Interview with Cezary Sledziewski, President, PZPPF

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owth, including generics and originator drugs, is today steady and sustainable, approximating 10% year on year. The market size is over five billion Euros which makes Poland the sixth biggest market in Europe. What are main the competitive advantages do you see in the Polish market compared to other European countries?

In my opinion, the Polish market is in fact quite similar to the European markets. There are obvious differences, as far as the healthcare mechanisms are concerned. However two elements are specific to the Polish market: the fact that it is a market driven by prescriptions, and the discount practices of the industry.

Could you give our readers an overview of how the market for generics has evolved in the recent years?

The Polish market for generics drugs had undergone a few significant changes. Twenty years ago, the whole system was completely amended. Whereas everything belonged to the state before 1990, all distributors, pharmacists, and manufacturers but the system changed through a quick process of privatisation. First the pharmacists became private, then the distributors, and lastly state-owned manufacturing companies were sold to private players. The first one was sold to GlaskoSmithKline (GSK). This first big change in the market lasted for almost a decade. There are still today two big factories owned by the state, Polfa Warszawa and Polfa Tarchomin. However, they are also currently in the process of privatization.

In Poland, regulated parties focus only on reimbursement. There is indeed no market regulation on over-the-counter (OTC) products, which means that prices are established freely on OTC. The reimbursement system at the moment is very unclear. Everything seems to be upside down. The government fixes maximum margins but they are not respected because the law is constructed in such a way that companies are able to overcome them. As a result pharmacies are getting some additional money from the manufactures and distributors.

The manufacturers fix the price of the drug with the Ministry of Health (MOH) and then the MOH shapes the price by adding official maximum percentages for the pharmacies. There are then two different prices for the same drug: the price fixed with MOH, and the effective pharmacistâ??s price. Ultimately the manufacturing price has disappeared from the system in the process. Companies explore this system, and there are big discounts under the table.

In Poland the average price of pharmaceutical products is very low, whereby the generic price is 70% of the originator price. Not only in terms of pricing, but also in terms of volume and regulation, what are the main specificities defining the pharma market for generics in Poland compared to Europeâ??s more mature markets?

Poland has in place a patent system for molecules since 1992. Before 1992, there were patents in Poland, but only for processes. The introduction of this system had at the time an impact on the market. However major pharmaceutical companies did not make patents for molecules in Poland. Data exclusivity was introduced when the country joined the European Union (EU). It was a six years exclusivity, which in the coming months is to be extended to a ten years data exclusivity. It had a great impact on the generic market. It gave the possibility for generics to grow.

In Poland the generic penetration is extremely high: 85% in terms of volume, 2/3 in value terms. Poland is very different to the biggest European markets in that respect with high volume of generics manufactured each year a the lowest prices market in the EU, after Romania and Hungary perhaps, but definitely the lowest when we talk about bigger markets.

Figures for generic penetration may vary whether you consider the pharmacy market or the hospital market. For instance, the chemical treatment of cancer is a special branch of the hospital market and implies high expenditures. On top of that, special therapeutic programs are signed directly between companies and the National Health Funds (NHF). The product does not go through the pharmacy chain.

But it is true to say that the overall consumption of generics is high in Poland. It is the result of the patent system and data exclusivity which allow Polish companies and importers to introduce generics quite earlier than in the Western Europe. There are in Poland some molecules that are already generics, whereas in Western Europe, generics for the very same molecule are not yet in the market.

However, contrary to Europeâ??s most mature markets where generics are taking more and more importance, in Poland it seems that innovators are gaining market shares. How long do you expect this trend to last?

It depends on the regulation of the market and its evolution. The final structure of the pharmaceutical industry will depend very much on the new law, therefore it is very difficult to predict the evolution of the market before new reimbursement law is passed.

In my opinion, chemotherapy will grow at a high pace, as well as the therapeutic programmes in general. The pharmacy market will be more or less the same. In a very short period of time, generics are to gain market shares for a molecule, where the original price has not changed. Generally in Europe, if the original product keeps a high price, it disappears very quickly form the market, practically within weeks. Therefore the situation in Poland will be more pro-generics. Two possibilities will remain for originators who had had so far a monopoly: either to lower their price in order to adapt to new market prices or to withdraw from the market.

How do you evaluate Polandâ??s potential for exports and to become a regional manufacturing hub?

