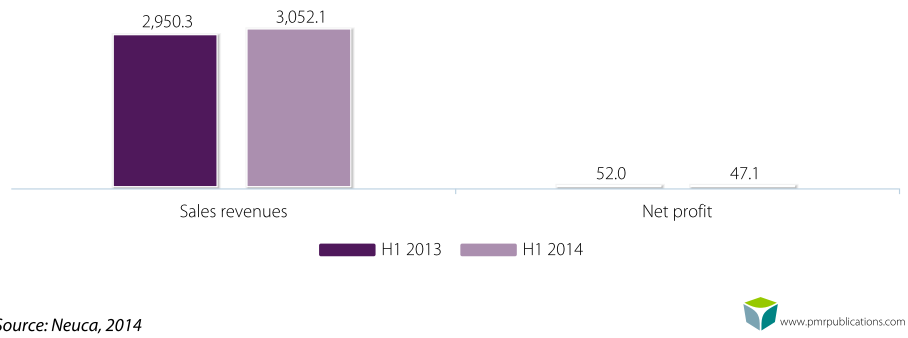
Neuca stands by its forecast that in 2014 as a whole it will earn a net profit to PLN 90m (€21.4m), excluding one-off items.

As of 1 September, Neuca will have nine products on the list of reimbursed medicines, Mr Sucharski revealed. It has already applied for the inclusion of a further seven drugs.

At the end of June the group had 260 medicines in its portfolio. It forecasts that the segment will generate a gross profit of PLN 10.5m (€2.5m) in the entire 2014, compared with PLN 8.2m (€1.9m) after H1 2014.

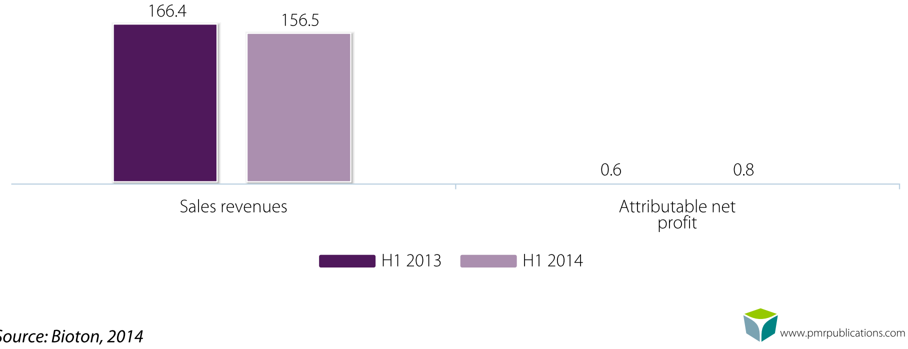
Neuca plans to acquire "more than 10" outpatient care providers over the next two years, spending approximately PLN 30m (€7.1m).

Neuca financial results (PLN m) in H1, 2013-2014



Source: Neuca, 2014

Bioton financial results (PLN m) in H1, 2013-2014



Source: Bioton, 2014

Bioton posts 6% sales dip in H1 despite better Q2

In the first six months of 2014 **Bioton** generated consolidated sales revenues of PLN 156.5m (€37.1m), a decrease of 5.9% compared to the equivalent period of 2013. In the second quarter alone, sales were roughly flat at PLN 79.9m (€19m).

Group revenues from the sale of insulin and its derivatives slumped by 23.2% y-o-y in H1 2014 to just below PLN 53m (€12.6m). Bioton SA, which accounts for the bulk of insulin sales, recorded a 23% y-o-y drop in domestic insulin sales to PLN 37.6m (€8.9m) and a 38.2% y-o-y fall in foreign insulin sales, to PLN 13.1m (€3.1m). The foreign weakness reflects lower sales of insulin forms in China, where Bayer Healthcare had to renew import licenses, and, especially, weaker sales of the active ingredient in India, where licenses also had to be renewed, with shipments postponed until H2 2014.

Group revenues from the sale of antibiotics and generic medicines, by contrast, rose

10.1% y-o-y to PLN 29.3m (€6.9m) while revenues from the sale of growth hormone decreased by 6.2% y-o-y to PLN 17.6m (€4.2m).

In terms of group entities, Bioton SA recorded a 7.3% y-o-y fall in sales to PLN 74.3m (€17.6m), MJ Biopharm a 9% y-o-y decline while SciGen generated a 8% y-o-y rise in H1 sales.

On the other hand, Bioton reported an almost 40% improvement in its attributable net profit for the January-June period, albeit from a low base, to just over PLN 0.8m (€0.2m). This contrasts with a net loss reported in Q1 2014. The group also improved its gross sales margin to 44.2% from 42.1%. The gross sales margin of Bioton SA improved to 57.4% from 56%, which Bioton attributed to optimisation of production costs, the start of its contract with **MSD** for the distribution of hospital products and the receipt of first payments under a contract with its new exclusive distribution partner in Russia (**Biotec**, which replaced **GlaxoSmithKline**).

Bioton reduces debt with early bond repayment

Shares of **Bioton** surged by 7.2% on the Warsaw Stock Exchange on 25 August, the first trading session after the company announced the completion of a partial early repayment of 7,920 B series bonds for a total of PLN 7.6m (€1.8m).

Early repayment of the bonds was a condition set by Bioton's bondholders to approve the sale by the biotech firm of its remaining 50% of shares in **Copernicus**, the maker of Gensupen insulin pens, for PLN 25m (€6m), which was concluded in June.

The latest repayment, announced on 22 August, came several weeks after a similar transaction worth PLN 3.96m (€0.95m). Together they reduced the biotech firm's debt by 11.6m (€2.8m).

