PMR Biweekly Review and Analysis

Published by PMR

PMR PHARMA & HEALTHCARE INSIGHT: CENTRAL EUROPE

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Issue No. 17 (154) – Wednesday / 19 / 08 / 2015

Published by PMR

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Hungarian Implementation of the EFPIA Disclosure Code

The EFPIA Disclosure Code ("Disclosure Code") was implemented in Hungary in 2014, and pharmaceutical member companies must comply with the relevant provisions as of 1 January 2015. Although the Hungarian version follows the provisions of the Disclosure Code, there are questions that may need to be answered prior to the first reporting in 2016. (…)

Respectable degree of growth expected in private healthcare market in Romania, Bulgaria and Poland between 2015 and 2020

The private healthcare market in Central Europe will grow by around 7-8% per annum in the years 2016-2020 to reach almost €30bn in 2020. The growth of fee-for-services will have the most extensive impact here because of the improvement in the macroeconomic situation and the fact that area of private insurance in underdeveloped in the countries analysed. (…)

Does Big Pharma have plan B in Russia?

Despite more relative stability in Q2, Russian drug market conditions remain precarious, with developments asking questions of foreign investor plans. Elsewhere, despite cost-containment-driven drug sector reform, key CEE pharma markets continued to attract foreign investment. (…)

News of the issue: Bayer sells Biovital portfolio in Poland to Egis

Bayer on 29 July announced that it has agreed to sell its portfolio of Biovitalvitamin products in Poland to Egis Pharmaceuticals, the Hungarian generics manufacturer. (…)

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Bulgaria

Tchaikapharma reports 24% rise in revenue in H1 2015

Tchaikapharma High Quality Medicines saw its net profit rise by 8.8% to BGN 3.9m (€2m) in the first half of 2015, an increase in comparison with BGN 3.6m (€1.8m) a year earlier. Its EBITDA rose by 17.4% to BGN 6.6m (€3.4m).

The company's revenues also advanced by 24% to BGN 15.1m (€7.7m). Drugs for the cardiovascular system accounted for BGN 10.4m (€5.2m) of its revenue, as opposed to BGN 6.7m (€3.4m) a year earlier.

In the first half of the year, the company received marketing authorisation in Bulgaria for several drugs for the treatment of diabetes and cardiovascular diseases – Pizona, Amarhyton, Co-Telsart and Cordacare Plus. It is waiting for marketing authorisations for another 15 drugs.

Tchaikapharma has received international marketing authorisation for Rossta tablets valid for Bulgaria, the Czech Republic, Poland, Romania and Greece. It is now waiting for the international marketing authorisation of Cardesart-Co.

Only two of 32 online pharmacies have EU logo

Only two of the 32 online pharmacies in Bulgaria have the EU logo for the online sale of medicines which had to be introduced by 1 July as a verification of authenticity, according to the Association of Active Consumers, a consumer protection organisation.

Representatives of the business have said that the logo has not become widespread in Bulgaria because of a lack of information.

Meanwhile, the Bulgarian Drug Agency (BDA) has not yet prepared a website to protect consumers against counterfeit medicines. Until the BDA and online pharmacies meet the new requirements, consumers can consult the BDA register to assess whether an online pharmacy is legal.

Health Ministry revokes hospital licence in Targovishte

Dr Petar Moskov, the health minister, has announced that the ministry has revoked the permit of the Papurov private hospital in Targovishte, in north-eastern Bulgaria. The revocation was carried out because of the misappropriation of BGN 200,000 (€102,000) of NHIF funds, the infringement of patients' rights, unnecessary hospital stays, etc.

Dr Moskov emphasised that there are concerns about irregularities at other hospitals and that once evidence is available, their permits will also be revoked.

In 2014, the health ministry revoked the licences of two municipal hospitals, Tarnovo and Godech, in Malko. In 2015, it revoked the licence of a hospital in Elin Pelin.

Fortex to invest up to BGN 9m in drug manufacturing facility

Georgi Filipov, the founder of **Fortex Nutraceuticals**, a Bulgarian dietary supplement manufacturer, has said in an interview for *investor.bg* that the company intends to invest BGN 7-9m (€3.6-4.6m) in a new drug manufacturing facility which will be completed within two or three years. The company recently announced plans to begin the production of drugs, and Mr Filipov explained that within four years its drug production business will outperform its dietary supplement business.

Fortex will have prepared its first drug application dossiers within six months. Its first drug will be an anti-flu product which will be launched in Bulgaria, Macedonia, Serbia, Greece and Romania. Otherwise, the company's drug portfolio will focus on endocrinology and neurology.

At present, the company has a portfolio of 70 dietary supplements. It exports to 18 countries, including Russia, Azerbaijan, Lithuania, Latvia and Estonia, Serbia and Macedonia.

Last year, Fortex generated BGN 5.2m (€2.7m) on the domestic market, whereas in 2015 it aims at revenue of BGN 6m (€3.1m) in Bulgaria, which represents a market share of 3%. By comparison, according to Mr Filipov, the market leader accounts for about 10%.

98% of outpatient care providers breach drug prescription rules

A National Health Insurance Fund (NHIF) report for 2014 suggests that 98% of outpatient care providers breach the rules pertaining to the prescription of drugs.

The NHIF has inspected 287 outpatient care providers and failed to detect irregularities at only seven of these. These involve disregard for the restrictions established in Annex 1 of the Positive Drug List, the overlapping of indications for the period for which the drugs are prescribed, the prescription of more than three drugs for the same disease, and the prescription of a dosage in excess of that regulated in the drug list.

Alvogen launches first generic version of Velcade in Bulgaria

Alvogen has launched the first generic version of the cancer drug Velcade (Bortezomib), a proteasome inhibitor anticancer drug, used for the targeted treatment of multiple myeloma and mantle cell lymphoma, in Bulgaria. The drug will be marketed under the Vortemyel brand name. Following the launch in Bulgaria, Vortemyel will also be rolled out across several other Central and Eastern European (CEE) markets.

Velcade is Millennium Pharmaceuticals/ Janssen Cilag's reference product, sales of which were worth more than $200m in CEE in 2014.

NHIF spends BGN 50.5m on outpatient drug reimbursement in May 2015

The National Health Insurance Fund (NHIF) in Bulgaria spent BGN 50.5m (€25.8m) on outpatient drug reimbursement in May 2015. Most of its resources were spent on alimentary tract and metabolism drugs.

In terms of single international non-proprietary names (INN), the most substantial amount, about BGN 2.7m (€1.4m), was spent on adalimumab.

In May, the NHIF spent BGN 19.3m (€9.9m) on oncology therapies, with Bevacizumab representing the largest share of spending with about BGN 3m (€1.5m).

MPs to discuss healthcare reform after summer recess

The Bulgarian parliament will proceed with its discussion of healthcare reform after its summer recess, but the amendments to the Healthcare Facilities Act proposed by the Health Ministry have raised objections among MPs.

All parliamentary groups therefore oppose the idea of privatising hospitals. Meanwhile, the ruling party, Gerb, has opposed the proposal for the mandatory accreditation of hospitals. The argument is that this is an additional administrative and financial burden for healthcare providers and that it does not guarantee quality of service. The ministry had proposed that from 2017 onwards, the National Health Insurance Fund (NHIF) should reimburse costs at accredited hospitals only.

Another issue of discord is the Health Map, which is intended to entitle the NHIF to select the hospitals whose costs it will reimburse. However, many MPs argue that this will create conditions for corruption.

Another issue to be discussed in the autumn will be the obligation of marketing authorisation holders (MAHs) whose products are fully or partially reimbursed by the NHIF to return some of the money to the NHIF in cases of public overspending.

Meanwhile, MPs have proposed that up to 10% of beds at public hospitals should be allocated to private patients.

Reimbursement costs (BGN) per ATC code in accordance with Annex 1 to the Positive Drug List in Bulgaria, May 2015

Code	Classification	Amount
A	Alimentary tract and metabolism	11,292,676
B	Blood and blood forming organs	4,995,533
C	Cardiovascular system	6,676,769
G	Genito-urinary system and sex hormones	874,912
H	Systemic hormonal preparations, excluding sex hormones and insulins	552,502
J	Antiinfectives for systemic use	1,235,248
L	Antineoplastic and immunomodulating agents	10,927,421
M	Musculo-skeletal system	276,664
N	Nervous system	5,121,411
P	Antiparasitic products, insecticides and repellents	10,293
R	Respiratory system	7,209,839
S	Sensory organs	613,034
V	Various	728,884
	Total	**50,515,187**

Source: NHIF, 2015

Reimbursement costs (BGN) per INN in accordance with Annex 1 to the Positive Drug List in Bulgaria, May 2015

INN	Amount
Adalimumab	2,715,464
Combination of salmeterol xinofoate and fluticasone propionate	1,744,176
Etanercept	1,361,362
Coagulation factor VIII	1,171,087
Combination of budesonid and formoterol	1,161,532
Insulin aspart	1,062,651
Human insulin	1,023,234
Combination of beclometasone dipropionate/ formoterol fumarate dihydrate	889,421
Tiotropium bromide	878,460
Paliperidone	848,058

Source: NHIF, 2015

Reimbursement costs (BGN) for oncology therapies, per INN, in Bulgaria, May 2015

INN	May 2014
Bevacizumab	3,025,211
Trastuzumab	2,642,770
Nilotinib	1,217,103
Abiraterone acetate	708,329
Imatinib	684,529
Rituximab	640,618
Everolimus	608,315
Erlotinib	592,587
Denosumab	588,087
Sunitinib	574,450
Total	**19,349,075**

Source: NHIF, 2015

470 clinical trials underway in Bulgaria

About 470 clinical trials are being carried out in Bulgaria at present, according to information provided by the Bulgarian Drug Agency (BDA) to *Zdrave.net*. The BDA has emphasised that it issues between 200 and 230 permits for clinical trials on average every year.

Statistics show that the number of clinical trials has risen in several areas – including oncology, neurology, psychiatry, cardiology, pulmonology, psychiatry, rheumatology, endocrinology and gastroenterology.

At present 325 healthcare providers are carrying out clinical trials.

Czech Republic

Czech health minister to use legal amendment to curb parallel exports

Svatopluk Nemecek, the Czech health minister, has proposed amendments to the Law on Pharmaceuticals to curb parallel exports of drugs from the country, according to an e15.cz report.

The Czech health ministry will, in cooperation with the State Institute for Drug Control, prepare a list of the so-called risk drugs, a shortage of which can endanger the health or lives of patients, but which have been re-exported in the past. The re-export of such items will no longer be allowed. The list will be publicly accessible and regularly updated. If the company wishes to export a drug which is on the list, it will have to ask for permission 30 days in advance.

The amendment will also introduce fines of up to CZK 20m (€730,000) or a ban on distributor activity for up to two years for breaking the law.

The Czech government is expected to receive and discuss the amendment in August 2015, and it is due to come into force in 2016.

The Health Ministry has had to deal with four shortages of medicine so far and has banned exports of the following: Antabus, Actilyse and Novomix Flexpen.

According to the Czech Chamber of Pharmacists, the restriction on re-exports of cheap drugs will not resolve the shortages on the Czech market, as most of these are caused by the fact that some drugs are distributed only to chosen pharmacies on purpose.

Parallel exports were worth CZK 3.6bn (€131m) in 2013.

Czech public health insurance system ends 2014 in the black

The total revenues of the Czech public health insurance system stood at CZK 241.2bn (€8.8bn) in 2014, a 5.6% year-on-year increase, whereas expenses reached CZK 239bn (€8.7bn), according to a report on the management of health insurance companies prepared by the Health and Finance Ministries.

The amount spent on healthcare services was CZK 231.9bn (€8.4bn), constituting 97% of the total. The operational expenses of insurance companies fell to CZK 5.3bn (€192.5m).

The state paid CZK 59.9bn (€2.2bn) for its insured citizens (including children and unemployed people), which was CZK 6.2bn (€230m) more than the previous year.

Revenues from public health insurance premiums came to CZK 178.6bn (€6.6bn), which represents a 3.8% year-on-year increase.

The average revenue per one insured person was CZK 23,167, or €841 – with the most substantial revenue earned by **Vseobecna Zdravotni Poistovna** (VZP): CZK 24,989, or €907, a 5.6% year-on-year increase, and the least by **Revirni bratrska pokladna** (CZK 19,912, or €723, a 7.9% year-on-year increase).

