Interview with Pawel Sztwiertnia, General Director, INFARMA

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Until very recently originator drugs had a very weak presence in central and east European countries including Poland, and there was no real patent legislation. Nevertheless, Poland has changed and become an attractive market for innovators. Could you give us an idea of how the market for innovative drugs has evolved in recent years?

Market growth for innovative drugs is quite sustainable in Poland, where the compound annual growth rate (CAGR% 2007 – 2010) is around 8.5%, which is much higher than other markets, especially those in the EU-15. This trend does not result from consumption growth, but rather from consumption habits. Patients purchase newer products, which in turn increases the average price of these products. These habits are the driving force of market growth because consumption, in terms of standard units, is rather stable. At a bit over five billion Euros, (depending on the exchange rate), Poland is the sixth biggest drug market in Europe according to the EphMRA A-V classification.

What makes our market special, compared to markets of comparable size such as Spain, is first, the generic penetration, which is extremely high in Poland. By volume it is 85%, by value it is two thirds. Second, the average price of innovative originator products is one of the lowest in Europe. On the other hand, there are expensive generic products in Poland, when compared to the average originator product prices in Europe, due to a market structure overpowered by generics. IMS Health data demonstrates that the average generic price is roughly 70% of that of an originator. Another

trend that makes Poland unique is its branded generic market. This in turn implies certain effects, one of which is access to innovation. There is a defined pool of funding for reimbursement, but most of it will be spent on generics, not necessarily due to the volume, but also value, as generics are expensive in comparison with innovative products in Poland. The only channels for innovation are special therapeutic programs that target specific diseases such as biological NRA or multiple sclerosis, programs and products that are not financed through the reimbursement channel of the pharmacy. It is a different sort of reimbursement where the National Health Fund (NHF) directly signs contracts with companies to provide the product. Thus this is very different from open pharmacy markets where pharmacy funds are set according to the prescription. Despite the growth of the market and progress in certain areas such as oncology or cardiology, innovation is still limited and special therapeutic programs are in fact the only area for innovation in Poland.

What are the limitations on innovation and what are the factors that contribute to improvements to innovative drugs?

The major reason for limited access to innovation is the level of public funding per capita. Poland's level of public funding for innovation is one of the lowest in Europe. According to data from the Organization for Economic Co-operation and Development (OECD), annual per capita spending by the government for drug reimbursement is less than $100 (the figure varies between $60 and $90), which represents between two or three times less than in Slovakia or in the Czech Republic, and five or six times less than in France or Germany. With this level of spending, even though our average prices for innovative products are among the lowest in Europe, access to innovation is limited because of the high co-pays due to Poland's reference pricing system. The system in Poland reduces the already very limited window for innovative products. When a company manages to establish its product on the reimbursement list, it can then be prescribed by any doctor and be made available in every pharmacy. Thus, from the government's perspective, there is always the fear that reimbursement costs will skyrocket if a new product is added to the list. Reimbursement costs are very difficult to control; monitoring of prescriptions is practically non-existent in Poland. There are no specialized categories of drugs that specialists could prescribe under certain conditions. For instance, because many patients need treatment for diabetes or cardiovascular diseases (CV), the government is afraid that costs would grow out of control.

Furthermore, the generic segment in Poland is very strong. Before EU accession, foreign innovative companies were hesitant to enter the Polish market; patent legislation in Poland was indeed not very clear. Marketing a product is no longer an issue for innovative companies in Poland as data protection is now being implemented. During the communist era local manufacturers were the only

providers of pharmaceutical products. There was some import but not on the present scale. Markets to the East collapsed in a way in terms of export opportunities for Polish companies. As they used to be the major direction for exports for local generic companies, these firms suddenly had to look elsewhere for business opportunities. The EU was not considered a possibility, so the local industry turned to and focused on its own domestic market. The challenge for them was to preserve market share and maintain the status quo. Generic companies such as Teva and Sandoz entered the market.