Farmacol reports lower sales, profits in Q2

In the second quarter of 2014 **Farmacol** recorded consolidated sales revenues of PLN 1.17bn (€278m), down 6.8% y-o-y, and earned a net profit of PLN 13m (€3.1m) , down 36% y-o-y. Both figures were markedly below market expectations.

In the first six months the group had revenues up 6.1% y-o-y to PLN 2.62bn (€622m) and a net profit down 38.4% y-o-y to PLN 31.4m (€7.5m).

First-half revenues from wholesale operations, the biggest source of revenue for Farmacol, amounted to nearly PLN 2.4bn (€570m) and were 8.3% higher than in the same period of 2013. Revenues from the pharmacy business, by contrast, declined by 14.5% y-o-y in January-June 2014, to PLN 199.4m (€47.3m).

As at the publication date of the half-yearly report, Farmacol's pharmacy network comprised 183 branches, up from 182 three months earlier. The number includes an online pharmacy operated by Cefarm Bialystok.

The deterioration of the group's profitability in H1 was due mainly to the reduction of the official margin on reimbursed medicines by a further point effective from 1 January, acting CEO Barbara Kaszowicz said in a letter to shareholders.

The half-yearly report also discloses that on 11 August a court in Katowice registered a new company called **Farmacol Plus**, whose role within the Farmacol group will be to manage wholesale sales to pharmacies.

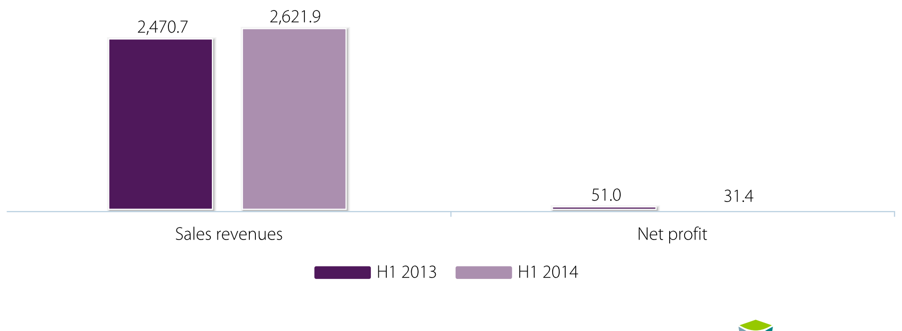
Polpharma to replace all machinery in Nowa Deba plant

Polpharma will invest PLN 50-80m (€11.9-19m) to upgrade its existing pharmaceuticals plant in Nowa Deba (Podkarpackie voivodship), an amount sufficient to replace its entire production equipment, Nowa Deba mayor Wieslaw Ordon revealed during a meeting of the local council in late August, citing information obtained by his officials.

The modernisation of the plant is part of a larger project, unveiled earlier this year, whose centrepiece is the construction of a new factory of medicines and dietary supplements in Nowa Deba over the next three years. Mr Ordon hopes the new plant will employ about 200 workers.

The Nowa Deba factory currently employs 158 people. It was built at a cost of PLN 100m (€23.7m) by Sanfarm, a unit of Polfa Warszawa established in 1999. It was acquired by Polpharma in 2012 as part of its takeover of Polfa Warszawa. According to Mr Ordon, Polpharma's plans for the plant are a confirmation that its decision to keep the facility instead of selling it to investors from Germany or Sweden was the right one.

Farmacol financial results (PLN m) in H1, 2013-2014



Source: Farmacol, 2014

R&D/medical news

Sejm approves cross-border directive bill

The Sejm on 29 August voted to approve a bill that transposes into Polish law the provisions of the EU directive on patient rights in cross-border healthcare, which gives patients the right to be reimbursed for healthcare received in another Member State of the European Union up to the level they would have been in their own country.

The directive came into force already in October 2013, but has yet to become a reality for Polish patients because of a delay in its implementation to the country's legal system.

The bill stipulates that in order to receive reimbursement for the cost of healthcare received elsewhere in the EU – importantly, "healthcare" also includes medicinal products and medical devices – the patient has to submit an application to the relevant regional branch of the National Health Fund (NFZ), enclosing a receipt from a foreign provider. In the case of some healthcare benefits, however, patients will be required to obtain a prior consent from the NFZ. The list of such benefits will be laid down in a Health Ministry regulation.

The bill also states that the NFZ will not reimburse the cost of vaccinations that are part of the obligatory vaccination programme in Poland. And it sets a cap of approximately PLN 1bn (€237m) on annual NFZ expenditures on cross-border reimbursement.

Despite the lack of relevant legislation, some patients are already applying for refunds from the NFZ. By 22 August, the Fund received 84 such applications for the total amount of PLN 1.95m (€0.46m), of which more than 50% were for cataract removal surgery, the NFZ told Polish Press Agency. Because the NFZ takes the view that until the directive is implemented into Polish law, there is no legal basis to reimburse the costs of healthcare received in the EU, 11 of these patients have taken the Fund to the court. There has been one first-instance ruling so far, in the patient's favour, but the Fund is appealing.

New cataract removal criteria to force 250,000 patients off waiting lists?

Only patients with visual acuity below 20/40 according to the Snellen chart will be qualified for cataract removal surgery within the National Health Fund (NFZ) system, under a proposal unveiled by the Health Ministry and scheduled to come into effect on 1 January 2015, *Gazeta Wyborcza* reported on 28 August. The consultation phase will last until 13 September.

According to experts from the ophthalmology field cited by the newspaper, the change could reduce the overall waiting list for NFZ-funded cataract removal, which currently stands at 493,000 people, by about half since well over 200,000 patients will lose eligibility. They will have to use the private sector instead, or wait until their visual acuity becomes sufficiently reduced.

In the words of Dr Joanna Oficjalska of **Lexum**, the new rules mean that patients with the worst acuity will receive treatment faster, but the proposal is very bad news for professionally active persons.