Three insurance companies, **Zdravotni poistovna ministerstva vnitra**, **Ceska prumyslova zdravotni pojistovna** and **RBP**, ended 2014 in the red.

By the end of 2014 the insurance companies had 10.4 million insured clients (over 75% of these were insured by VZP).

CzechMed criticises amendment to medical equipment law

The Czech Association of Suppliers of Medical Devices (CzechMed) fears that the prepared amendment to the medical equipment law will radically shrink the fully reimbursed range of medical devices, according to e15.cz. In addition, patients will not be able to choose and will have to pay extra for their preferred device.

According to CzechMed, the proposed amendment to the concept of prices and payments for medical equipment will be impossible to implement in practice. The reimbursement level will be based on a price referencing system, with the lowest EU price for a given device to serve as a basis for negotiations in the proceedings, but official databases of this kind do not exist, as this area is regulated individually in each country of the EU.

The process introduced in the amendment is already in use in the regulation of drugs and is highly demanding for staff. Over 50 employees manage the agenda pertaining to more than 9,000 drugs at the Czech State Institute for Drug Control (SUKL). The medical devices would add some 40,000 items to the agenda, and there should be only 25 employees involved.

Furthermore, CzechMed claims that it is likely that the lowest possible price per unit will remain the main criterion, irrespective of the quality of the appliance, and that this is, therefore, unconstitutional.

Czech Health Ministry mulls over CZK 10bn investment into state hospitals

The Czech Ministry of Health plans to invest CZK 10.3bn (€380.7m) into seven state hospitals by 2020, news agency CTK reported, adding that the implementation of the plan will depend on the financial capabilities of the state budget.

CZK 3bn (€110.9m) will be covered from hospitals' own resources, while further CZK 2bn (€73.9m) will be obtained from the sale of the hospitals' redundant assets, so the net impact on the state budget would amount to CZK 5.3bn (€195.9m).

The investments will be directed into three medical facilities in Prague, as well as to university hospitals Brno, Olomouc, Plzen and Hradec Kralove. The ministry says that the hospitals in question are underfunded, while their infrastructure needs modernisation.

Proton treatment will be reimbursed if approved by comprehensive cancer centre

In accordance with the Transparency Amendment signed by the Czech president on 6 August 2015, the health insurance companies will reimburse proton treatment only if approved by experts at the comprehensive cancer centre (there are 13 such centres in the Czech Republic). This is valid for treatment at any of the centres in Prague or Munich at which Czech patients receive treatment.

Vseobecna Zdravotni Pojistovna (VZP), the largest Czech health insurance company, is the only one of the seven Czech in-

surance companies which does not yet have a contract with the Proton Therapy Centre in Prague, but it seems that the matter is proceeding to a successful conclusion. The amendment essentially approved VZP's request that proton treatment must be indicated by one of the comprehensive cancer centres.

According to the findings of the Czech Press Agency, since 2013 VZP has received 108 requests for the covering of proton treatment and 87 cases have been evaluated in a positive light. Treatment approved by experts is also covered without a contract and is negotiated individually for each patient. Whereas 54 patients insured by VZP received treatment at the proton centre in Prague, the figure for the proton centre in Munich was 32.

The total expenses of VZP for proton treatment at the centres have exceeded CZK 46m (€1.7m) in Prague and CZK 17m (€617,000) in Munich since 2013. Whereas most patients receiving treatment at the proton centre in Prague have been children, the adult patients are sent to Munich.

Hartenberg to strengthen its dietary supplement business

Hartenberg Capital, which is the general partner and trustee of **Hartenberg Holding**, a €200m investment fund which last year acquired several companies operating on the private healthcare and biotechnology markets in the Czech Republic and Slovakia, is planning to strengthen its dietary supplement business on the Czech market, according to e15.cz.

Imunoglukan, one of the acquired companies based in Slovakia, which produces and distributes dietary supplements for the immune system, and for children in particular, has established a new company – Imunoglukan CZ – in the Czech Republic. The company will introduce its own team of medical representatives who specialise in working with pharmacies and doctors.

There is also a plan to strengthen Imunoglukan on its domestic Slovak market. According to Jozef Janov, because of the increase in demand, it is searching for a location for a new production plant near Bratislava in which to invest several million euro.

In addition to the increase in sales on the Slovak and Czech markets, the company has also started to export to Vietnam.

Czech Euroclinicum expands regional presence with new acquisition

The Czech outpatient healthcare services provider **Euroclinicum** acquired a 100% stake in **G-Medica screening**, a company, which through its facilities in Brno and Olomouc provides breast screening, diagnostic mammography and sonography services.

Euroclinicum said that the aim of the acquisition is to strengthen its regional presence and further expand the range of services offered in the Czech Republic. The acquisition also confirms the group's long-term strategy aimed to build a comprehensive network of healthcare facilities with a focus on outpatient and diagnostic services.

The financial details of the transaction were not disclosed.

Benzina to launch sales of OTC products at its stations

Benzina, the largest petrol station chain in the Czech Republic in terms of the number of stations, will begin sales of OTC products at 50 of its 338 petrol stations by the end of August.

Most of these will be OTC drugs for fever or nausea: there will be 15 OTC drugs and 20 additional remedies and dietary supplements in total.

Unipetrol has begun sales at its petrol stations on the main highways and first class roads which have heavy traffic and in cities with non-stop open petrol stations.

According to the Unipetrol holding, which owns the Benzina chain, its main competitor – MOL already has OTC products at some of its petrol stations.

Hungary

Some provisions of Primary Healthcare Act take effect in August 2015

Specific provisions of the Act on Primary Healthcare, which was approved by parliament in July 2015, including the delegation of primary care obligations to municipal governments, came into force on 1 August 2015, making it easier for general practitioners to purchase practices and addressing waiting list issues.

As part of the new Act, some amendments, including those related to interest subsidies for GP privatisation provided by the government and additional remuneration for general practitioners operating with additional specialist qualifications, will come into force in January 2016.

Hungarian Implementation of the EFPIA Disclosure Code

The EFPIA Disclosure Code ("Disclosure Code") was implemented in Hungary in 2014, and pharmaceutical member companies must comply with the relevant provisions as of 1 January 2015. Although the Hungarian version follows the provisions of the Disclosure Code, there are questions that may need to be answered prior to the first reporting in 2016.

Disclosure Code

The Disclosure Code was adopted by the Statutory General Assembly of the European Federation of Pharmaceutical Industries and Associations (EFPIA) on 24 June 2013 primarily to accelerate the disclosure of transfers of values between pharmaceutical companies and Healthcare Professionals (HCPs) or Healthcare Organisations (HCOs).

As the Disclosure Code is a result of sectoral self-regulation, it only affects EFPIA's full members, affiliate members, and non-member companies party to EFPIA Working Groups directly. The pharmaceutical member companies of the EFPIA member associations are affected by the Disclosure Code indirectly.

According to the Disclosure Code, the provisions had to be transposed into national codes by the national affiliate members until 31 December 2013, and pharmaceutical companies subject to the regulation had to start to collect data for disclosure on 1 January 2015. The data collected will have to be disclosed starting as of 1 January 2016.

Hungarian implementation procedure

The Hungarian affiliate member of the EFPIA, the Association of Innovative Pharmaceutical Manufacturers (AIPM), adopted the final text of the Hungarian national code on the implementation of the Disclosure Code (Transparency Code) in September 2014. The Transparency Code complies with Hungarian data protection and competition regulations as well as the new Hungarian Civil Code.

Scope of the Transparency Code

The first and main difference between the Disclosure Code and the Transparency Code is that under the latter, transfers of value (ToV) shall be disclosed pursuant to the national code of the country where the pharmaceutical company subject to the Transparency Code has its physical address irrespective of the place of residence of the recipient of the ToV[1]. This is the opposite of the Disclosure Code's regulatory scheme, which is based on the recipient's physical address.

Individual disclosure of transfers of value

The Transparency Code implemented the Disclosure Code's provisions related to individual disclosure of ToV without any major deviation: each pharmaceutical company must document and disclose the following ToVs it makes, directly or indirectly, to or for the benefit of any HCOs:

- Donations and grants to HCOs that support healthcare, including donations and grants to institutions, organisations, or associations that are comprised of HCPs and/or provide healthcare services.
- Contribution to costs related to professional events, via HCOs or third parties, including sponsorship of HCPs to attend events, such as registration fees; sponsorship agreements with HCOs or third parties appointed by an HCO to manage an event; and travel and accommodation.
- ToV resulting from, or related to, contracts between pharmaceutical companies and research institutions, organisations or associations of HCPs, healthcare service providers, professional organisations of HCPs, or any other organisations linked to healthcare, under which such institutions, organisations, or associations provide any type of services to a pharmaceutical company or any other type of funding not covered above.

[1] *Section 2.05 of the Transparency Code*

In addition, each pharmaceutical company must document and disclose the following ToVs it makes, directly or indirectly, to or for the benefit of HCPs:

- Contributions to costs related to professional events, such as registration fees and cost of travel and accommodation.
- ToV resulting from, or related to, contracts between pharmaceutical companies and HCPs, under which such HCPs provide any type of services or consulting to a pharmaceutical company or any other type of funding not covered above.

According to the Transparency Code, ToV means any direct and indirect transfer of value whether in cash, in kind, or otherwise made, whether for promotional purposes or otherwise, in connection with the development and sale of prescription-only medicinal products exclusively for human use.

Direct ToV is made by a pharmaceutical company for the benefit of an HCP/HCO, whereas indirect ToV is made by another entity acting on behalf of a pharmaceutical company for the benefit of a HCP/HCO, or through an intermediary, where the pharmaceutical company knows or can identify the HCP/HCO that will benefit from the ToV.

Exception from the disclosure obligation

The Transparency Code also reflects the relevant provisions of the Disclosure Code with only a minor deviation: e.g., only "inexpensive meals" instead of "meals and drinks"[2] provided to HCPs/HCOs do not have to be disclosed. Everything else over this amount must be disclosed. The term "inexpensive meals" is not defined by the Transparency Code therefore the relevant definition[3] of Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products (Drug Economy Law) should apply, and pharmaceutical companies should calculate the amount based on the prevailing monthly minimum wage. Accordingly, an inexpensive meal currently cannot cost more than HUF 5,120 (approximately €16). Other elements of the Transparency Code's exemption list are essentially identical to the relevant list of the Disclosure Code, such as:

- ToV related to OTC medicines;
- Supply of assets for medical and educational purposes;
- Supply of free product samples to HCPs; and
- ToV related to the regular pharmaceutical procurement and sales processes.

Aggregate disclosure

AIPM did not want to create a new and different regulation related to the aggregate disclosure, and in the Transparency Code it implemented the Disclosure Code's provisions without changes. According to the Transparency Code, companies subject to the regulation must disclose ToV on an aggregate basis if the amounts attributable to such ToVs cannot be disclosed on an individual basis under the applicable Hungarian laws. This can happen if the HCP does not consent to the individual disclosure of his/her personal data. (See below.) Aggregate disclosure must identify, for each category, the number of HCPs/HCOs covered by such disclosure on an absolute basis and as a percentage of all recipients, as well as the aggregate amount attributable to ToV to such recipients.

Companies must publish aggregate reports on R&D related ToV for each reporting period. Costs of professional events that are clearly related to R&D can be included in the aggregate amount under the "R&D ToV" category instead of individual reporting.

Revocation of recipients' consent

According to Hungarian data protection provisions[4], the consent of the data subject is required to collect, record, and disclose personal data related to the data subject. Therefore, the recipient of a ToV as data subject must be informed prior to the planned collection of specific data with the aim of disclosing them on the website of the pharmaceutical company. The HCP in question may revoke his/her consent to disclosure at any time without reasoning. In that case, the pharmaceutical company must remove the personal data from its website but may still include such data in the aggregate disclosure.

Sanctions

During the implementation procedure, AIPM set up a Transparency Committee to monitor the compliance with the provisions of the Transparency Code based on the provisions of the Disclosure Code, which required member associations to adopt rules set forth by the framework for the enforcement of sanctions in accordance with local legal provisions[5].

According to the Transparency Code, the Transparency Committee must conduct a so-called Transparency Audit Procedure in the event of any suspected violation of the Transparency Code. The Transparency Procedure is commenced in response to complaints or *ex officio* in cases violations are noticed by the Transparency Committee. Companies (including their employees) as well as other companies, organisations, and natural persons may also file complaints.