Innovative companies have invested hundreds of millions of dollars in Poland through the privatization process of state owned companies. GlaskoSmithKline (GSK), Sanofi-Aventis, and Novartis among others have their own factories in Poland and employ thousands of people. In that respect the division between Polish and foreign companies is quite blurred. Innovators produce here for the local market and look to exporting. For instance, one of GSK's most strategic plants is based in Poland. Despite the challenges for the innovative industry in Poland I have mentioned, this is a market of almost 40 million people and the prospects are rather good. Polish consumption is seventh overall in the EU and is driven by a rather high consumption of over-the-counter (OTC) products. Indeed, Poles like to self medicate given that the access to physicians is difficult.

Officials often say we are witnessing over consumption. However, independent sources do not confirm such an opinion. If we consider prescription products, actually we are in the middle of the scale. Consumption of OTC products changes the whole picture. Consumption in Finland and Greece is among the highest in Europe.

Compared to Europe's more mature markets, what are the main specificities defining the pharma market for originators in Poland, and which therapeutic areas are driving the growth?

Oncology has had a very strong growth. Fighting cancer has been a priority for the government for several years. There are national programs to develop oncology treatments, such as screening. The rate of early detection is quite low in Poland today. The survival rate is also lower than in other countries. Overall, access to medicines has meant tremendous progress for specific therapeutic areas. The double-digit growth of this sector in terms of spending is over 20% year on year. It is an increase that concerns only very specific medical problems such as Rheumatoid Arthritis (RA), oncology, and hematology. As for cardiology, respiratory, asthma, GI, or diabetes, there has not been a major breakthrough in terms of access to innovation. These areas have had more or less stable growth. The Health Minister updates reimbursement lists basically by adding new generics or setting price limits to reduce payer expenditures, which of course has an effect on patients because the co-pays are higher with the same level of funding.

Thus far only two original Polish medicines, Vitrazolin and Davercin, have penetrated the market as approved drugs. How do you assess the situation of Research and Development (R&D) and innovation in Poland?

Generic companies innovate in a way by investing in R&D in order to develop new chemicals and new entities. This requires a lot of funding. They are also innovative in terms of production by developing new production lines and processes.

We also wanted to address regulatory issues in Poland with you. In April 2009, the association addressed its concerns to the health minister, Ewa Kopacz, in a written letter about the pending applications of your members for drug approvals. Delays from the URPL, the medicines registration office, could force companies to halt production of certain medicines. How has this situation evolved? What are the main changes to the Polish regulatory system suggested by INFARMA?

There has been a tremendous effort made in terms of market authorization. When Poland entered the EU, documentation for registration of Polish products was not in line with EU directives. Therefore, they had to be harmonized and updated to meet EU requirements and a derogation period was part of the Accession Treaty. As the process was costly and required a lot of work, most of the local companies waited until the last moment. The registration office was thus jammed with work, and that affected the current ongoing registration. There have been delays, but as far as I know, this is currently improving. On the other hand, innovative companies had the files for European standards, given that they operate globally. There was a mutual recognition procedure stating that companies may actually register their products in another EU country. Also, multinationals could obtain a central authorization registration through the European Medicines Evaluation Agency (EMEA) in London. So innovators have several options; the problem concerns only local Polish companies desiring to operate abroad.

Despite the slow processes as well as the lack of funding you mentioned, and with regard to the improvements in terms of regulatory procedures and adaptation to EU standards, are you optimistic for innovators in Poland and for the pharmaceutical industry as a whole?

There is a lack of rewards for innovation in Poland. INFARMA’s work is based on presenting data and information such as, for instance, highlighting that the average price for innovative products in Poland is among the lowest in Europe. Two things are often mixed up between the official price and the patient co-pay. The media claim that drugs are expensive, but they are expensive when a patient goes to a pharmacy with a prescription and has to pay a lot out of pocket.

The government is proposing major healthcare reform. The reimbursement bill that is currently in the Parliament and soon to be passed will reshape the entire market. It is the most important bill for the whole pharmaceutical industry in Poland. Unfortunately, no dialogue preceded the project's preparation, even though it will have a significant effect on every party, including patients.

The whole bill is very much anti-industry and is going to affect our companies. Our position regarding this bill was very above all very constructive. In principle we understand all the ideas in this bill, but we do have question marks on the implementation level.