Another ophthalmologist, speaking on condition of anonymity, said that the new proposal was bad for patients as it would increase the risk of complications.

However, the ministry wants to strengthen the eligibility criteria because it reckons that the current waiting lists are inflated, with some patients being qualified too early. As a result, some do not even to turn up for surgery.

The change would also reduce the number of patients potentially likely to travel to other EU countries, such as the Czech Republic, to receive surgery and claim reimbursement from the NFZ under the EU's cross-border healthcare directive.

In the first half of 2014, a total of over 112,000 cataract removal procedures were carried out within the NFZ system, an increase of more than 15% over a year earlier, thanks to a new financing policy adopted by the Fund in 2013 that forced providers to perform more surgeries (the unit prices were reduced by an average of 20% with contracts left unchanged).

Mercator Medical delivers positive H1 results

Mercator Medical, the domestic manufacturer and distributor of medical gloves and other disposable medical materials, in the first half of 2014 generated consolidated sales revenues of PLN 76.3m (€18.2m), which represents an increase of 8.5% compared to the equivalent period of 2013.

Sales of gloves rose 4.8% y-o-y to PLN 68.7m (€16.4m), while sales of wound dressings jumped by 37.6% y-o-y to PLN 4.1m (€1m) and sales of non-woven fabrics and other products (mainly disposable clothing and drapes for surgical areas) almost doubled to over PLN 3.5m (€0.8m).

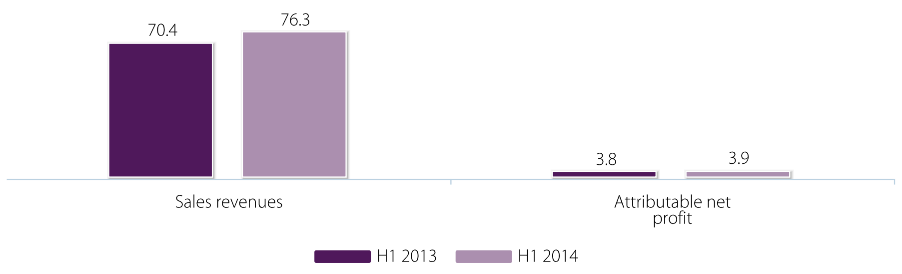
Geographically, sales in Poland rose 4.7% y-o-y to reach almost PLN 33m (€7.9m). Sales in Saudi Arabia increased by 25% y-o-y to PLN 9.1m (€2.2m) and in Ukraine by 10.8% y-o-y to PLN 7.8m (€1.9m) while sales in Russia, where in contrast to Ukraine Mercator does not have a subsidiary, surged by 87.4% y-o-y to nearly PLN 6.7m (€1.6m). Sales in Romania were up by 13.3% y-o-y to PLN 5.1m (€1.2m) and in Hungary by 4.5% y-o-y to PLN 3.1 (€0.7m).

On the other hand, sales in Thailand slumped by more than half to PLN 0.6m (€0.14m).

The company experienced a "slow" decrease in sales margins on goods in H1 2014, particularly in Poland (by 1.7 p.p. compared with a year earlier), due to growing competition, Mercator's half-yearly report notes.

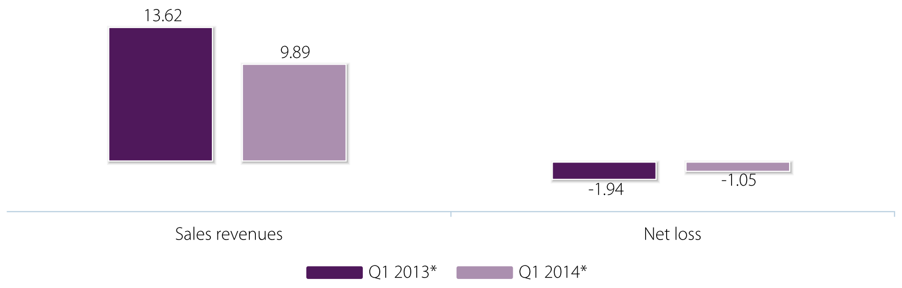
In the six months to June Mercator Medical made a net profit of PLN 3.9m (€0.9m), up 2.6% y-o-y.

Mercator Medical financial results (PLN m) in H1, 2013-2014



Source: Mercator Medical, 2014

Swissmed financial results (PLN m) in Q1, 2013-2014



** the first quarter of Swissmed´s fiscal year (April-June)*

Source: Swissmed, 2014

Swissmed posts 27% sales fall in April-June due to strategic overhaul

In the three months to June, i.e. the first quarter of its fiscal year, **Swissmed** recorded consolidated sales revenues of PLN 9.89m (€2.36m), which represents a drop of 27.4% in comparison with the corresponding period of 2013, according to official figures published on 14 August.

At the same time, the group narrowed its net loss by nearly half, to PLN 1.05m (€0.25m).

Swissmed says that the decline in revenues recorded in April-June is due chiefly to the separation of cardiovascular hospital services provided under National Health Fund (NFZ) contracts into Swissmed Vascular (subsequently sold to American Heart of Poland), and the fact that Swissmed Centrum Zdrowia SA, the parent company, as of July 2013 ceased providing services under NFZ contracts.

As a result, Swissmed's revenues from NFZ contracts amounted to just PLN 1.69m (€0.40m) in April-June 2014, down by 71.5% y-o-y and representing only 21.6% of its total medical revenues. Revenues from commercial patients also decreased, albeit slightly, by 3.5% y-o-y to PLN 6.12m (€1.46m). They accounted for 78.4% of Swissmed's total medical revenues over this period.

Revenues from hospital care slumped by 57.4% y-o-y to PLN 2.82m (€0.67m). Revenues from ambulatory care fell by 11.6% y-o-y to PLN 4.98m (€1.19m). In April-June outpatient services contributed nearly 64% of Swissmed's medical revenues, compared with 46% last year.