In case of any violation of the Transparency Code, the Transparency Committee may order any of the following sanctions (or a combination of sanctions), depending on the gravity of the actual violation of the Transparency Code:

- Warn the infringing company in writing;
- Request the company to cease the infringing conduct and to comply with the Transparency Code, and notify the Transparency Committee on the steps taken;
- Publish the name of the infringing company on AIPM's website until the violation is remedied; or
- Suspend the AIPM membership of the infringing company simultaneously with the publication of its company name on AIPM's websites and the Hungarian Medical Chamber and Hungarian Chamber of Pharmacists among "Non-Transparent Pharmaceutical Manufacturers" until the conduct is ceased and remedied.

[2] *Section 1.02 of the Disclosure Code*

[3] *Section 3(8) of the Drug Economy Law*

[4] *Act CXII of 2011 on the Right of Informational Self-Determination and on Freedom of Information*

[5] *Section 4.01 of the Disclosure Code*

Conclusions and further questions

AIPM has fulfilled its task and successfully transposed the provisions of the Disclosure Code into a Hungarian code. There are, however, certain issues that already concern some pharmaceutical companies.

First, pharmaceutical member companies have had to collect the data for disclosure since 1 January 2015, which will be first disclosed in 2016. HCPs as individuals, however, must be informed about the processing of their personal data and provide their consent before the data processing begins. Main questions regarding this issue are:

- when does the data procession start and
- when must HCPs be informed about the processing of their data?

Some argue that collecting personal data for disclosure based on the Disclosure Code does not qualify as data processing, as this data should also be collected based on other legal provisions, and therefore, HCPs affected by data processing should be informed only before the disclosure of the relevant personal data. Others assert that the collection of the above mentioned data qualify as data processing, and therefore, they are already obtaining the consents of the affected HCPs. If the competent data protection authority agrees with the latter argument, pharmaceutical companies collecting personal data without any consent may seriously breach the relevant legal provisions.

Second, individually disclosed data must contain all the ToVs a HCP receives during the a year, including the cost of inexpensive airplane tickets, registration fees, accommodation to one or more conferences abroad, etc. If this data is posted on publicly available websites, it will also be available to the national tax authority (NAV), which may want to review and compare the data with the annual tax returns filed by the HCPs. It is obvious to ask the question, why would an HCP risk a tax audit based on a voluntarily disclosed data if the relevant data can be disclosed on an aggregate basis and meet the requirement of the Disclosure Code?

Finally, the role of the competent Hungarian authority, the National Institute of Pharmacy and Nutrition (OGYEI) is also unclear. There are many questions whether the Transparency Code would ever serve as the basis for a future legislation. Will OGYEI review the disclosed information? One thing, however, is certain: data submitted to OGYEI based on the current legal provisions must be in line with data disclosed under the Transparency Code. Otherwise, it may trigger further investigations by OGYEI.

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KNP LAW Nagy Koppany Varga and Partners (KNP LAW) is an independent Hungarian law firm whose main practice areas include life sciences law. The firm's life sciences team focuses on corporate, commercial, contract, IP, and regulatory matters and closely cooperates with the litigation and arbitration group on product liability and administrative cases.

Gedeon Richter proffers more optimistic annual revenue expectations

Erik Bogsch, the CEO of **Geden Richter** has said, of the surprisingly good Q2 figures of the company, that the results of a quarter should not be overrated. The company's sales revenues rose by 11.4% to HUF 96bn (€311.2m), and its after-tax profit by 62.6% to HUF 22.46bn (€72.8m), both year on year, well in excess of the expectations of analysts. According to Mr Bogsch, the results mainly reflected sales growth in the American and Western European market, along with the strengthening of the dollar, compensating for the collapse of the Ukrainian market.

Mr Bogsch expects annual revenue to fall by 2% in euro, in contrast to the previous forecast of 7-8%. In Ukraine it expects a 73% reduction, but for the regions it has presented more optimistic expectations of changes in its 2015 revenue.

Gedeon Richter sales forecast change, 2015

Region	Change (%, y-o-y)	Currency
Hungary	0-5	HUF
Ukraine	-73	USD
Other CIS countries	0	USD
Poland	5	PLN
Romania	-5	RON
EU 10	-10	EUR
EU 15	10	EUR
USA	-(5-10)	USD
China	15	EUR
Latin America	5	USD
Total	**-2**	**EUR**

Source: Gedeon Richter, 2015

However, Mr Bogsch has also said that the H2 results are likely to fall short of those of the first half of the year.

Biomed and Szeged University cooperate to develop new dietary supplement

The Institute of Pharmacognosy at the University of Szeged has announced that it and **Biomed** have jointly developed Allimed, a plant-based dietary supplement. The product is manufactured with the use of garlic, wild garlic and hawthorne, which are said to have protective cardiovascular properties.

Dezso Csupor, a lecturer at the institute, was quoted as saying that the product was developed within a year and a half. According to the communique, the company and the university both intend to extend their cooperation.

The product is already available on the market.

Gedeon Richter signs agreement with Stada for sale of Pegfilgrastim

The Hungarian pharmaceutical manufacturer **Gedeon Richter** has signed a licence and distribution agreement with Germany's **Stada Arzneimittel** to sell the former's biosimilar product Pegfilgrastim in Europe. In accordance with the agreement, Stada will receive non-exclusive distribution rights for Europe (with the exception of Russia), whereas Gedeon Richter retains its rights to distribute and market Pegfilgrastim worldwide.

In addition to an advance payment pertaining to the signing of the contract, Stada is obliged to make further payments depending on the progress of the project. It will report the resulting sales and make further licence-related payments. The product has not yet been registered, and its registration application will be submitted in Q4 2015, with approval expected in Q1 2016, according to a report in *Portfolio.hu*.

OGYEI suspends marketing authorisation of nine medicines

The National Institute of Pharmacy and Nutrition (OGYEI) has announced that, in the wake of the implementing decision of the European Commission pertaining to medicinal products whose bioequivalence studies were carried out at the **GVK Biosciences** Hyderabad site, the marketing authorisations of nine products have been suspended.

The medicines are: the Inaller 5 mg film-coated tablets, the Gluforlyn XR 500 mg prolonged-release tablets, the Trimetazidine Mylan 35 mg prolonged-release tablets, Esomeprazol Mylan 20 mg hard capsules, Esomeprazol Mylan 40 mg hard capsules, the Apstar 35 mg prolonged-release tablets, the Desloratadine Teva 2.5 mg orodispersible tablets, the Desloratadine Teva 5 mg orodispersible tablets and the Trimetazidine Sandoz 35 mg prolonged-release tablets.

Poland

Pharmacy sales up 2.4% in July

The Polish pharmacy market was worth PLN 2.37bn (€565m) in July 2015, which represents an increase of 2.4% compared with the same period of 2014, according to data from PharmaExpert. Sales of reimbursed prescription medicines grew by 3.3% y-o-y to PLN 905m (€216m). Sales of fully-paid prescription medicines went up by 6% y-o-y to PLN 547m (€130m).

Sales of OTC products, by contrast, decreased by 1.1% y-o-y to PLN 889m (€212m). The average pharmacy generated sales turnover of PLN 164,000 (€39,000) in July 2015, down by 0.9% y-o-y. Of this, drug reimbursement amounted to PLN 44,550 (€10.600), down 2.8% y-o-y.

The average pharmacy handled 3,360 transactions in July, up from 3,270 a year earlier. The average bill amounted to PLN 48.81 (€11.63), down from PLN 50.61 (€12.06). The average price of product sold was PLN 16.98 (€4.05), up from PLN 16.54 (€3.94).

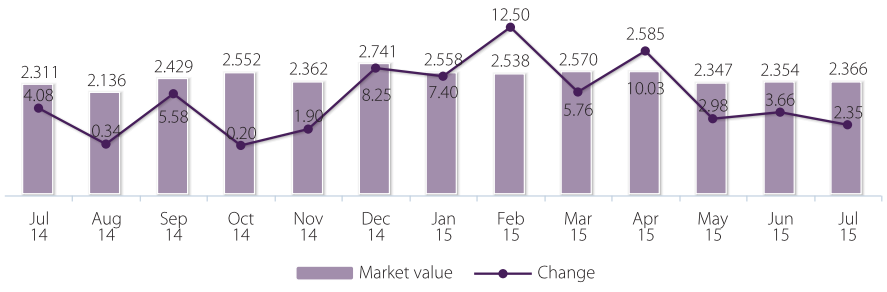
The average pharmacy margin decreased from 26.42% to 25.35%.

The share of drug reimbursement in the average pharmacy's total turnover amounted to 27.16%, down from 27.68% in July 2014. The share of drug reimbursement in the average pharmacy's turnover from the sale of reimbursed medicines decreased from 73.05% to 71%.

In the first seven months of 2015 the pharmacy market grew by 6.4% y-o-y.

PharmaExpert forecasts that in 2015 as a whole the pharmacy market will grow by 5.2% to just under PLN 30bn (€7.1bn). Drug reimbursement is projected to rise by 5% to almost PLN 8bn (€1.9bn).

Polish pharmacy market value (PLN bn) and change (%, y-o-y), July 2014-July 2015



Source: PharmaExpert, 2015

www.pmrpublications.com

Reimbursement Act cost Polish drug makers PLN 500m in reduced revenue

The introduction of the Reimbursement Act has cost domestic drug manufacturers over PLN 500m (€119.1m) so far in reduced revenue, as companies implemented price cuts totalling 7%, according to calculations by the Polish Association of Pharmaceutical Industry Employers (PZPPF).

The Association calculates that the average price per package of a medicine manufactured in Poland is PLN 14 (€3.3), compared to PLN 18 (€4.3) for an imported one. This is a difference that brings savings for the National Health Fund (NFZ), PZPPF president Cezary Sledziewski told MPs on the Sejm health committee on 21 July.

Drugs manufactured in Poland account for 50% of the reimbursed medicines market by volume and for 30% by value, which shows that they are accessible pricewise, he added.

The prices of generics in Poland are also much lower on average than in Europe – about €3 per package vs. €5. The average price of a reimbursed generic is higher, but latest data from IMS Health on the re-

imbursement costs of seven key therapeutic groups in Europe also demonstrate that they are the lowest in Poland, according to Mr Sledziewski.

The PZPPF would like the ministry to ensure that the Reimbursement Act, and especially the provisions on price negotiations, continue to be observed. Furthermore, in the opinion of Mr Sledziewski the ministry should in the future take into account other factors than merely price, such as for example the security of supply that the domestic industry offers, or expenditures on capital investments and R&D.

Sejm to give hospitals yet more time to buy insurance, upgrade infrastructure

MPs are working on legislation that will extend by one more year the deadlines for hospitals to buy insurance against medical malpractice claims, and to bring their infrastructure into line with EU technical standards, *Rzeczpospolita* reported.

The former deadline is to be delayed from 1 January 2016 to 1 January 2017. The latter deadline is to be postponed from 31 December 2016 to 31 December 2017.

MPs from the ruling Civic Platform (PO) party are hoping to push through one more piece of healthcare legislation before the current Parliament term expires, the paper has learnt. They have submitted a legal proposal envisaging the establishment of dedicated children's units within hospital emergency departments – one per one milion inhabitants.

The proposal sets equipment and personnel requirements for these units – each will be required to possess an anaesthesiology and intensive care ward, an operating suite and a child surgery ward, as well as access to laboratory diagnostics and diagnostic imaging facilities, for example. Experts praise the idea, but point out that the proposal appears hastily put together.

Senate backs new financing system for obligatory vaccinations

The Senate on 7 August approved, without changes, legislation that shifts the responsibility for the financing of obligatory vaccinations for patients with mandatory health insurance from the Health Ministry to the National Health Fund (NFZ) effective from 1 January 2017.

The funding levels will be specified in the NFZ's annual financial plans. The Health Ministry will continue to purchase vaccines for uninsured patients only.

According to the law's authors – a group of MPs from the ruling Civic Platform (PO) party – the change will enable successive expansion of the Obligatory Vaccination Programme in accordance with epidemiological needs, as the NFZ has more financial resources at its disposal than the ministry. It is expected, for example, that the new system will make possible the introduction of universal vaccination against pneumococcal disease, HPV or meningococcal disease.