The Polish industry was under high pressure to adjust to EU standards when joining the union. Within the last decade, Poland has heavily invested in the production. An investment of 2,5 billion Euros allowed new modern production lines to be built. Poland has therefore today up to date industrial capacities. However following the European trend, many Polish companies closed their chemical production. All manufacturers in Poland used to produce chemicals before the system

changed, most of them being state manufacturers. With the opening of the market, the competition became tougher, so many manufacturers were forced to halt their production of chemicals and closed down several facilities. Most chemicals manufacturers in Poland could not withstand the new competition from India.

After accession to the EU, until 2008, Poland had to adapt to European standards in terms of registration files. All the files in Poland are now consistent with European standards, which is not the case for all European countries. This adaptation has cost industry 500 millions Euros.

Now that Poland has adapted files and production capacities, there are possibilities to export. As a matter of fact, export of pharmaceuticals is growing. Traditionally export is directed to the East with Russia as main market. However after accession export to EU market is growing quickly. Total value of export is more than 1 billion Euro.

The growing interest for export of generics is a European trend as well. Generics all over Europe used to be focused on local markets rather than on exports. It is changing in Western Europe with an increasing consolidation of the market: the big pharma industry is buying more and more the generic industry, which leads to more export activities.

You were mentioning the rising competition from India or China in terms of manufacturing capabilities with quasi unlimited supply at low prices; to what extent is Poland capable to resist to this competition?

In fact it depends on our government policy and on new reimbursement law which is und legislation procedure in our Parliament. Unfortunately it is expected that pay-back system will be imposed on generic medicines which will make competition more.

In the past few years, the line between generic companies and R&D based companies seems to be less and less relevant, where R&D based multinationals are purchasing generic manufacturers, and at the same time former generic manufacturers climb up the value chain and patent products. How does this impact the balance and existing relations between Innovators and generic companies in Poland? How is this trend affecting your agenda at PZPPF?

In Poland, the expenditures per capita for pharmaceutical products are one of the lowest; Poland appears at the bottom of European rankings. Innovative companies cannot expect that suddenly there will be business opportunities in Poland simply because the funding per Capita is so low. Neither the NHF nor patients have enough money for the industry to grow. In my opinion, Poland needs to spend very carefully on innovative drugs, i.e. only if it is necessary.

Even though some disagreements exist e.g. on patent legislations or on civil procedures, there is no war between generics and innovators. The clash is artificial. In fact, there are no practical difference between generics and innovators.

We interviewed yesterday your counterpart at INFARMA Mr. PaweÅ? Sztwiertnia; he told us that there was no real dialogue between the association and the ministry of health, and that the relationship between the public and the private sector were tough in general in the pharmaceutical sector. He also told us the generics are politically stronger. Does PZPPF find the same difficulties in working together with the authorities to promote the pharma sector? How would you describe your relationship with the government?

I must say we had a very good dialogue with the previous liberal government with which everyone was happy. The situation has changed and the dialogue with authorities did become more difficult.

Polish minister of health cares about patients but do not consider the value of the local industry. Nevertheless, it is exaggerated to say that there is strictly no dialogue with the current MOH.

What were PZPPFâ??s main initiatives in 2009 and 2010 to protect the rights and represent the interests of employers before the authorities?

PZPPF prepared a draft on the reimbursement law which was introduced to the government. Within this draft, PZPPF aimed to get rid of unofficial discounts. It took us a long time to come up with this potential solution for the pharma industry in Poland.

How would you define PZPPFâ??s role in contributing to the growth of the pharma sector in Poland?

The association is active in many fields, such as Intellectual Property (IP) issues, on which we are often in disagreements with innovators. However, generics and innovators share the same approaches and have common objectives in most of other topics including regulatory issues, registrations and market authorizations of the drugs. We are also involved in regulatory and reimbursement issues connected with legislation and implementation of EU law.

We are a member of the European Generic Medicines Association (EGA) and I am having a chair in the National Association Committee.

What are the main areas of focus for PZPPF for the next five years and what are your expectations for the pharmaceutical industry as a whole?

Everything will depend on new reimbursement coming law which enter into force in 2012, but final shape is unknown yet. As generics are operating on small profits with limited margins, any slight change on regulation, any market trend, has significant consequences on the generic industry

I would like to address a final message on behalf of the European industry, as a member of the EGA. There should be a sustainable condition for the European industry in Europe. In a way, the pharmaceutical industry can be compared to the weapons industry. I could not imagine that the Europeans would transfer the production of arms to China. Why should we transfer the production of pharmaceuticals to the East? I believe it is very dangerous. Some branches of production including pharmaceuticals should remain in Europe â?? itâ??s a question of safety people leaving in Europe. EU needs common economical policy on pharmaceutical industry.

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