Swissmed aims to continue the restructuring process in the coming months. It will concentrate on developing new services at its ambulatory clinics, particularly the new segment of 24-hour care and rehabilitation services for seniors and for post-hospital and post-operative patients who, due to disability or health condition, cannot function independently in a home setting. Meanwhile, the group will move forward with a plan to merge Swissmed Centrum Zdrowia SA with Swissmed Prywatne Centrum Medyczne, the two main units.

Polmed reports strong H1 figures

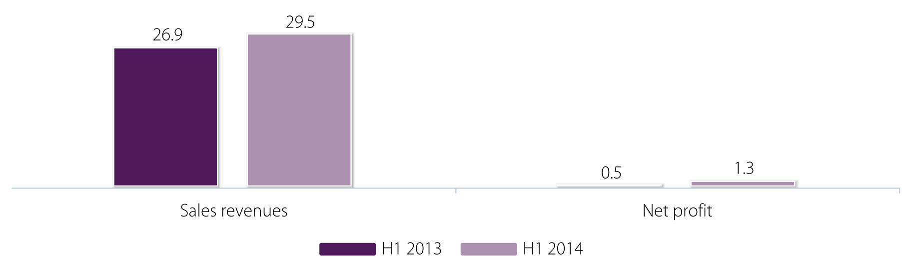
Polmed, the listed ambulatory care group, in the first half of 2014 generated consolidated sales revenues of almost PLN 29.5m (€7m), an increase of 9.7% compared with a year earlier, and made a net profit of over PLN 1.3m (€0.3m), more than double the figure that it earned in H1 2013.

Revenues from National Health Fund (NFZ) contracts decreased by 1% y-o-y in January-June 2014, to PLN 8.1m (€1.9m), but revenues from occupational medicine jumped by 18.9% y-o-y to PLN 11.1m (€2.6m), revenues from insurance companies were up by 4.8% y-o-y to almost PLN 7.1m (€1.7m) while revenues from individual commercial patients leapt by 28.4% y-o-y to PLN 2.6m (€0.6m).

As per the publication date of its half-yearly report Polmed had 21 clinics.

Polmed is in talks to bring in an investor. The bidders reportedly include healthcare providers, insurer PZU, and investment funds. Early this year Polmed was in negotiations with Medicover, but the talks fell through.

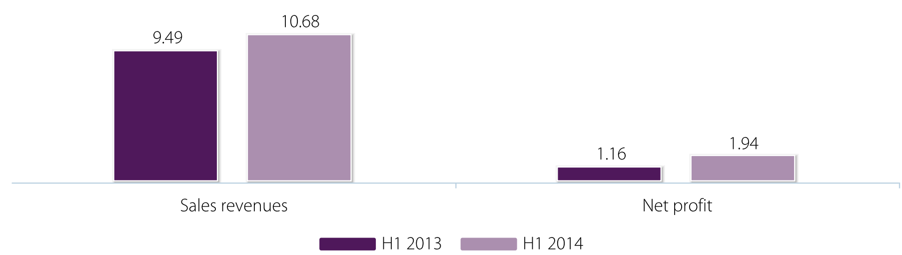
Polmed financial results (PLN m) in H1, 2013-2014



Source: Polmed, 2014

www.pmrpublications.com

Pani Teresa Medica financial results (PLN m) in H1, 2013-2014



Source: Pani Teresa Medica, 2014

www.pmrpublications.com

Pani Teresa Medica posts 13% sales rise in H1, announces takeover in Germany

Pani Teresa Medica, the listed maker of medical textile products, in the first half of 2014 recorded revenues of nearly PLN 10.7m (€2.5m), which represents an increase of 12.6% compared to the equivalent period of 2013. Its net profit increased by 67.7% y-o-y in January-June 2014 to exceed PLN 1.9m (€0.5m).

Sales in Poland grew by 8.8% y-o-y to almost PLN 9.2m (€2.2m) while exports jumped by 41.9% y-o-y to over PLN 1.5m (€0.4m), driven by Slovakia, where sales rose by more than 50% y-o-y to exceed PLN 1.2m (€0.3m). At the same time, sales in Ukraine slumped by almost 60% y-o-y to less than PLN 0.1m (€24,000).

In its half-yearly report, which was published on 29 August, Pani Teresa Medica also for the first time made public that on 2 July 2014 it bought 100% of shares in **AS Business Center**, a distributor of medical devices and healthcare products on the territory of Germany, Austria and Switzerland. The Frankfurt/Oder-based company is currently at the stage of acquiring clients and developing markets for its products and so there is a likelihood that it will end 2014 with a loss, the report notes.

PZ Cormay appoints former Zelmer chief to CEO post as financial investors take control

The supervisory board of **PZ Cormay**, the in vitro diagnostics group, on 26 August unexpectedly dismissed Tomasz Tuora from the post of CEO and handed the top role to Janusz Plocica, until June the CEO of Zelmer, the white goods manufacturer, with immediate effect.

Barbara Tuora-Wysocka, the other member of Cormay's executive board, was also replaced.

The members of the supervisory board were themselves appointed just hours earlier during an Extraordinary General Meeting of Cormay shareholders.

The changes are a consequence of recent shifts in PZ Cormay's shareholder structure, which is now dominated by financial investors. Mr Tuora, the company's co-founder and until recently its main shareholder, now has only about 12% of its shares while Total FIZ, an investment fund, has almost 24%.

Since Total FIZ first bought PZ Cormay shares back in 2009 the company has increased its scale sharply but the management has made many mistakes," Konrad Lapinski of Total FIZ explained in *Puls Biznesu*. The acquisitions in Ireland and Italy were ill-prepared and executed, according to Mr Lapinski, and there was also concern about the ongoing transfer of PZ Cormay's assets to its subsidiary Orphee, with Mr Tuora reducing his holding in the parent company and increasing his stake in Orphee.