The law now goes for presidential signature.

Drug reimbursement up 7% y-o-y in January-June 2015

The National Health Fund (NFZ) spent a total of PLN 5.3bn (€1.27bn) on drug reimbursement in the first six months of 2015. This represents an increase of 7.1% comparing to the same period a year earlier. The figure constitutes 48.7% of the Fund's total reimbursement budget for 2015, which is PLN 10.9bn (€2.60bn).

Expenditures on the reimbursement of medicines, foods for particular nutritional uses and medical devices available upon prescription in the pharmacy channel amounted to PLN 4bn (€954m) in January-June 2015, up 8.7% y-o-y and 51.6% of the annual plan (PLN 7.78bn or €1.85bn).

Reimbursement via drug programmes totalled PLN 1.06bn (€253m), up 1% y-o-y and 41.8% of the annual plan (PLN 2.53bn or €603m).

Expenditures on chemotherapy drugs came to PLN 241m (€57m), up 9.5% y-o-y and 40.4% of the annual plan (PLN 597m or €142m).

Homeopathic medicines to lose prescription status

The Health Ministry will cease assigning prescription status to homeopathic medicines, health minister Marian Zembala revealed during a meeting with the Polish Council of Physicians and Dentists (NRL) on 5 August.

This means that those homeopathic products that currently have prescription status in Poland will lose it in the near future, as the Rx classification is given for a definite period and subject to renewal every five years.

The ministry's decision is a response to calls from the self-governing bodies of the medical profession, which have been pushing for a reduction in medical recommendations that have no scientific basis.

Telemedicine regulations to be enacted before election?

The medical sector is hoping that the current Sejm will enact provisions that will for the first time explicitly regulate and allow telemedicine in Poland before it disbands ahead of October's election, *Puls Biznesu* reported.

The Sejm health committee is currently working on a government-sponsored amendment to the Information system in healthcare act and some other acts that is necessary for the implementation of an ICT system for healthcare. The sector wants to use this opportunity to insert several clauses pertaining to telemedicine, and the plan is realistic given that there are two more parliamentary sessions to be held in September and that the current health minister has included telemedicine and viceoconsultations among strategic priorities for the years 2016-2020. A working group has been established to develop the proposals, composed of representatives of telemedicine firms but also insurers, pharmaceutical companies and large public and private providers.

As Michal Czarnuch, lawyer at Domanski Zakrzewski Palinka law firm, who is involved in the process, explained, the new clauses would specify what health services can be performed remotely, and what kind of connections should be used for this purpose so as to ensure data protection. They would also permit remote diagnosis. And they would significantly relax or even abolish certain requirements, for example regarding premises, for providers specialising in telemedicine. At the moment, they have to meet the same standards as traditional brick-and-mortar facilities.

Number of DiLO cards exceeds 150,000 but figures vary across regions

Between 1 January and 27 July 2015, a total of 152,053 Oncology Diagnosis and Treatment (DiLO) cards were granted to patients across the country, the Health Ministry announced.

The number of initial diagnoses given to DiLO patients totalled 20,681, of which 92.4% were performed within the time limit, whereas the number of in-depth diagnoses reached 36,334 (84.5%).

Also, a total of 60,188 conferences on DiLO patients were held during this period, nearly all of them (99.5%) within the time limit.

The overall picture masks considerable regional differences, however, according to calculations by *Dziennik Gazeta Prawna*. Thus in Swietokrzyskie, Dolnoslaskie, Mazowieckie or Kujawsko-Pomorskie the ratio of DiLO cards issued per 100,000 inhabitants stands at about 450-455, but in Podlaskie it is almost three times lower at 164, with Podkarpackie and Lubuskie scoring second from bottom.

Wielkopolskie's first radiotherapy centre outside Poznan to open at turn of 2015/2016

A new radiotherapy centre in Kalisz, built as as a local unit of the Wielkopolskie Oncology Centre (WCO) in Poznan, has remained idle for almost a year now due to failure to obtain National Cancer Programme (NPZChN) funding for the purchase of accelerators, after a change in Health Ministry policy, *Gazeta Wyborcza* reported.

The Kalisz centre is the first radiotherapy facility in Wielkopolskie outside Poznan. Earlier this year the WCO moved one of its eight accelerators from Poznan to Kalisz to allow the unit to treat patients. The National Health Fund (NFZ) refused to sanction such an arrangement because a radiotherapy centre is required by law to possess at least two accelerators, so as to ensure continuity of treatment. Hence the need for a second accelerator, which will be purchased with the help of the regional government grant in the amount of PLN 9.7m (€2.3m) and could be installed towards the end of 2015. For the moment, the Kalisz centre offers oncology consultations only.

The Wielkopolskie region has 10 accelerators at present – seven at the WCO in Poznan, one at the Kalisz centre, and two at the HCP hospital in Poznan – whereas there should be at least 14, according to Prof. Piotr Milecki of the WCO.

Bayer sells Biovital portfolio in Poland to Egis

Bayer on 29 July announced that it has agreed to sell its portfolio of Biovitalvitamin products in Poland to **Egis Pharmaceuticals**, the Hungarian generics manufacturer.

The transaction covers the Biovital and Kinder Biovital brands. It is expected to be finalised in the third quarter of 2015.

The value of the transaction was not disclosed. However, Egis told Hungarian MTI news agency that the Biovital portfolio in Poland generates revenues of about HUF 1bn (€3.2m) a year.

Maspex files to buy stake in Sequoia supplements maker

Grupa Maspex Wadowice, a big Polish food group, has filed a request with the Office of Competition and Consumer Protection (UOKiK) to approve its acquisition of 44% of shares in **Sequoia**, a Warsaw-based domestic manufacturer of dietary supplements, it was announced on 11 August. The seller is an investment fund managed by Paan Capital.

Maspex expects to receive anti-trust clearance for the transaction within two to three months. Maspex CEO Krzysztof Pawinski explained that the company has no plans to increase the stake and treats Sequoia as a financial investment.

Sequoia was founded barely five years ago and has grown very fast, helped by an expanding market but also smart marketing campaigns, according to IMS Health quoted by *Puls Biznesu*. The company's revenues rose from PLN 30m (€7.1m) in 2012 to PLN 60m (€14.3m) to PLN 90m (€21.4m) in 2014, fuelled in large part by Sambucol, a cold and flu supplement. Other brands of Sequoia include Omegamed, Actiferol, Maximed, or Pedicetamol. The products are used in the treatment of flu and respiratory infections, fever, pain, wounds, allergies, blood deficiency, as well as for the protection of the digestive tract or in the prevention of rickets.

Maspex has in its portfolio a vitamins and dietary supplements business, with brands such as Plusssz or Asparan. In 2003 it acquired Polski Lek.

GNS will spend PLN 60m on capex in 2015-2018

Grupa Nowy Szpital (GNS), the private hospital management group, has a plan to acquire one hospital a year in the medium run, and to accelerate to four acquisitions per year in a longer-term perspective, DM Vestor stock brokerage says in a report, a copy of which was obtained by *Puls Biznesu*.

GNS operates 12 hospitals at the moment, but is reportedly in advanced negotiations about investing in three facilities, while preliminary talks are underway regarding a further 10 hospitals.

According to the report, the group intends to spend PLN 60m (€14.4m) on capital investments in 2015-2018 (including PLN 27m or €6.5m from EU funds), primarily to bring its hospital infrastructure into line with new requirements.

DM Vestor values GNS at PLN 120-139m (€29-33m), which translates into a price-earnings ratio of PLN 8.7-9.7. This is a very attractive valuation compared to the price paid for fellow provider EMC Instytut Medyczny by Penta Investments, the stock brokerage notes. Based on the valuation multiples used in the EMC takeover, GNS is worth PLN 240-282m (€57-67m).

The major downside risk to the valuation and forecasts are possible regulatory changes affecting the functioning of the National Health Fund (NFZ), which accounts for nearly 90% of GNS' revenues, DM Vestor says.

Synektik to receive PLN 5.6m EU grant for cardiac tracer project

Synektik, the listed diagnostic imaging and radiopharmaceuticals group, stands to receive PLN 5.6m (€1.3m) from the National Centre for Research and Development (NCBR) under the Intelligent Development Operational Programme (POIR) for a project titled "Development of a new 18(F)-labelled cardiac PET tracer for assessing myocardial perfusion and for diagnosing ischaemic hear disease."

The project is among a list of 34 projects recommended for funding in the first round of POIR (out of a total of 175 submissions), published by the NCBR on 3 August.

The total value of the project is PLN 10.5m (€2.5m) and it is to be accounted for by 31 August 2021, Synektik said in a statement to the stock exchange on 4 August.

Konopna Farmacja enters new cities as legal concerns abate

Konopna Farmacja, the retail chain selling dermocosmetics and food products based on cannabis sativa, is expanding to new cities, despite its debut store in Katowice having attracted police interest.

As Lukasz Dzieciaczek, who holds the master franchise license for Poland, told franchising.pl in July, the inspection by police officials found nothing irregular about the store's product assortment.

The first Konopna Farmacja store opened in March this year, and the chain has since grown to six locations – in Katowice, Rzeszow, Rybnik, Nowy Targ, Poznan, and Plock. (The Plock store opened on 8 August.) There have been no more inspections, Mr Dzieciaczek said.

The chain is looking for franchise partners in cities with more than 100,000 residents, and expects to enter Warsaw and Krakow in the near future, among other markets.

Konopna Farmacja originates from the Czech Republic.

NovoTek ups bid for Bioton

NovoTek Pharmaceuticals on 10 August raised its bid for 33% of shares in **Bioton** to PLN 9 (€2.1m) per share from previously PLN 7 (€1.7), valuing the Polish firm at PLN 254.7m (€60.7m).

Subscriptions started on 31 July and will end on 13 August.

NovoTek previously said that it will go through with the bid if at least 30% of Bioton's shares are tendered.

The improved offer is very attractive and it is a final one, said Dr Jubo Liu, founded and CEO of NovoTek Pharmaceuticals. Opening up new markets and opportunities for Bioton will not be possible without the strong support of a strategic investor with an established in the pharmaceutical sector, and the bid price demonstrates the seriousness of NovoTek's intentions, Mr Liu added.

A financial investor from China, Bimeda Holding Limited (a unit of China CEE Investment Co-Operation Fund), is also in the process of buying Bioton shares, with the aim of accumulating a 30-33% stake within a year.

According to *Puls Biznesu*, if NovoTek's bid succeeds, the company will probably want to take care of the distribution of Bioton's products in the Middle Country on its own, which the other investor might not like.

GNS to complete share sale to institutional investors in September

Grupa Nowy Szpital (GNS), the private hospital management group, expects to complete the sale of shares to institutional investors in early September, CEO Marcin Szulwinski told *Puls Biznesu*. The level of interest is high and the offering looks set to end in success, he said.

The shares are being sold by Adam Roslewski, who is the joint owner of GNS with Mr Szulwinski, each owning a 50% stake. The plan is for Mr Roslewski to sell half of his interest to Mr Szulwinski and the other half to new investors. GNS also plans to issue new shares or bonds to raise capital for growth. The next step will be a listing on the Warsaw Stock Exchange.

Some experts are questioning the merits of this plan. In the opinion of Adrian Kowollik, Managing Partner at East Value Research, quoted by *Puls Biznesu*, a stock market debut is not a good idea for a relatively small hospital group that is GNS. It would be a better idea for the provider to find a financial or strategic investor and to continue to grow outside the stock market, as its business is a long-term and capital-intensive one. A fund manager, who wished not to be named, expressed a similar view. GNS should instead consider merging with EMC to create a large hospital group, he said.

Mr Szulwinski intends to remain a majority shareholder, however, and rules out such a scenario.

Mazowieckie facing oversupply of radiotherapy centres

Three public hospitals in Warsaw – in Szaserow, Woloska and Banacha streets – are preparing to launch their own radiation therapy centres. This could soon lead to an excess of radiotherapy capacity in the Mazowieckie region, the local edition of *Gazeta Wyborcza* reported.

According to the paper, the reason behind the high level of investment activity in the sector is that radiotherapy is lucrative – the amounts paid by the National Health Fund (NFZ) mean that profit margins can be as high as 60%.

