# Interview: Zdzisław Sabiłło – President, Polish Association of the Pharmaceutical Industry Employers (PZPPF)



***"We must focus heavily on legislation and the amendments made to the reimbursement act in regard to ensuring the payback system is acceptable from an industry perspective."***

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*Zszisław Sabiłło, president of the Polish Association of the Pharmaceutical Industry Employers (PZPPF), discusses the significance of the Polish generics market in terms of volume and sales market share, and highlights the obstacles that the generics ecosystem faces in light of the new reimbursement act. Furthermore, he provides insights into the introduction of biosimilars as well as the nation's production capabilities and the steps being taken to promote future pharmaceutical investments into the Polish healthcare ecosystem.*

**As the president of the PZPPF, what is your mission?**

The association aims to safeguard the local generics industry in Poland and continue to strengthen our position in the marketplace. Our objective is to be perceived as the strongest and most influential organization in the polish healthcare marketplace.

The association's strategy was prepared and agreed upon in June this year by our general assembly, and we are now implementing this plan based on a three-pronged approach. Firstly, legislation; we must focus on the legislative framework as certain rulings pose concerns for our members. Secondly, PR; being active in the media to strengthen our voice and leverage our influence. Lastly, education; delivering correct information to all the stakeholders involved, such as the public, students, law, pharmacists and physicians.

**What is the importance of the generics market within the domestic pharmaceutical ecosystem?**

The Polish market is dominated by generics in terms of volume, encompassing 70 percent of the market share and sales making up 45 percent. More than 50 percent of the drug volume, and 30 percent of the sales value in Poland is supplied by local generic manufacturers. All in all, it is obvious to see that generics companies are providing a large quantity of affordable products that allows Poland to construct a more sustainable healthcare model.

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**The hot topic is the introduction of the Wide Amendment of the Reimbursement Act (DNUR). How does this influence the generics ecosystem?**

Due to the 2012 Reimbursement act, generics have a strong position within the Polish market. The current process is a limit price system, in which pricing is based on the cheapest generic within a large limit group. Nevertheless, the 2016 D.N.U.R., that is currently being discussed, is concerning us in relation to certain amendments.

The most critical shift will be the proposed payback scheme. At present, the system acts by the National Health Fund (NFZ) setting a prescription budget, and any amount over this set limit is payed 50 percent by the NFZ and the other 50 percent by the pharmaceutical industry. Under the new proposal this will shift to 100 percent of this clawback being payed-back by the pharmaceutical community; a huge jump, and a concerning move.

Despite the fact a more constricted healthcare budget at times can be beneficial for the generics industry, we are strongly opposed to such a change. The PZPFF is of the belief that generics companies should not be part of the payback scheme, as they are being punished, rather than rewarded, for delivering a treatment that significantly decreases spending for the entire reimbursement system. This generics-free clawback method occurs in other nations, and our vision is Poland can equally take this approach.

**What are the obstacles associated with having the reimbursement list updated every two months?**

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It is a challenge as companies must renegotiate prices each time the new reimbursement list is released, touching on the topic of pricing pressures placed upon generics. This is problematic for

our members as they are not able to constantly lower prices, especially considering the large-scale investments they have located within Poland. We believe generic manufacturers in Poland should be rewarded in negotiations with the relevant stakeholders via a pricing premium; therefore, allowing large Polish investors to be treated differently to a company that solely imports their drugs.

We must continue to convey this message, especially considering our members make up a good share of the nation's annual GDP, and indirectly supply some 100 thousand jobs to the Polish population. Furthermore, we are paying around 2.5 billion PLN in taxes to Poland, which is equal to the 2.5 billion PLN reimbursement share we take up; therefore, the government is not paying anything out of pocket to deliver our member's products, and this should be dually taken into consideration.

**How does the RTR plan properly reward investments into Poland?**

When we first saw this proposal, we were very positive as it is designed to promote investment – although – after looking at the fine details we have realised it is not as simple as first thought. In our opinion it does not reward true investment influx, as it does not differentiate between areas such as clinical trials to jobs, taxes and a company's physical investment positioning within Polish boarders: it is all too vague. The majority of the drugs our members are producing are consumed by the Polish people; therefore, we believe our input should be safeguarded and rewarded further as Polish patients are dependent on the service we deliver.

**Many nations are constructing legislative frameworks that differentiate between generics and biosimilars to promote this new therapeutic wave. In what way, is Poland preparing to introduce this new wave of biological generics?**

The PZPPF is very open to incorporating biosimilars into the market, and local polish companies, such as Adamed and Polpharma, are investing huge sums of money into biotechnology to develop this new wave of treatments. Nevertheless, our drive to stimulate their market introduction has been encountered with by a number of barriers.

First and foremost, we have observed that the innovative side of the pharmaceutical community is delivering a campaign to drive the Polish healthcare ecosystem away from biosimilars, stating they are not as effective as the originator. Therefore, it is PZPPF's role to launch education initiatives to teach the relevant stakeholders about the fact that this false perception is far from reality. Biosimilars are an important step in delivering world class care to Polish patients and constructing a sustainable healthcare ecosystem.

**What are the advantages of conducting Polish manufacturing operations?**

Poland has a tradition of production, engraved in the pharmaceutical markets as a strong sector of the nation. Furthermore, we have an extremely well educated and talented workforce, and compared to other western European nations, our manufacturing is generally more cost efficient to run.

Nevertheless, we must continue to be an attractive location to further the country’s manufacturing capabilities. The RTR plan is a good start if it is implemented correctly, though the government should find a balance between catalysing new investments and rewarding current investors.

**Do you believe Poland has the potential to become a production hub?**

Definitely, yes! The Morawiecki Plan is designed to push R&D, and the pharmaceutical industry is seen as a key sector to develop, especially the budding biotechnology scene. The framework for this program has been agreed upon and will be launched over the next few weeks. All in all, it is an encouraging step forward, though as aforementioned, the government must focus equally on new and current investors.

**What are the future ambitions of the PZPPF?**

We must focus heavily on legislation and the amendments made to the reimbursement act in regard to ensuring the payback system is acceptable from an industry perspective. Furthermore, we must continue to educate the key stakeholders; therefore, allowing the generics sector to leverage itself correctly. We must show that a strong generics market, both from a production and penetration aspect, is incredibly important in ensuring Poland can deliver a long-term sustainable healthcare system that delivers world-class treatments for Polish patients.

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