Janusz Plocica served as CEO of Zelmer between 2005 and 2014, during which time he transformed the firm into the market leader in Poland and the number three player in Central and Eastern Europe in its category. PZ Cormay's shareholders expect the company to benefit from his extensive knowledge and experience, particularly in such key areas as foreign sales and R&D.

■

Romania

Market news

More than 120 drug reimbursement list applications submitted

The health minister, Nicolae Banicioiu, has told Mediafax that the Romanian National Agency for Drugs and Medical Devices (ANMDM) has received over 120 applications requesting the addition of drugs to the reimbursed drug list.

He added that the files are currently being evaluated and that drugs already on the list are also being examined, in order to see if they meet the new criteria.

The ANMDM president, Marius Savu, has told Mediafaxthat one-quarter of the requests are for cancer treatments but that there are also applications for hepatitis and rheumatoid arthritis therapy.

Both officials have said before that the evaluation process pertaining to the new and existing molecules for the reimbursed drug list would be completed by the end of August, whereas the list itself could be ready this autumn.

Authorised pharmacies could sell OTC drugs over the internet

Authorized Romanian pharmacies could officially be allowed to sell OTC drugs over the internet, according to a Health Ministry project currently under debate. The project targets modifying and completing Pharmacy law no. 226/2008.

Online sales will be possible under some conditions, said Oana Grigore, head of Communication for the Health Ministry, which will be made public through the implemented rules of the future law.

The project also stipulates that the demographic criteria for opening a pharmacy should be maintained.

At present, in the capital city it is possible to open a pharmacy for every 3,000 inhabitants; in county capitals for every 3,500 inhabitants; while in other towns for every 4,000 people. There are no limitations in rural areas.

In case the ministry's project is not approved, at the beginning of 2015 no restrictions will exist regarding the opening of pharmacies in Romania.

Almost 1,200 jobs available at units of Romanian Health Ministry

The health minister, Nicolae Banicioiu, has told *Mediafax* that almost 1,200 jobs have been made available at medical units managed by the Romanian Health Ministry, most of them in hospitals and others at emergency service establishments.

The minister stated that the total number of jobs made available in the medical system is actually much higher, but that most hospitals are managed by local authorities and not by the Health Ministry.

Since 2009, public institutions in Romania have been able to take on a new person only if seven others leave the service in question, because of the difficult economic conditions. Nevertheless, the medical system has been exempted from this rule since 2012, but only if the HR unit has paid its debts and if the salary costs fit the budget.

Company news

Biofarm launches buyback offer for 10% of its shares

The Romanian drug manufacturer **Biofarm**, which is controlled by regional investment funds, has announced that it will start a buyback offer for up to 109.48 million of its shares, which represent 10% of the capital.

The company has said it will offer RON 0.305 (€0.07) per share. The offer is, therefore, worth RON 33.3m (€7.5m) in total.

The offer, scheduled for 26 August-15 September, will be brokered by **Swiss Capital**.

At present, Biofarm owns 0.0007% of its own shares. The **SIF Muntenia** investment fund owns 51.7% of the shares, **SIF Banat-Crisana** controls 21.29%, and Danut Vasile, the drug producer's manager, owns 1.87%.

According to some market analysts, the buyback offer is a step toward the delisting of Biofarm from the Bucharest Stock Exchange, with regional investment funds gaining total control of the company.

Ecofarmacia aims at 15% increase in revenue in 2014

Ecofarmacia, a Romanian pharmacy chain, expects its revenue for 2014 to reach €15m, after achieving a figure of RON 56m (€13m) in 2013, according to the company's minority shareholder, Marius Chereches, who holds 25% of the stock. The company has been profitable and hopes to end the year in the black.

Mr Chereches told *Ziarul Financiar* that the network was set up in 2010 and that its initial plan was to have 20 pharmacies in the area between the cities of Brasov and Cluj. The chain has now reached 26 units, covering the western part of the country. In addition, it targets districts in small cities.

The company has just bought its 27th licence for a unit. According to Mr Chereches, the licences cost between €10,000 and €30,000, whereas the fitting work cost an additional €20,000-€30,000

Mr Chereches has said that the decision to set up a pharmacy business during the crisis was prompted by the fact that such a business is more affordable. The remaining shareholders are the drug manufacturer and distributor **Bio Eel** (50%) and Ioan Radu Pavel (25%), an entrepreneur who has invested in the pharmaceutical industry before.

Gedeon Richter pharmacy network in Romania decreased its capital by €2.5m

Gedeon Richter Farmacia, which operates the 120-pharmacy network belonging to the Hungarian pharmaceutical group **Gedeon Richter**, lowered its capital by RON 11.38m (€2.5m), all shareholders decreasing their number of shares proportionally with their quota.

Thus, the number of shares owned by **Armedica Trading** decreased by 11,380,145 shares, to 112,499, each valuing RON 1. Also, the number of shares owned by the **Pharmafarm** wholesale company decreased by 77, to only one share, with a value of RON 1. Both companies are directly controlled by the Hungarian group.

According to data from the Romanian Finance Ministry, Gedeon Richter Farmacia ended with losses every year in the period 2008–2013. Nevertheless, last year its losses were down by 11.7% compared with 2012, reaching RON 8.2m (€1.8m), after an increase of 131% in net losses the year before.

New painkiller launched by Sandoz Romania

The Romanian subsidiary of the pharmaceutical company **Sandoz** has launched Dexketoprofen trometamol, a painkiller which targets dental and muscle-skeletal pain, along with dysmenorrhea.

The product is available in boxes of 20 tablets, at a 25 mg dose. It can be bought on prescription and is on the list of reimbursed drugs.