At the moment, two facilities in Mazowieckie – the Oncology Centre in Warsaw and the privately-owned oncological hospital in Wieliszew (Mazowiecki Szpital Onkologiczny) – are providing radiotherapy services under NFZ contracts. The former treated over 12,000 patients last year and the latter, more than 3,500. In the opinion of Prof. Andrzej Kawecki, the region's radiotherapy consultant, the two cetres are sufficient to meet demand.

Meanwhile, **Affidea**'s centre in nearby Otwock, built two years ago, ceased admitting patients this month after repeated failure to secure NFZ funding.

A private radiotherapy centre is also under construction in Radom, while the Mazowieckie government is promoting the idea of a new centre in Siedlce. In the opinion of Prof. Kawecki, these projects make more sense because they would bring treatment closer to patients from more remote parts of the province, potentially reducing unnecessary hospitalisations.

New private hospital to debut in Poznan market in Q4

A new private multi-specialty hospital will open in Poznan in the fourth quarter of 2015, **Wielkopolskie Centrum Medyczne** (WCM), the investor, has announced.

At the heart of the facility will be a two-room operating suite equipped with state-of-the-art medical technologies including low-invasive laparoscopic techniques. The hospital will also feature a two-room endoscopy suite, as well as consulting and treatment rooms, dental care rooms, a medical testing laboratory, a diagnostic imaging unit, and a pharmacy.

More details about the service offer are to be unveiled at the launch of the hospital in Q4.

Poznan-based WCM was entered in the register of healthcare providers in 2012.

Biomed-Lublin to produce first blood derivatives in Poland in 2016

Biomed-Lublin would like blood plasma derivative products to generate approximately 80-90% of it total revenues in the future, and

reckons that it can achieve this target already in 2017, CEO Waldemar Sierocki told *Parkiet*.

The company temporarily relies on LFB Biomedicaments, its French partner, for the fractionation of its plasma into therapeutic products, but expects to launch its own plant in Mielec (Podkarpackie) next year. The first products from Mielec should reach the market towards the end of 2016, Mr Sierocki said, adding that the factory will have a permanent workforce of over 200.

Biomed-Lublin booked the first revenues from the sale of blood plasma derivatives – manufactured in France – in the second quarter of this year, but expects to earn "significant" amounts from this source only in Q3 and Q4, said its CEO.

According to Mr Sierocki, products made in France are likely to have the decisive impact on its financial results in 2016, but this will begin to change already in 2017.

Biomed-Lublin also manufactures probiotics, suppositories and vaccines.

Biomed-Lublin to conduct PLN 15m bond issue to support blood plasma business

The management of **Biomed-Lublin** on 27 July approved the issue of up to 150,000 A series bonds with the nominal value of PLN 100 (€24) each.

The company plans to raise up to PLN 15m (€3.6m) from the issue. The funds will be used to strengthen its working capital, and specifically to fund operations related to the contract-fractionation of its blood plasma by its French partner **LFB Biomedicaments**, Biomed-Lublin said in a statement to the stock exchange.

OncoArendi to receive PLN 23m EU grant for development of asthma drug

OncoArendi Therapeutics, a Polish biopharmaceutical firm dedicated to developing and commercialising novel therapeutics for neoplastic and inflammatory diseases, will receive PLN 22.8m (€5.5m) from the National Centre for Research and Development (NCBR) under the Intelligent Development Operational Programme (POIR) for a project titled "Preclinical and clinical trials of an innovative drug candidate for asthma and non-specific inflammatory bowel diseases (IBD)."

The total value of the project is nearly PLN 30m (€7.2m).

As CEO Marcin Szumowski told *Puls Biznesu*, the asthma version is the more advanced of the two and should enter Phase II clinical trials in less than four years.

In fact, the project's initial focus was exclusively on asthma, but in the course of development work it transpired that the technology could also find application in the treatment of non-specific IBD such as Crohn's disease or ulcerative colitis. It could represent a genuine breakthrough because there are no effective therapies for these conditions at the moment, Mr Szumowski said.

As he revealed, there is a high level interest from pharmaceutical companies in this version of the product, which is expected to enter clinical trials in three years' time. Some of these companies are prepared to buy licensing rights to the candidate once its effectiveness has been demonstrated on animal models, which according to OncoArendi CEO should happen in 2-3 years.

Adiuvo's new fund to invest in two Polish devices makers

Joint Polish Investment Fund (JPIF), a new fund managed by NewConnect-listed biotechnology investment firm **Adiuvo**, is in advanced talks to buy into four early-stage companies from the medical devices sector – two Polish ones and two US ones, *Parkiet* reported.

JPIF has already completed due diligence audits on all four targets and expects to finalise two of the transactions later this month and the other two before the end of 2015, Adiuvo board member Anna Aranowska-Bablok told the paper.

These are completely new projects unrelated to Adiuvo, she added.

As Mrs. Aranowska-Bablok explained, the investments will have a time horizon of three years, i.e. until the anticipated launch of the companies' products on the market, and will be divided into milestones. In three of the four cases, JPIF plans to invest a total of PLN 4-5m (€1-1.2m) over this timeframe.

The Fund will not be a passive investor. It wants to have control over key strategic decisions and a say in day-today operations, at least in cases where the portfolio company is at an early stage of development. It will therefore seek to appoint its own supervisory board members and perhaps even executive board members, Mrs. Aranowska-Bablok said.

JPIF has resources of PLN 157.5m (€37.5m). Of this, the National Centre for Research and Development (NCBR) will provide PLN 82.5m (€19.7m) and the rest will come from private investors, mainly Adiuvo (PLN 70m or €16.7m). The structure is unusual in that the NCBR will for the first time provide repayable money – if the projects bring positive returns, the Centre will recoup up to PLN 66.5m or €15.8m (the remaining PLN 16m or €3.8m is non-repayable).

NovoTek CEO: Partnership would boost Bioton's sales in Asia-Pacific and Middle East

NovoTek Pharmaceuticals, with its extensive distribution network that includes 22 partners in nine countries on three continents, could help **Bioton** to significantly increase sales not just in China but also in South Korea, Malaysia, Hongkong, Macau and the Middle East, CEO Jubo Liu said in an interview with *Parkiet* on 12 August.

Having analysed Bioton's current presence in the Asia-Pacific region, its sales there can be described as relatively low, Mr Liu said.

NovoTek estimates that Bioton needs approximately $40m (€36m) a year for R&D into new products. According to Mr Liu, the necessary funds could be obtained from the projected increase in foreign sales, with debt financing also an option. Certainly the development of insulin analogues is important for Bioton and NovoTek would make a good partner in this respect as well, given its extensive R&D experience and distribution network

The first effects of the proposed strategic partnership would show up in Bioton's sales figures already in early 2016, according to Mr Liu.

For these plans to materialise, however, NovoTek's friendly bid for 33% of shares in Bioton first has to succeed, he noted.

In a separate interview with ISB News Mr Liu said that NovoTek „at the least" wants to become Bioton's biggest shareholder (the current biggest shareholder has 13.2%). The company has yet to perform an in-depth due diligence audit on Bioton and will not want to get involved unless it has sufficient influence.

Mabion enters into consultations with EMA over MabionCD20

Mabion on 13 August announced that it has entered into scientific consultations with the European Medicines Agency (EMA) re-

garding its MabionCD20 drug biosimilar to MabThera/Rituxan, to be used in the treatment of blood cancers and rheumatoid arthritis.

As the company explained, the consultations represent a preliminary phase before filing a formal request for marketing approval. The objective is to clarify any issues pertaining to the registration dossier. The consultations will address the scope of the biosimilarity study and methods of statistical analysis in the clinical trial. Mabion will also discuss with the EMA the possibility of reducing the number of patients enrolled in the study in case the actual variability in the data and statistical power are more favourable than initially assumed.

Mabion plans to register MabionCD20 on all markets where the reference products are sold.

Selvita to open second US office

Selvita has decided to open a second office in the United States – in the San Francisco Bay area – later this year, CEO Pawel Przewiezlikowski revealed on 13 August.

The company's recently established subsidiaries in the US and the United Kingdom – Selvita Inc., seated in the Greater Boston area, and Selvita Ltd., seated in Cambridge, respectively – have already won first orders, he also revealed.

Selvita's backlog of orders for 2015 has reached almost PLN 44.6m (€10.6m), according to data published in August, which represents an increase of 20% compared with the equivalent period of 2014, the company announced on 13 August.

Particularly noteworthy is the 52% y-o-y jump in orders at the services division, to PLN 20.1m (€4.8m), Selvita said.

The figure also includes PLN 10.6m (€2.5m) worth of orders at the research division and PLN 13.9m (€3.3m) from research grants.

To cope with rising orders for the services division, Selvita has expanded its facilities in Krakow by 300 m^2 and stepped up preparations for the launch of a new laboratory in one of the country's academic hubs.

Takes-care.com targets 1.5 million users in two years

Polish consultancy firm Hawk-Eyed has launched **Takes-care.com**, an online platform that offers patients electronic management of their medical documentation, video consultations with physicians, and medication reminders, among other features, and is also integrated with a remote ECG monitor. The service, which operates in seven language versions, has 600 active accounts at the moment and plans to increase that 1.5 million within two years, Hawk-Eyed owner Domink Mazur told *Puls Biznesu*. Approximately 10,000 users will be enough for Takes-care.com to break even, he estimates. The monthly subscription fee ranges from PLN 9-19 (€2.1-4.5) depending on the number of persons covered by an account.

The company is in the process of building an extensive database of doctors and clinics, whom it offers a free profile on the portal with a video consultation feature, an online appointment booking service, a virtual calendar and other features. It is in talks with a number of professional associations and expects to finalise first collaboration agreements in September.

Hawk-Eyed's telemedicine partner is **Pro Plus**, a Polish maker of telehealth solutions for medical centres. The two firms are currently working on adding two new e-health functions to the portal, namely blood pressure and glucose measurement. These are expected to be launched in October.

Takes-care.com directs its marketing efforts mainly at women, knowing that it is women who tend to assume responsibility for the health of other family members – elderly parents, children, or the husband.

Apart from Poland, the company is eyeing German-speaking countries, France, Ireland, the UK, the US, Turkey, Argentine or China. In the UK and Ireland it will initially target Polish expats.

Romania

Drug producers ask for independent audit of claw-back tax base

Drug manufacturers are asking for an independent audit of the data used by Romania's National Health Insurance House (CNAS) for the calculation of the claw-back tax, saying that it was kept at an unsustainably high level in the second quarter.

The "p" percentage in the claw-back tax scheme was 24% in the second quarter, a slight reduction from 26% in the first quarter, according to a joint press release of the Romanian Association of International Medicine Manufacturers (ARPIM) and the Generic Drug Manufacturers' Association in Romania (APMGR), which states that the fact that the claw-back tax has been kept at roughly the same level, whereas the drug consumption figure has fallen by more than 10%, according to Cegedim data, is raising doubts about the calculation methods of the CNAS.

The two associations have said they were very surprised by the small difference between the claw-back tax in Q1 and that in Q2, because, for example, Cegedim estimated the claw-back tax for Q2 to be between 15% and 20%, because of the Rx drug price update process, which forced most companies in the industry to work with very low stocks until the approval of the new, sensibly reduced, price.

Dragos Damian, the APMGR president, has said that there are even companies which need to pay tax which almost matches their sales revenue for Q2 2015. He added that several pharmaceutical companies have sued the CNAS because of the tax.

The associations have warned that without independent control, the maintenance of the current system will lead to losses for both the government, which may be forced by the courts to repay some of the money to companies which contested their tax calculations, and the drug producers, which discern ever higher costs emanating from the tax, forcing them to cancel investments and delist medicines from the Romanian market.

Slight contraction in Romania's drug wholesale market in 2014

The total sales revenues of pharmaceutical wholesalers in Romania came to RON 23bn (€5.2bn) in 2014, which represents a 1.7% reduction on an annual basis, according to Finance Ministry data quoted by *Ziarul Financiar*. This is the first reduction in seven years.

The unpredictability in the pharmaceutical industry and the economic crisis which has affected Romania since 2009 have accelerated the consolidation of the market, which saw several large players, such as **Montero**, **Relad** and **ADM Farm**, lose ground or even vanish. Meanwhile, the number of companies registered as drug distributors has risen in the past few years, as parallel exports have flourished.

Romania drafts drug brokerage legislation

The Romanian authorities have drafted legislation which will introduce drug brokers this autumn. A drug wholesale broker may engage in the wholesale distribution of pharmaceutical products without taking physical possession of the drugs. The role of the broker would be that of negotiating prices and mediating between wholesale companies and drug producers.

