Interview: Zdzislaw Sabillo, Founder & CEO, PBA Consultancy



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The founder of PBA Consultancy offers a critical analysis of the new Reimbursement Act, looking at what could still be done to improve the system.

Could you give us the positive and negative aspects of the new legislative framework implemented in January 2012?

The positive aspects of the Reimbursement Act are twofold only. Firstly, this law has implemented regulations in Poland already present in other European countries, and has raised Polish standards. Secondly it implemented more transparent criteria for establishing drug prices in Poland.

However, this new law has not changed the reimbursement system. Our reimbursement system, introduced in the early 1990s is incomparable to any other in Europe. With our level state spending on the reimbursement system, the bulk of spending is actually on the shoulder of patients. With this new 2012 legislation, the situation for patients has deteriorated, as well as that of the industry, doctors, hospitals, pharmacies, distributors, and wholesalers.

The only stakeholder that benefits from this new law is the state.

Fixed price regime (which replaced former flexible pricing system), constant lowering of the reimbursement level (through setting the payment limits on the prices of cheaper and cheaper generics) aggravated patient situation: in fact – now patients are paying more than before!

The state budget will earn approximately PLN 5 billion (USD 1.25 billion) by 2015. At the same time, copayment has risen, from 36 percent in the past to 40 percent today; but this is only for

reimbursed products. However, if we calculate the total copayment for the whole pharmaceutical sector, this copayment level rises to 60 percent; this is the reality!

Finally, because of this new law, as many as 1,300 pharmacies and 17 wholesalers went bankrupt, while at the same time thousands lost their employment.

For the system to change, pure generics should be introduced which means international nonproprietary name (INN) prescription."**With the ongoing challenges this system is facing, how do you think it could be improved?**

We need to have a system where, for instance, we could set a fixed price of PLN 10 (2.5 dollars) for a single prescription reimbursed product, which is a price affordable for everyone. It is so simple and yet no one sees the benefits. We are part of a modern society where patients should be the government's priority and with this system patients are despised.

In Poland, savings are not reallocated to bring new innovative products, nor are they used to improve hospital quality and services for patients. This is once again proof that this legislative framework is not working according to its initial purpose, which was improve Poland's healthcare system and bring affordable quality products to patients.

Moreover, Poland does not have pure generics but branded ones. For the system to change, pure generics should be introduced which means international nonproprietary name (INN) prescription. By changing this approach, they could introduce the system they have in the Netherlands or Italy, called the tender system, which would bring tremendous savings to the reimbursement system and give more opportunities for innovation in Poland.

Unfortunately INN will most probably not reach Poland as this would threaten the local industry, which is very strong today. Given that the pharmaceutical industry is highly strategic and contributes greatly to Poland's economic performance, reforming the industry to such extent would be extremely difficult.

In the end, real savings happen with a real revolution and it is not the one we are having right now.

The Polish pharma market is growing again, which entails a positive landscape for the pharma market to grow. Wouldn't you agree?

The Polish pharma market's value has still not recovered to the level it was at three years ago. Although it is growing, the industry is still suffering. And other aspects like parallel trading are weakening our country. Plus, welfare and manufacturing costs are increasing, as Poland is slowly adapting to the general EU standards present in other countries.

Many MNCs are here because they invested in Poland more than 20 years ago and have experienced great expansion by acquiring manufacturing facilities, local players and building a strong brand reputation among patients. However, the three main MNCs with manufacturing facilities in Poland, GSK, Sanofi and Novartis, are not making any substantial investments anymore.

The Polish market is so uncertain at the moment that it is difficult to predict what will happen in the future. Hence, it is normal to be cautious and wait for real opportunities to finally invest.

In this changing environment what do you see as the right strategy for companies to succeed here?

Pure innovative companies like Sanofi are moving towards generics by acquiring generic players (Zentiva) and local OTC companies (Nepentes). This three leg strategy is becoming a trend and is really helping these companies achieve results in such challenging times. On the local industry side, the real champions are Polpharma and Adamed, which have also diversified with OTC products.

The total value of the OTC market in Poland today is around PLN eight billion (USD two billion), while the total Polish pharmaceutical market value in 2013 is PLN 24.8 billion (USD six billion) according to IMS. Many companies are moving towards OTC, as this is where they can really generate their turnover. As a consultant, I see that more and more companies are interested in entering the Polish market with food supplement and OTC products.

Do you see companies entering in Poland using different strategies than in the past?

Absolutely! In the past companies entering the Polish market would first register their products, and then would open offices to start their operations. Today this model does not exist anymore. Now companies wanting to move to Poland demand consultancy companies like PBA Consultancy to help them register their products and then have wholesalers take care of the commercialization process in exchange for royalties or a fixed percentage of sales. Now, foreign investors are not interested in opening their own entities: they simply want to export their products to Poland through a third party.

Today the majority of companies wanting to sell their products in Poland are of small or medium size, and of Russian, Indian, Chinese, Vietnamese and Swiss nationality.

With our current legislative framework it is highly unlikely we will ever bridge this gap with the best European pharma markets."**Is Poland ready to bridge the gap with the five largest pharma countries in Europe?**

The Polish pharma market is still two and a half times smaller than the Spanish one, so bridging the gap with the fifth largest market in Europe will take a long time. When it comes to innovative products we are in ninth position in Europe and still six times smaller than the Spanish market for innovative products. So the Polish market is on the one hand huge in terms of volume, but on the other hand tiny in terms of value, as prices are extremely low and it is a highly penetrated generics market.

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What are the most important changes the Polish pharma market has to go through to expect positive outcomes for the future?

Polish pharma market is unstable and instability does not go together with good financial outcomes and improved investment in the country. Poland really needs to bring stability and this will only begin the day it changes the current legislative framework. Poland is a large market and it has the potential to grow, but without the right structural foundations, bright days ahead are a mirage.

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