According to data made available by the company, muscle-skeletal pain (general, lumbar and neck-related) and pain caused by injuries are among the five most common factors which reduce quality of life in Romania. In addition, the most common symptoms are headaches (79%), back pain (62%) and dental pain (38%), followed by rheumatic and joint pain, menstrual pain, muscle pain and pain caused by injuries.

New general manager and CFO for Polisano

Octavian Iacob, the former CEO of **Farmexpert** and **ADM Farma** – two prominent wholesalers in Romania, has been appointed general manager at the **Polisano** wholesale company. The former manager of the firm was Cascaval Coca.

The decision comes only one week after the lawyer Remus Borza was appointed president of the Polisano group, two months after the suicide of its founder, Ilie Vonica.

Mr Borza also appointed Andreea Pirvu – the former manager of the **Advent International** investment fund – as chief financial officer of the company and said that his main target at Polisano is cost optimisation.

R&D/medical news

Romanian Health Ministry to buy anti-flu vaccines

The Romanian Health Ministry will buy anti-flu vaccines for almost RON 7m (€1.6m), because the **Cantacuzino Institute of Research and Development for Microbiology and Immunology**, the traditional local vaccine manufacturer, lacks production authorisation and is in the midst of a criminal trial.

Nicolae Banicioiu, the health minister, has told *Mediafax* that the supplier for 500,000 doses of anti-flu vaccines, which will be freely administered to those at a high risk of infection, will be decided in the wake of an auction. He also stated that he plans to have a national strategy for vaccination in December, to extend the acquisition periods.

Mr Banicioiu added that a similar strategy will be applied to other vaccines, such as those for Hepatitis B and BCG.

Three new hospitals to be built in Romania with European funds

In Romania three regional hospitals will built in Iasi (in the north-east), Cluj (in the centre) and Craiova (in the south) exclusively with European funds, according to the health minister, Nicolae Banicioiu, quoted by *Mediafax*.

Mr Banicioiu explained that the Romanian authorities have concluded a partnership agreement for 2014-2020 between Romania and the European Commission, thought to be worth €1bn, of which the construction of the three new hospitals will represent the most substantial amount. The entire sum will be spent on infrastructure, screening, research and personnel training.

The areas in which the new medical units will be built were chosen in accordance with the state of the current facilities and the number of potential patients covered.

According to the health minister, other local units, in addition to the three hospitals, will be modernised.

Government reserve fund to pay for construction work on maternity wards

Victor Ponta, the Romanian prime minister, has asked the health minister, Nicolae Banicioiu, to create a list of all maternity units/hospitals being built, in order to make the government's reserve fund available to pay for the work. Mr Ponta said that he was planning to pass an Emergency Ordinance for this purpose.

In addition, the government will allocate RON 8m (€1.8m) from the same fund for the renovation of the obstetrics and neonatology departments at the St. Pantelimon Emergency Hospital in Bucharest. The work will involve the creation of a ward for premature babies and the repair of the heating and alarm systems. At the end of the project, the hospital will have 18 intensive care beds, 50 beds for pregnant women and new mothers, six beds for premature babies and eight wards with 21 beds for mothers and babies to remain together.

The completion of the work on the obstetrics and neonatology departments at the St. Pantelimon hospital is a strict necessity, according to the Romanian authorities, given that the number of women at risk of premature birth has risen in Bucharest because of the development of artificial insemination activities.

Romanian authorities want centre specialised in cutaneous melanoma

The health minister Nicolae Banicioiu and the capital city's mayor, Sorin Oprescu, announced they have decided to create a centre of excellence that specializes in diagnosing and treating cutaneous melanoma.

The centre would be hosted by the Colentina Hospital in Bucharest, the oldest institution working in dermatology in Romania.

The officials mentioned that cutaneous melanoma is the most aggressive cancer type. When it is diagnosed in late stages, it is lethal. The Romanian health minister also said that, within the centre, a national register for melanoma could be set up.

Regina Maria exceeds full-year subscriber target

Fady Chreih, the chief executive of the Romanian private healthcare services provider **Regina Maria**, has said in an interview with *Ziarul Financiar*, that the company reached 255,000 subscribers by the end of July, more than the 250,000 targeted for the whole of 2014. Regina Maria had 195,000 subscribers last year, according to the available data. The company reported a 17% increase in sales revenue in the first seven months of the year.

Mr Chreih estimates that sales of medical subscriptions (excluding occupational medicine) are worth 650,000 a year in Romania. At an average monthly fee of €5, the amount comes to €40m per year, according to *Ziarul Financiar* calculations. Most transactions involve companies, which buy subscriptions for their employees as part of the salary package, but individual patients also buy subscriptions.

Regina Maria obtains 36% of its annual sales revenues from such subscriptions, and the figure could reach €55m in 2014. The contract with the National Health Insurance House (CNAS) generates another 5-8%, whereas the remainder of the revenue comes from cash payments by patients.

This revenue breakdown has remained unchanged since the end of 2012, according to Mr Chreih, who added that he did not expect any changes until 2015.

He also stated that the company is obtaining offers to buy even medium-sized companies earning revenue of several million euro in Bucharest and elsewhere in the country but has not found anything worth buying which could provide Regina Maria with added value.

Intermedicas expected to generate sales revenues of €500,000 in 2014

Ana-Maria Marian, the managing director of **Intermedicas**, a Romanian company which offers online medical consultancy services, has told *Ziarul Financiar* that the company expects sales revenues of €500,000 in 2014. The company, which was founded three years ago by Dan Mitrea, a doctor, gives Romanian patients access to a second opinion both from doctors in the country and abroad.

The most substantial numbers of requests are in the areas of oncology, neurosurgery and paediatrics. The company registers around 50 patients per month, of which between 15 and 20 leave Romania for treatment.