According to a Health Ministry official, a drug broker is a qualified person who only establishes the conditions of drug distribution, and there is no risk of the negotiated contracts being used for parallel exports.

The draft law is the subject of public debate and could take effect in September.

Health ministry prepares two new action programmes

Romania's Health Ministry is preparing two new programmes, involving endovascular surgery and gastro-intestinal interventional endoscopy, to add to the five priority action programmes launched last year.

The ministry has allocated RON 244m (€55m) for the seven programmes for 2015, including around RON 2m (€0.45m) for the newly-launched programmes.

Eight hospitals will receive funding for the materials needed for endovascular surgery, whereas 18 hospitals will be funded from the interventional endoscopy programme.

According to the ministry, the five programmes launched in 2014 helped to ensure urgent medical care for more than 100,000 critical patients and a reduction in the mortality rate of heart attacks from 13% to 5%.

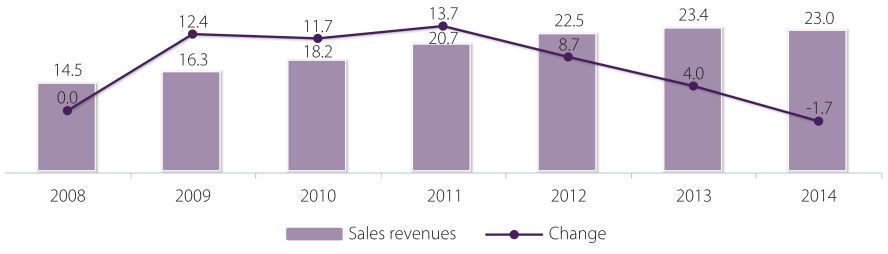
Health Ministry plans construction of new cancer institute in Timisoara

A spokesperson for the Romanian Health Ministry has told *Mediafax* that the ministry wants to invest around RON 500m (€112.6m) in a regional oncology institute in Timisoara, with the use of from European funds, along with money from the state budget and sponsorships.

In 2009 the government approved a plan to establish the cancer institute in Timisoara, allotting a 5.5-hectare area on the outskirts of the city. On the site the construction of a hospital started in 1994, but the project was abandoned shortly afterwards.

The construction of the new institute might start next year, and the work is expected to take three years at least.

Total sales revenues of pharmaceutical wholesalers in Romania (RON bn) and change (%, y-o-y), 2008-2014



Source: Finance Ministry, 2015

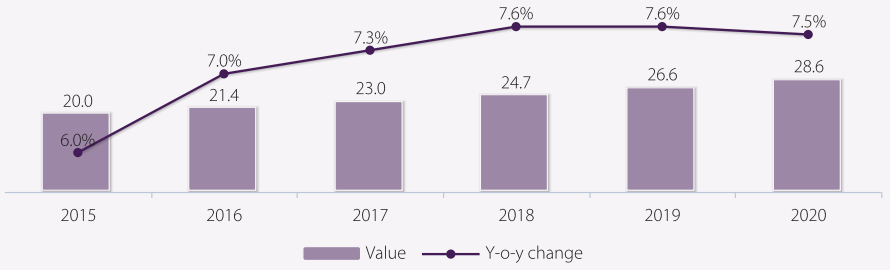
Respectable degree of growth expected in private healthcare market in Romania, Bulgaria and Poland between 2015 and 2020

The private healthcare market in Central Europe will grow by around 7-8% per annum in the years 2016-2020 to reach almost €30bn in 2020. The growth of fee-for-services will have the most extensive impact here because of the improvement in the macroeconomic situation and the fact that area of private insurance in underdeveloped in the countries analysed. The most substantial growth figures for private healthcare markets in the region will be recorded in Romania, Bulgaria and Poland, because of the low level of saturation and the investment boom, according to the most recent PMR report *Private healthcare in Central Europe 2015. Development forecasts for 2015-2020*.

In general, the forecasts for the private healthcare market understood as services only will (excluding spending on drugs and medical goods) be a few points higher than the current understanding of the market which, in accordance with the Eurostat definition, includes fully-paid drugs and medical goods. This pertains to trends in the majority of countries, with the exception of Hungary, where the growth of private healthcare services is somewhat impeded.

Poland and Hungary account for the most substantial proportions because of the relative affluence of society, the large populations, and the relatively efficient reforms (Poland), along with the substantial amount spent on drugs (Hungary). Between 2014 and 2020, Slovakia and the Czech Republic will record the most substantial reductions in market share in the wake of unfavourable reforms. This will also pertain to Hungary, as the share of private services as a proportion of this value will be reduced at the expense of drugs.

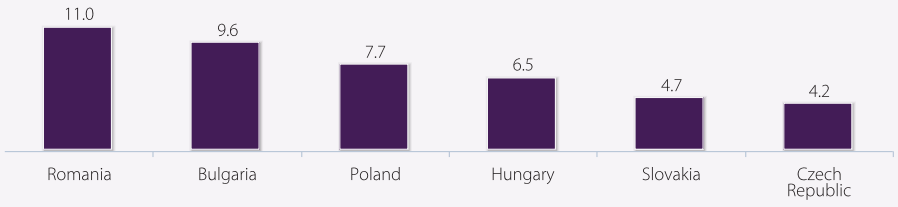
Forecast value (€ bn) and change (%) of the private healthcare market in Central Europe, 2015-2020



Note: including drugs and medical goods.

Source: PMR, 2015

Average CAGR for development of private healthcare markets in CE countries analysed (%), 2015-2020



Source: PMR, 2015

Poor healthcare infrastructure drives growth of private healthcare

Hospitals in the region continued to lack efficiency, grappling with overcapacity, a lack of funding and poor managerial expertise. In Hungary, public resentment towards private initiatives in hospitals has made matters worse.

Major developments on this market have been observed in Romania and Poland, where the past three years have seen a frenzy of investment in private hospitals. The private hospital market has also grown in Bulgaria. The worst situation is still observed in Hungary, where in 2009 the hospital market witnessed the most serious bankruptcy of a hospital operator in the region, HospInvest and in 2013 Telki hospital was closed. There are now no typical large private hospitals in the country. Slovakia has followed the Hungarian path, abandoning the hospital privatisation plans.

The past two years have seen moves by governments across the region to reduce hospital capacities as part of their attempt to cut spending in the healthcare system (and further steps are planned), for example:

In the Czech Republic, in 2013 there was a reduction of 2,571 in the number of acute care beds, whereas 189 aftercare beds were introduced.

The number of beds in Slovak hospitals will have been reduced from the current 34,000 to 19,000 by 2030, in step with a strategic healthcare plan approved by the Slovak government in December 2013. In the future, Slovak hospitals will focus mainly on acute care, with the role of the primary care sector to be strengthened to reduce the number of patients ending up in hospitals or going there without necessary tests/examinations. The ministry estimates that in 2030, the number of acute beds will amount to 13,500 with usage rate amounting to 85%.

In Romania in the last three years the number of beds in hospitals in Romania has fallen by 2,548. The government decided in 2014 that the number should be reduced by 1,000 per annum until 2016.

In 2016, the number of hospitals in Bulgaria could be reduced by 50 if the amendments to the Healthcare Providers Act are passed. The amendments will entitle the NHIF to select the hospitals with which to sign reimbursement contracts in accordance with the needs of the population.

Creation of basic and complementary insurance: a market driver in Bulgaria over the next 5 years

In Bulgaria the rates of growth of private healthcare expenditure will eventually be, on average, lower than those witnessed before the crisis. This will reflect not only a less substantial increase in GDP, but also of the weakening of specific positive market trends and the saturation of the market, given the current degree of affluence.

In 2013, according to our estimates, private healthcare spending in Bulgaria increased by almost 8%, in comparison with the 2012 figure, mainly because of the fact that the expected acceleration in GDP growth actually took place. From 2016 onwards, the expected acceleration in GDP growth, combined with a faster increase in social transfers (pensions), will boost the increase in private healthcare spending to 9-11% (in 2016-2020). The forecast for economic factors indicates that the private healthcare market will be more significant, but in light of the changes in the law (the limitation on hospital funding and the planned limitation of the number of new private hospitals opened), along with further planned amendments, the growth will fall short of market potential. On the other hand, the main market driver will be the creation of basic and complementary insurance.

According to PMR's respondents, the private market is unpredictable because of the political instability in the country (e.g. the frequent changes of ministers) and the fact that politicians often break their promises.

Number of hospital beds in CE countries analysed per 1,000 of population, 1995 and 2008-2013

	1995	2008	2009	2010	2011	2012	2013
Hungary	9.0	7.1	7.1	7.1	7.2	7.0	7.0
Slovakia	8.3	6.6	6.5	6.5	6.1	6.0	5.9
Bulgaria	10.3	6.0	6.1	6.1	6.5	6.6	6.8
Romania	7.6	6.4	6.5	6.2	6.0	6.1	-
Czech Republic	7.2	6.0	6.0	5.9	-	5.6	5.4
Poland	6.5	6.6	6.6	6.6	-	5.0	-

Source: PMR, 2015

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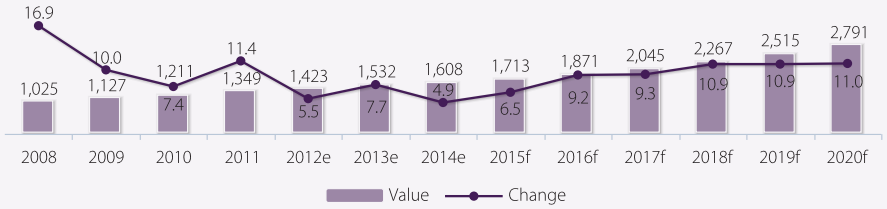
Value (€ m) and change (%, y-o-y) of the private medical services market in Bulgaria, 2008-2020



Note: including drugs and medical goods
e - estimate
f - forecast

Source: PMR, 2015

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The opportunities include for the development of private healthcare market in Bulgaria include:

Medicine as a science and practice in the country still has a solid basis: highly qualified doctors, traditions, widespread and rapid access to specialist care and treatment and the competence of hospital managers in the private sector, including the optimisation of processes, quality control, service to patients and patient satisfaction.

The openness of Bulgaria and specialists in the exchange of experience. The latest achievements in therapeutic protocols, medical consumables and innovative drugs become part of Bulgarian practice extremely rapidly; as a result patients are on an equal footing with those in the more developed countries. Private hospitals have programmes for the exchange of experience with renowned medical specialists via practical seminars and the visits of foreign doctors who treat Bulgarian patients in the country instead of having patients travelling abroad to receive treatment.

Bulgaria has substantial potential for the development of medical tourism. Its private hospitals offer high-quality services, and prices are competitive. The lack of a language barrier with the Russian Federation and the Western Balkan countries is an additional advantage, along with relative geographical and historical compatibility.

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Mid Europa Partners acquires Regina Maria

The private equity firm **Mid Europa Partners** has announced that it has signed a binding agreement to acquire the Romanian private healthcare services provider **Regina Maria**, in a transaction estimated by *Ziarul Financiar* to be worth more than €100m. The transaction is subject to anti-trust clearance and is expected to be concluded in Q4 2015.

80% of Regina Maria was controlled by the private equity company **Advent International**, whereas its founder, Wargha Enayati, owned the remaining 20%.

Mid Europa Partners bought the whole network operated by Regina Maria on a national level: i.e., 22 clinics, four hospitals, 11 laboratories and five imaging diagnostics facilities.

Mid Europa Partners to carry out more acquisitions in Romania

Wargha Enayati, the founder of the Romanian private healthcare services provider **Regina Maria**, has said, in an interview with *Ziarul Financiar* that the private equity firm **Mid Europa Partners**, which recently announced that it had signed a binding agreement to acquire Regina Maria, is planning to buy other players in the field.

Without offering any further details, Mr Enayati said that Mid Europa Partners' plans will open up new vistas for the growth of Regina Maria.

The transaction between Mid Europa Partners and Regina Maria is subject to anti-trust clearance and is expected to be concluded in Q4 2015. According to sources quoted by *Ziarul Financiar*, the transaction was thought to be worth more than €100m, whereas other sources cited by the *Mediafax* news agency estimate that it is worth approximately €165m.