The government has four objectives related to the bill: to implement transparency directive information, to contain the costs of reimbursement, to lower the level of patient co-pays (among the highest in Europe), and to eliminate promotion of products by pharmacists. Experts and opinion leaders have strongly expressed their concerns, saying that the effects will be quite the contrary to those claimed by the Ministry of Health. It is evident that the real goal of the bill is to cut spending further on drug reimbursement.

As an industry, we are not opposing the bill. On the contrary, several times we have asked for full implementation of the transparency directive. The biggest problem in the bill that INFARMA has noticed is the patient perspective. The government claims patients will pay less with the new reform, that prices and margins should be unified and fixed. This way patients would not have to compare prices. INFARMA's position is not against fixed prices and fixed margins. This solution should be implemented similarly to other markets where it has proven to be efficient. However, in those countries the co-pays are very low, or the patient pays fixed flat rate fees, or the price of the product is not a concern to a patient at all. Prices are then negotiated between the government and the industry. However, the situation is completely different in Poland. The co-pays are high because the reference prices are set at a very low level. When a patient goes to a pharmacy, he or she is faced with high co-pays. Having fixed margins and prices in this market will cause patients to pay more. According to various studies from IMS Health, PharmaExpert, and different research organizations, the effect of this bill could be negative for patients. Unfortunately, these results of this bill were not taken into consideration by its authors. The MOH plans to negotiate prices at such a level to make sure patients will not pay more. But then the question really is, how far can we further lower the prices, which are already the lowest in Europe?

You mean, for the industry to remain sustainable?

Yes. INFARMA's members operate globally. That is why some innovative companies, after doing a business analysis, might opt for the non-reimbursement segment, while still remaining on the

market. The bill imposes tough measures on the industry. The budget cap is set at the very low level of 17% of the total budget, which is much lower than the current spending on reimbursement. According to the PwC forecast, it would mean that the budget may be frozen for about ten years. Poland has one of the lowest budget expenditures per capita and the Minister of Health is planning to lower the prices further.

Locally there are still problems in understanding innovation at the government level. The prices of innovative products are so low in total that the phenomenon of parallel export is growing rapidly. Poland imports mostly OTC and contraceptives, whereas the country exports mainly prescription products that are reimbursed. The price differences are so high for certain products when compared to the EU that patient access to these products is limited. They are exported to countries where the prices are higher, e.g. Germany. According to IMS Health, the reimbursement bill will have the effect of tripling the size of parallel export.

What have been your initiatives to actually encourage innovation in Poland and what is in the pipeline for INFARMA today?

INFARMA has been conducting a few projects which are aimed at building awareness and expertise within particular fields. First of all, INFARMA jointly with GCPpl commissioned a report entitled “Clinical Trials in Poland – key challenges” which describes the condition of the clinical trial market in Poland and possible scenarios for its growth. It stresses an impact of clinical trials on different entities such as, patients, physicians, the public payer, and the budget. We already received a feedback that the report is very appealing especially for those who are precisely involved in clinical trials field.

Secondly, INFARMA along with PwC is currently working on the report aimed at demonstrating impact of the innovative pharma industry on the Polish economy in segments such as investments, suppliers, and therapeutic programs. The report will be launched during Economic Forum in Krynica 2011. Speaking of Krynica, as last year, we will be present this year as well. We call it the Polish Davos. The event has been held every year for twenty years and is attended by the Prime Minister and the President. It is an annual business meeting that always takes place in September. It is three days of intense networking, a unique opportunity in that respect, gathering leaders and decision makers both from the political and business world.

This year we are going to organise three panels devoted to healthcare on the mentioned economic impact of the industry on economy, private health care insurance to be jointly arranged with Polish Chamber of Insurance and lastly, value of innovation for health care system.
The next year appears to be a very intensive and challenging both for the pharmaceutical industry

and Ministry of Health in particular as the reimbursement bill will be adopted. The bill impacts practically every part of distribution channel. We fully declare our readiness and willingness to cooperate with the ministry in order to carry out the entire reimbursement process smoothly.

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