Last year Ana-Maria Marian, Ioana Elisei and Sergiu Negut, former managers of the Romanian private healthcare services provider **Regina Maria**, joined the company, which works with 90 doctors in Europe, America and Japan, in addition to a local network of partners.

Slovakia

Market news

Slovak insurers wants more funds for healthcare from 2015 state budget

Slovakia's Association of Health Insurance Companies, which represents privately-owned public health insurance providers, believes that the country's government should review its draft 2015 budget with regard to the healthcare sector, news agency TASR reported.

As PMR noted on a previous occasion, the 2015 draft budget earmarked €1.2bn for the healthcare sector, down by €16.6m compared with the current year.

The association believes that less money from the state budget means less funds for healthcare services, development of new projects or addressing various issues of the sector, including the increase of doctors' salaries.

The association also argues that it is unclear from the current budget proposal whether the state is planning to increase insurance contributions for state-insured persons next year, pointing out that state-insured persons, including children or pensioners, account for over 50% spending in the healthcare sector.

The Ministry of Finance says that 2015 budget spending in the area of healthcare is still a subject of discussions and refused to provide further comments, the news agency noted.

R&D/medical news

Slovak to see drop in 2015 public health insurance revenues?

Slovak public health insurance providers will collect in 2015 €250m less in health insurance premiums than in 2014 and will pay €108m less to healthcare providers for their services, news agency TASR reported, citing Viliam Novotny, the deputy chairman of Slovak opposition party SDKU-DS.

Mr Novotny says that the drop will be caused by reduction in public health insurance deductions from people with low incomes, which will deprive the healthcare system of €150m.

Mr Novotny also calculated that public health insurance contributions for state-insured persons will reach around 3.67% instead of the legal minimum of 4% of the average salary over the past two years, which will reduce the healthcare sector's budget by €75m compared with 2014. The MP also criticised the government for ignoring the rising debts of hospitals, which – according to the politician – is growing at a rate of "€190 per minute."

The Slovak Ministry of Health argues that public health insurance premiums for state-insured persons will definitely reach at least 4%, hoping that this percentage rate will even be increased. The ministry also maintains that the overall revenues of the public healthcare sector will reach €4.27bn in 2015, with expenses estimated at €3.99bn, which means that the sector will be in the black.

Slovak health insurers estimate costs for treatment abroad at €5m

Slovak public health insurance providers allowed 815 patients to carry out their treatment abroad last year, with total preliminary costs amounting to almost €5m, news agency TASR reported.

The majority of treatments carried abroad, amounting to 595 cases, was approved by **Vseobecna Zdravotna Poistovna** (VsZP). The approved treatments were mostly performed in the Czech Republic. The total estimated cost of the approved treatments reached €4.3m, up by €14,000 year on year.

Insurer **Dovera** approved 180 cases of treatment abroad in 2013, with the estimated costs totaling around €500,000, up by 14% compared with 2012. **Union** allowed 40 patients to get treatment abroad, also mostly in the Czech Republic, and estimates the costs at around €189,000.

Organ transplantations were one of the most frequent and most expensive treatments approved by insurers to be carried abroad. Other frequent patients' requests for treatment abroad included gamma knife surgeries, the news agency noted.

Slovakia's Nitra region plans equipment, reconstruction investment in local hospital

Slovakia's Nitra Region earmarked €371,000 for the purchase of instrumentation and technical equipment for operating rooms in Topolcany-based hospital, news agency TASR reported. The investment is related to a major reconstruction project that the hospital has been preparing for a while.

The value of the total reconstruction project is estimated at €2.7m, with a tender for a construction company to carry out the planned modernisation will be launched in September, after the project documentation is complete.

The hospital said that the reconstruction of its operating rooms and providing them with new equipment is necessary in order for the facility to increase the number of performed operating procedures.

Slovak hospitals owe almost €105m in workers social insurance

Slovak medical facilities owed the country's social insurer **Socialna Poistovna** €104.8m at the end of July 2014 in unpaid employee social insurance premiums, with the debt increasing by €18.5m compared with the end of 2013, news agency TASR reported.

State-run medical facilities owed €69.6m at the end of July, a monthly increase by €2.2m, with the debt increasing mainly in University Hospital Banska Bystrica and Children's University Hospital Bratislava.

Social insurance debts of municipal and regional medical facilities amounted to €35.2m at the end of July, a monthly increase by around €520,000.

Interview: Update of reimbursement list is essential in Romania

PMR talks to Mr Gabor Sztaniszlav, the Country Director of Amgen Romania and the President of the Local American Working Group (LAWG)[1], an organisation founded in 2010 by the leading American pharmaceutical research and biotechnology companies in Romania, about the update of the reimbursement list in the country, the introduction of legal changes pertaining to the pharmaceutical market and the dominant trends on this market.

Justyna Kukian: How do you assess the new criteria for drug reimbursement in Romania[2]?

Gabor Sztaniszlav: The addition of reimbursed medicines to the list is an immediate necessity for Romanian patients who should have access to more efficient therapeutic standards. This update has been postponed for six years, and we are supportive of the current efforts of the health authorities to establish criteria for drug reimbursement which will lead to an increase in access for patients to innovative products.

The new health technology assessment methodology approved in July 2014 is largely modelled on international examples such as those of France, the United Kingdom and Germany but also takes real-life data from Romania into consideration. It is designed to evaluate the safety, efficacy and cost-effectiveness implications of molecules before new medicines are added to the reimbursement list. The score for evaluating the new molecules varies in accordance with the number of countries in which a medicine is reimbursed and the budgetary impact.

My two main concerns are the actual time which will pass before these products physically reach patients and the number of molecules which will gain reimbursement status. Our first estimates and the statements of various government officials suggest that only 30-40 molecules might meet the criteria and finally be granted reimbursement status, which, of more than 170 applications, seems to me to indicate an excessively restrictive evaluation methodology.