Regina Maria opens new clinic in Constanta

The Romanian private healthcare provider **Regina Maria** recently opened its second clinic in Constanta, a paediatric unit which represents an investment of €300,000.

The company is preparing for two other units in Iasi and Timisoara which will target corporate clients, as several business have expanded to these cities, according to Fady Chreih, its general manager, quoted by *Ziarul Financiar*.

The Iasi clinic, which will include a diagnostic imaging centre, is due to open in September. Both this clinic and that in Timisoara take up 1,000 m^2. Taking these two into account, the national clinic network of Regina Maria will reach 24 units.

The total investment budget for 2015 comes to €6m and will include, in addition to the clinics described above, several centres for the collection of laboratory samples to be opened by the end of the year.

Ponderas hospital aims for 25% increase in revenue in 2015

The Romanian weight loss surgery hospital **Ponderas** expects revenue of €13m this year, an increase of 25% in comparison with 2014, after its transfer to a new location early this year at which it expects an occupancy rate of at least 50%.

In an interview with *Ziarul Financiar*, Alina Ambrozie, the chief executive of Ponderas, said that the first half results already confirm the projected trend.

If it achieves the 25% growth target, this year's revenue will match the initial amount invested, which stood at about €13m four years ago.

Mrs Ambrozie added that, whereas last year's occupancy rate at the hospital was 70%, this year it will fall to 50%, after an increase in capacity to 141 beds.

Increase in revenue but reduction in profit for Zentiva Bucharest in H1 2015

Zentiva Bucharest, a unit of the French pharmaceutical group Sanofi, earned net revenues of RON 209m (€47m) for the first year-half, a 4% increase in comparison with RON 200.1m (€45m) in the corresponding period of 2014. However, the company said in its quarterly financial report, without providing the reasons, that its net profit fell from RON 27.2m (€6.1m) to RON 17.9m (€4m).

The report showed that the company's operating revenue increased by 13%, to RON 230.2m (€51.8m) but that this was not enough to make up for a 21% rise in operating expenses, which reached RON 206m (€46.4m).

The increase in expenditure mainly reflected the higher costs of raw materials and consumables, which grew by almost one-third, from RON 100m (€22.5m) in H1 2014 to RON 131.3m (€29.5m) between January and June 2015.

5.6% fall in sales revenue for Farmaceutica Remedia in H1 2015

The Romanian pharmaceutical company **Farmaceutica Remedia** reported sales revenues of RON 113.1m (€25.5m) in the first half of 2015, which represents a 5.6% reduction on an annual basis. This was a result of the authorities' price change decision, which was initially announced for 1 May but which took effect only on 1 July.

Most pharmaceutical companies have, therefore, operated with very low inventories, to avoid substantial losses, as the price cuts were expected to reach more than 20%. In addition, Farmaceutica Remedia, which has both wholesale and retail operations, has said that its management chose to supply only reliable customers, because of the high risk of non-payment.

As sales fell, the company's overall costs were also reduced to RON 115.1m (€25.9m), from RON 119.9m (€27m) in H1 2014. Farmaceutica succeeded in ending the first six months with a small net profit, of almost RON 65,800 (€14,800), in comparison with RON 1.25m (€0.3m) a year before.

Reduction in sales in first half of year for Antibiotice

The Romanian state-run drug manufacturer **Antibiotice Iasi** reported an 11.6% reduction in sales revenue in the first half of 2015, to RON 132.4m (€29.8m), in a difficult market environment, marked by price cuts and a higher claw-back tax.

The fall in sales came mostly from the local market, as exports were relatively stable at around RON 45.9m (€10.3m), according to a company financial report.

Antibiotice's net profit came to RON 15.3m (€3.5m) between January and June, a 16.4% year-on-year reduction, because of the higher claw-back tax. The company paid RON 18.2m (€4m) in claw-back tax, a 55% increase in comparison with the RON 11.7m (€2.6m) paid in H1 2014.

The figures were still higher than those included in the company's revenue and expenditure budget, which predicted sales revenue of RON 130.7m (€29.4m) and a net profit of RON 13.83m (€3.1m) for the first half of 2015.

Biofarm reports small increase in net profit in H1 2015

The Romanian pharmaceutical producer **Biofarm** has reported a first-half net profit of RON 15m (€3.4m), a 2% increase on an annual basis. Biofarm's sales revenue increased by 15% year on year to RON 70.2m (€15.8m) between January and June, fuelling a 20% rise in operating profit, according to a company quarterly financial report. The total operating costs stood at RON 55.5m (€12.5m), a 17% increase in comparison with H1 2014.

The report showed that the company's liabilities fell to RON 36.8m (€8.3m) at the end of June, from RON 39.7m (€8.9m) at the end of 2014, and that it succeeded in improving the collection of debts from customers during the first six months. Debt owed by customers had fallen to RON 50.6m (€11.4m) at the end of June, as opposed to RON 64m (€14.4m) in December 2014.

12% increase in Ropharma sales revenue in H1 2015

The Romanian pharmaceutical company **Ropharma** earned sales revenues of RON 227.9m (€51.3m) in the first half of 2015 (taking discounts into account), reflecting a 12% annual increase in the sales of retail and wholesale operations.

Two-thirds of Ropharma's revenue came from its retail operations, which involve 129 pharmacies, making this one of the largest pharmacy networks in Romania. Retail sales revenue rose by 9% year on year to RON 153.7m (€34.6m). The wholesale activity brought in sales revenue of RON 77.8m (€17.5m), a 24% increase in comparison with RON 62.8m (€14.1m) in the first half of last year. According to the financial report, the company is the eighth largest wholesaler on the pharmacy market.

Ropharma has said that its earnings before interest, tax, depreciation and amortisation (EBITDA) rose by 14% to RON 9.3m (€2.1m) in the first half of 2015, as opposed to RON 8.2m (€1.8m) a year before. In the wake of an increase in sales, net profit rose by 16% year on year to RON 4.7m (€1.1m).

Reckitt Benckiser sold 1.6 million packets of Strepsils in Romania in 2014

In Romania sales of Strepsils, a **Reckitt Benckiser** medicine for sore throats, were worth approximately RON 33m (€7.4m) in 2014, making this one of the best-selling OTC drugs on the local market, according to *Ziarul Financiar*. Last year, Romanian customers bought 1.6 million packets of the product.

However, Nurofen Cold and Flu, Nurofen for Children and Nurofen Forte were the OTC drugs in Reckitt Benckiser's portfolio which sold best in 2014. Overall, sales of the three painkillers were worth RON 133m (€29.9m), with 6.7 million packets sold in total, according to company data.

Romvac expects increase in revenue from sales of dietary supplements

Romvac, a Romanian manufacturer of veterinary medicines and vaccines, expects to boost its sales by 8-10% year on year in the second half of 2015 from the portfolio of dietary supplements for human use which the company plans to expand, according to *Ziarul Financiar*.

At present, the company has one dietary supplement on the market in different forms and doses.

Romvac reported sales revenue of almost RON 30m (€6.7m) in H1 2015, a 4% year-on-year increase, reflecting an increase in the number of customers and new product launches, including that of a human dietary supplement.

In Romania, Romvac operates a network of veterinary pharmacies under the Pongo All Pets brand name.

Last year, the company earned sales revenue of approximately €12m.

Slovakia

Novalgin most frequently dispensed drug in Slovak pharmacies in Q1 2015

Novalgin was the most frequently acquired Rx drug covered from the public health insurance system in the first quarter fo 2015, followed by inflammation and blood clot product Anopyrin and high pressure medicine Concor, according to data released by the National Health Information Centre.

The three most frequently purchased Rx medicines paid for by Slovak patients included Cavinton used to treat speech, memory or movement disorders, Detralex used to treat vein problems and Algifen Neo prescribed for metabolism and digestive tract problems.

The three most frequently acquired OTC products included Ibalgin used to relieve inflammation, Paralen to treat elevated temperature and Muconasal plus for nasal congestion relief.

Dovera simplifies access to cancer proton treatment in Prague

The public health insurance provider **Dovera** said it simplified access of its clients to cancer therapy offered by Prague-based **Proton Therapy Centre**, one year after signing a services agreement with the Czech facility.

The insurer said that the whole administrative process related to accessing the treatment by patients meeting certain criteria has been significantly streamlined, thanks to which they can start the therapy much faster.

Dovera is the only Slovak public health insurance provider that has a contract with the Prague Proton Therapy Centre. First Dovera client was treated in the facility at the end of 2013. Since then, the insurer approved treatment of further 13 patients in the Centre.

Vaccination grows less popular in Slovakia

According to the Public Health Authority, 36 counties (of 79) did not reach the 95% level of vaccination in 2014, which is said by the World Health Organisation to be the critical level under which vaccination loses its protective function, according to sme.sk, which was quoting the Public Health Authority.

The reasons for the low vaccination rate include anti-vaccination campaigns, contraindications and the resistance of the Roma population to vaccination.

Kosice and Bratislava are among the regions which have faced the problem.

Svet zdravia starts investment projects at recently acquired hospitals

The Slovak hospital operator **Svet zdravia** launched the first phase of investments into the recently acquired hospitals in the towns of Galanta and Dunajska Streda.

As part of this first investment phase, the hospital operator plans to spend €4.8m on the facilities' medical equipment, building modernisation and information technology, with €3m earmarked for the hospital in Galanta and €1.8m – for the Dunajska Streda facility.

A significant part of the planned investment projects should be launched already in 2015, Svet zdravia noted.

Svet zdravia plans to invest €20.4m into the hospitals over the next five years. In addition to their modernisation, the new owner also needs to solve the problems of their debts, amounting to €1.9m for the Galanta hospital and €7.3m for the Dunajska Streda facility.

Top 5 Rx reimbursed medicines dispensed by Slovak pharmacies, Q1 2015

Medicines	Pharmaceutical form	Manufacturer	Number of packages issued
Novalgin	20x500 mg film-coated tablets	Sanofi	358,621.20
Anopyrin	56x100 mg tablets	Zentiva (Sanofi)	209,007.63
Concor	30x5 mg film-coated tablets	Merck Serono	172,768.50
Agen 5	30x5 mg tablets	Zentiva (Sanofi)	171,820.00
Milurit	30x300 mg tablets	Egis	170,420.00

Source: National Health Information Centre, 2015

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Top 5 Rx non-reimbursed medicines dispensed by Slovak pharmacies, Q1 2015

Medicines	Pharmaceutical form	Manufacturer	Number of packages issued
Cavinton	50x5 mg tablets	Gedeon Richter	69,091.20
Detralex	120 film-coated tablets	Les Laboratoires Servier	66,312.11
Algifen neo	Granulate for oral solution 1x25 ml	Teva Pharmaceuticals	58,118.00
Mydocalm	30x150 mg film-coated tablets	Gedeon Richter	58,027.34
Trifed Expectorant	Syrup 100 ml	Hikma Farmaceutica	39,785.00

Source: National Health Information Centre, 2015

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Top 5 OTC medicines dispensed by Slovak pharmacies, Q1 2015

Medicines	Pharmaceutical form	Manufacturer	Number of packages issued
Ibalgin 400	24x400 mg tablets	Zentiva (Sanofi)	371,914.68
Paralen 500	24x500 mg tablets	Zentiva (Sanofi)	353,849.40
Muconasal plus	1x10 ml nasal spray	Boehringer Ingelheim	187,946.00
Acylpyrin	10x500 mg tablets	Herbacos Recordati	182,592.83
Paralen 500	12x500 mg tablets	Zentiva (Sanofi)	146,091.43

Source: National Health Information Centre, 2015

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Does Big Pharma have plan B in Russia?

Despite more relative stability in Q2, Russian drug market conditions remain precarious, with developments asking questions of foreign investor plans. Elsewhere, despite cost-containment-driven drug sector reform, key CEE pharma markets continued to attract foreign investment.

FDI continues in Russia but is Big Pharma preparing for the worst?

That the Russian pharmaceutical market continued to see mid- and high-level foreign direct investment (FDI) in Q2 should come as little surprise. Global drugmakers are too entrenched and there is too much potential for an abrupt change in strategy. Furthermore, it is not beyond the realms of possibility that political and thus trade conditions could improve. Withdrawing from Russia or significantly scaling back in the country risks giving up a strong position should the climate become less fractious.

During Q2, Danish diabetes giant Novo Nordisk opened a new insulin formulation and filling plant in Russia and announced plans to continue its expansion in the country, while Sanofi unveiled plans to begin exporting insulin from its Russia plant and Novartis reported the opening of its new €121m Russian factory in St. Petersburg. In addition, NovaMedica signed an agreement to market Ferring's innovative GI products in Russia and Krka commenced preparations for the next stage of its Krka-Rus 2 project.

However, all market scenarios must be planned for and Sanofi' news in the second quarter was of particular interest. The company indicated that it is to export insulin products from its Russian plant to European markets. Global drugmakers have long looked to CEE drug markets as a cost-efficiency exercise, with production bases in these countries costing less to operate than those in Western Europe and other developed market regions. However, to date Russia has not fulfilled this role on the same scale as the likes of Poland, the Czech Republic, etc. So why the change now? Perhaps it's a way of reducing the risk of its exposure to Russia – with the local market under severe pressure, revenues under attack as spending power plummets and few signs of an end to the political friction, doesn't it make sense to ensure production facilities meet more than just local demand? Russia has been mentioned as potential platform for expansion in CIS drug markets, so why not as a production base for markets in Central and Eastern Europe or Western Europe?

The major caveat here is the Russian government and its reaction if the strategy becomes harmful to the aims of the Pharma2020 plan, in particular those relating to the local production of essential drugs for the local market (it is not difficult to imagine foreign drug manufacturers wanting to restrict their supply to the local market if the value of sales is significantly reduced). Regulatory developments in recent years do little to suggest that the Russian authorities would take kindly to such a move. Events in Q2 were no different: during the second quarter, it was reported that the government had taken the decision to give priority to locally produced pharmaceuticals during public tenders. In addition, it was reported that Russian drugmakers are planning to produce copies of expensive imported drugs. While many proposals are never anything other than that, the thinking and intent behind them are clear.

Market share (%) of leading players on Russian pharmacy drug market, 2013-2014

Company	2013	2014
Bayer Healthcare	5.6	5.7
Sanofi	5.6	5.7
Octopharm	5.8	5.3
Sandoz Group	4.9	4.7
Novartis	4.4	4.0
Stada	3.7	3.5
Menarini	3.5	3.4
Johnson & Johnson	3.0	3.2
Teva	3.0	2.9
Nycomed/Takeda	2.4	2.5
Top 10	42.0	40.9

Source: AIPM, 2015

Leading domestic pharmaceutical manufacturers in Russia, by production value ($ m), March 2015

Company	Value
OTCPharm	24.64
Pharmstandart	15.31
Valenta	12.33
Stada	11.98
Sotex	9.83
Krka	9.31
Nearmedic Plus	7.86
Ozon	7.86
Veropharm	7.75
Materia Medica	7.44

Source: AIPM, 2015

Can the local production sector flourish amid deteriorating market conditions?

A discussion of local production in Russia must also include Russian drugmakers and Q2 presented further evidence of this sector's ongoing expansion. Russian pharma investment and R&D group ChemRar and local distributor Lancet announced a partnership for the development and production of novel drugs in Russia, while leading Russian drugmaker R-Pharm announced an agreement with Kyorin Pharmaceutical for the production of the Japanese drug company's products in the country. In addition, cardiovascular and nervous disease treatment specialist Severnaya Zvezda unveiled plans to a build a pharmaceutical plant in Leningrad and state-backed Rostec signalled its intent to become Russia's leading drugmaker.

The growth is all part of the government's Pharma2020 plan, whose principal aim is to dramatically reduce the country's reliance on imported drugs. There have been lots of headline-grabbing developments, but what is the future for the new Russian pharma elite? Given the current condition of the market – drug prices continue to rise, spending power is being affected by the de-

cline of the rouble and the manufacturers of cheaper drugs are only being saved from collapse by government handouts – the short term at least seems challenging. It is notable that Pharmstandart announced a 28% drop in sales for 2014 in Q2. Furthermore, the plan may be for the indigenous sector to meet a significant proportion of essential drug demand, but at the moment, this project is very much a work in process and the role of foreign drugmakers remains vital.

Will downturn in market value influence Big Pharma strategy?

So, what of the prospects of the Russian drug market? Even against the background of economic sanctions, collapsing market sectors and increasingly alienating reform, market forecasts have remained solid. However, there are signs that the picture is changing. According to IMS Health, in volume terms, the Russian drug market declined by 9% between January and April 2015, while in Euro terms, the market shrank by 21% over the same period. Rising prices of imported drugs, on which the market remains reliant, is a key contributory factor and with no end in sight for this trend, continued decline seems likely. The DSM Group has predicted an 18% decrease in US dollar terms for the year, with volume consumption down 2%. For all the focus on the country's often divisive regulatory reform in recent years, perhaps it will be a significant downturn in the market's value that has more influence on foreign investor strategy.

Ukraine pharma looks to the future but current conditions remain bleak

Events in Q2 gave more credence to the view that pharmaceutical sector development in Ukraine is continuing along two very distinct paths. For all the efforts to develop pharmaceutical sector infrastructure in the country, market conditions remains bleak. During the second quarter, the government announced that it expects to launch a new health insurance system and a new drug reimbursement system in 2016, as well as a new healthcare information management system. In addition, the Ukrainian health ministry indicated that it could spend up to $1bn a year on primary care.

However, for all these positives, the performance of key drugmakers suggested that operating conditions in Ukraine remain very challenging. Regional generics major Krka followed up an 18% contraction in sales in Ukraine for 2014 with a 79% drop in Q1 2015. The company has forecast a 10% decrease for the whole of 2015. Another key regional generics company, Gedeon Richter, posted a significant decline (54.9% in Euro terms) in sales for the first quarter of the year, while European generics powerhouse Stada also reported a sharp fall in sales in Euro terms in Ukraine for the period. Underlining the severity of conditions in the Ukrainian healthcare was news in Q2 that a significant portion of Ukrainians are travelling abroad for certain healthcare treatment and that the health ministry has allocated UAH 204m for such treatment in 2015.

How long can CEE pharma maintain cost-cutting vs growth balancing act?

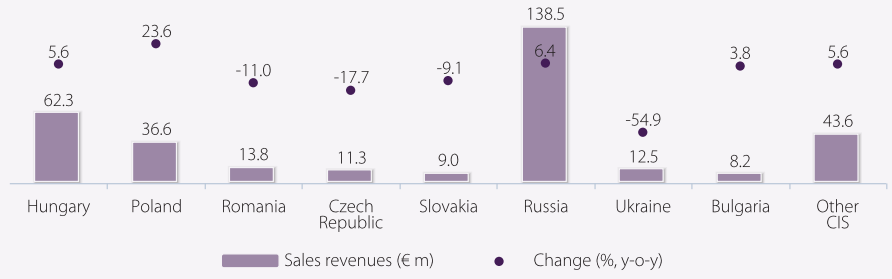
Significant pharmaceutical sector infrastructure reform is also under way in Romania, Bulgaria and Hungary. Events in Q2 underlined the dual nature of development: despite the cost-containment-driven nature of reform and the resultant pressure on drug prices and profits, these markets remain attractive to foreign drug companies, as demonstrated by ongoing investment.

In Bulgaria, it was reported in Q2 that the health ministry will adopt a new four-pronged strategy towards cutting public spending. Underscoring its efforts will be the greater embracing of generics, and this pro-generics policy includes moves to stop the withdrawal of generics from the market and the introduction of e-tenders for drugs, with the lowest price the main criterion for the selection of the product. The further reduction of reimbursed drug prices is also likely – it was revealed in Q2 by the National Council on the Prices and Reimbursement of Medicinal Products that the prices of over 1,000 reimbursed drugs were reduced in 2014.

Underlining the pressure on public finances is news from the quarter that the Bulgarian government has set up the Central Body for Public Procurement Awards in Healthcare, which will be responsible for the central public procurement of reimbursed drugs for hospitals, and that Bulgaria and Romania are to open joint tenders for expensive drugs.

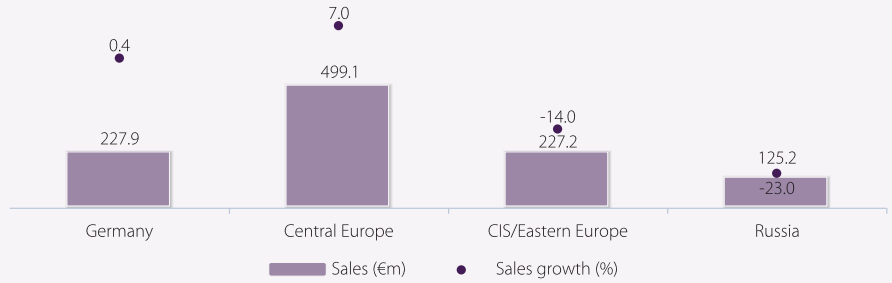
In Romania, a new drug-pricing system was proposed in Q2. Under the new system, innovative drugs with generic equivalents will not be able to be priced higher than the reference generic price, with the prices of all drugs reviewed on an annual basis. Furthermore, the Health Ministry also proposed the introduction of two price lists for

Gedeon Richter pharmaceutical sales by Key Central and Eastern European Markets, H1 2015



Source: Gedeon Richter, 2015

Stada Arzneimittel sales by selected regional markets, H1 2015



Note: data for CIS/Eastern Europe include sales for Russia.

Source: Stada Arzneimittel, 2015

reimbursed drugs to ensure the lowest price levels, while the prices of more than 1,000 prescription drugs were expected to fall from June. In Hungary, managing the public bill for drug reimbursement spending remains a priority, with reports in Q2 that this expenditure is expected to rise in 2016.

Despite the strong cost-containment focus, foreign investment continues in these markets. American multinational Amgen announced plans to target a top 20 position in Romania in Q2, while Mylan claimed a spot in this leading group following its acquisition of the non-US developed market and branded generics business of Abbott Laboratories. With regard to overall market performance in Romania, growth of nearly 11% (in terms of value) was reported for Q1. In Bulgaria, the market share of the top three pharma companies rose in Q1 2015, while the overall market posted growth of 11% for the quarter according to IMS Health. In Hungary, new figures showed that the local drug market has posted CAGR of 10% over the last decade, with its value at HUF 599bn in 2014.

Does Poland pharma have the most to gain from cost-containment deceleration?

As in the rest of the CEE region, drug sector development in Poland is also following the two separate paths: cost-containment-focused reform on one hand and foreign investment on the other. Again, one of the key discussions is the same: is this development path sustainble? However, for Poland, which is widely considered the most attractive regional market for foreign investors outside of Russia, the question of its future takes on greater urgency.

Drug reimbursement continues to rise – up by 9% to PLN 3.55bn (€850m) between January and April according to the National Health Fund – so there is little reason to expect any significant change to sector policy. Notably, in Q2, there was discussion of the proposed rise on VAT on medical supplies to 23% and how it will generate costs of up to PLN 600m for hospitals. Yet, during the quarter, Servier launched a new PLN 4m bottling line, Novartis generics business Sandoz opened a PLN 171m packaging plant and Bayer expanded its service centre in Gdansk. Furthermore, with regard to the latter development, it was reported that pharma companies are increasingly favouring Poland over other regional markets for the location of SSCs. The Polish pharmacy market is expected to post growth of 5% to PLN 30bn in 2015.

Poland is in a very interesting position. If the deterioriation of the Russian market continues, it could benefit from a displacement of regional resources. However, it must remain attractive to foreign investors, and while it is seemingly achieving this goal, it must continue to get the balancing act between cost-containment and foreign investor viability right.

Q2 once again illustrated the precarious condition of the Russian drug market and its influence on regional market development. Foreign investment continues, yet a change in attitude has become perceptible of late, with talk of exporting to European markets suggesting that Big Pharma is thinking about plan Bs. Will other key regional markets be part of any plan Bs? Much may depend on how attitudes to cost-containment develop.

John Morgan
Pharmaceutical Market Analyst

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e-mail: aaguiar@opalgroup.net
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Analytical Method Development, Validation and Transfer – Informa Life Sciences

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PMR Pharma & Healthcare Insight: Central Europe – Biweekly Review and Analysis – A prime source of market intelligence for pharma professionals
Published by PMR, www.ceepharma.com

Editorial staff: Justyna Kukian – Managing Editor; Agnieszka Skonieczna, Monika Stefańczyk – Editors; Anna Sorówka-Łach – Sub-editor
DTP: Michał Grzywacz, Przemysław Brożek
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