Do you think that the new reimbursement list can actually be updated in the autumn? How do you assess the way in which the Health Ministry is working on this update?

The industry has tried to stay in close contact with the health authorities on the topic of reimbursement, and with the Health Ministry and the National Agency for Drugs and Medical Devices (ANMDM) in particular. An update to the list which involves the addition of reimbursed medicines is expected by the end of this year. We acknowledge the efforts of the government in introducing 17 orphan medicines for rare diseases in recent months. However, there are still products which have not yet reached Romanian patients, as more than 170 medicines are still waiting for approval. More importantly, a reimbursement decision is only the first step, as it takes time for the new medicines to be made available to patients at retail pharmacies and hospitals, and we have to bear in mind the fact that these patients have already been waiting for six years.

What is your opinion on the claw-back tax? How should it be changed?

The claw-back tax was introduced in 2009 as a temporary support measure, by which all reimbursement spending which exceeds the budget for medicines is supported by the pharmaceutical producers. At this point, the companies are contributing more than 20% of the reimbursed sales on a quarterly basis, permitting treatment for 2 out of every 10 patients. It is, therefore, difficult for the pharmaceutical industry to sustain this level of taxation. The Local American Working Group supports the long term development of the healthcare market, but the corporate sector in Romania is also aiming at a more transparent, predictable and sustainable business environment for medicine producers. One of the short-term needs of the system is the correlation of the budget for reimbursed medicines with the actual level of consumption – as the threshold has not been updated for three years, this would also affect the claw-back by making it more bearable for the industry.

Do you think that we can expect the introduction of any fundamental legal changes pertaining to the pharmaceutical market in Romania in the immediate future?

There are several requirements in the system. The molecules on the waiting list are expected to be reimbursed after they have been through the HTA process. The reimbursement of medicines gives patients access to new life-saving therapies but also gives companies the opportunity to develop new molecules in the process of advancing innovation. Access to innovative products for Romanian patients also has economic implications, in terms of the growth of the labour force and productivity. On the one hand, it is critical for every country with growing economic prospects and more optimistic forecasts for its inhabitants to live their lives in good health, keeping as physically active as possible. On the other, these people also want to enjoy their lives after their retirement as long as possible. New innovative medicines can help to reach both goals. At present, Romania has, after Bulgaria, the lowest life expectancy among the EU countries. A few years ago the LAWG and the Institute for Economic Forecasting developed a study on the economic implications for the pharmaceutical industry in Romania. The research suggested that by improving the health of the Romanian population in terms of reducing the number of healthy years lost because of diseases (calculated by DALY) to the average level in the EU, a surplus in economic out-

[1] The LAWG is an affiliate of Pharmaceutical Research and Manufacturers of America (PhRMA), an organisation which aims to promote medical innovation around the world. The Group represents Abbvie, Amgen, AstraZeneca, Bristol Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck Sharp & Dohme, Novartis and Pfizer.

[2] New drugs will receive 25% of the maximum score if they are already more than 50% reimbursed in more than half of the European countries. New treatments can attract another 30% of the maximum if they are more than 5% cheaper than the current equivalent treatments.

put of €6.7bn (6% of the 2010 GDP) will be achieved, given the increase in labour force participation and productivity.

In addition, it is important to note that the health budget, and the budget for medicines in particular, needs further funding to meet consumption requirements. If new medicines are added to the list while the reference health budget allocated by the Ministry of Health remains the same, we expect the clawback to grow. It is difficult to say whether we, as producers, will be able to support another increase in the clawback percentage. As a result, the current discussions with the health authorities include finding ways to make the fiscal burden more sustainable by sharing the costs.

Will the generic market develop faster than its innovative counterpart in Romania in the coming years? How will the value of the innovative medicines and generic medicines markets in Romania change in 2014?

Estimates suggest that, at the moment in Romania, highly innovative drugs account for 65% of the total value of medicines sold and only 25% of the volume. In terms of expectations pertaining to the value of the Romanian pharmaceutical market in 2014, the initial predictions took the list update into account and showed a slight increase. However, at this moment, when we are hoping that the list will be updated by the end of the year, it seems that no positive effect on the market will be visible in 2014. At this point it should also be made clear that the market growth of the most recent period is – because of the lack of a reimbursement list update – based on the growth of generic manufacturers. Some grew more rapidly than many of their innovative counterparts, whose portfolios matured before they were able to launch their latest innovative products. Cegedim recently reviewed its predictions and anticipated a reduction in the market of -0.3% because of the delay in updating the list.

Are there any dominant trends on the Romanian pharmaceutical market?

One disagreeable trend is the fact that many products are not available to Romanian patients to the extent that they are in other EU countries. This is relevant to generics also and, as explained before, to many innovative products. The relevant factors here are the stagnating market performance, increases in the tax burden and the high level of unpredictability of the legal environment.

It is important to note that the healthcare budget allocation in Romania is less than 4% of GDP. This is much lower than the EU average, which grew constantly every year, according to the EFPIA report in 2012. Romania is, therefore, working on converging to the European level of health indicators for the population, and such efforts can only be successful through close collaboration between the pharmaceutical industry and the authorities. In this regard, the LAWG is prepared to continue the dialogue and to support the Romanian authorities in terms of long term improvements in patient access to efficient treatments, in the healthcare system and in the business environment.

Upcoming events

Distribution on the pharmaceutical market in Central Europe – current status, key trends and development prospects – PMR

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Published by PMR, www.ceepharma.com
ul. Dekerta 24, 30-703 Kraków, Poland, Tel. /48/ 12 618 90 00, Fax /48/ 12 618 90 08, pmr@pmrpublications.com

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