

Interview: Witold Włodarczyk – Director General Polmed, Poland



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Witold Włodarczyk, director general of Polmed (Polish chamber for medical devices), discusses the Polish medical device landscape and the policy surrounding the sector, especially the proposed 2016 reimbursement act. Furthermore, he highlights challenges the insured must overcome to promote the sector, the educational campaigns of the chamber, and his pleasant outlook on the future, bolstered by the government’s new open approach to discussions.

As the director general of Polmed, could you introduce the Chamber to our international audience?

Polmed is the largest chamber of commerce in Poland for medical devices, covering the entire nation and we have around 100 members that entail roughly 65 percent of total revenue in the sector within Poland. The chamber is divided into sections of medical devices such as individual treatment, hospitals and dressings, and commissions that separate our activities, such as VAT, ethics and innovation.

Equally, an important part of our operations is the legislative process, as we represent our members in assessing the medical devices laws while putting together proposals. For example, the new reimbursement law was put forward by the Ministry of Health (MOH) in 2016. Our members were against the proposed changes as the medtech industry was being classified in the same manner as the pharmaceutical side of healthcare. Therefore, we have put together a proposal and this is being discussed currently with the new undersecretary of state of the MOH, Marcin Czech.

What are the current figures of the Polish medical device sector?

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The value of products sold by the Polish medical device market is roughly three billion USD; inclusive of sales in Poland and exports. A chief characteristic of the Polish medical device sector is the abundance of domestic small to medium size companies, and overall only around 20 larger players.

Additionally, standards are defined by the EU; therefore, the production of medical devices in Poland is of extremely high quality and safety, while generally offering a more cost-efficient solution to neighbouring countries, such as Germany and Austria. This offers an abundance of opportunities for manufacturing moving forward.

What is the budget being allocated by the National Health Fund (NFZ) for medical devices?

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The healthcare expenditure for public health in Poland is around 4.6 percent of total GDP, with the aims of increasing this to six percent over the upcoming years. If we look at the NFZ's budget, it is divided into 16 divisions. One of these is for medical devices for individual use and is roughly 1 billion PLN (300 million USD), with this amount rising 5 to 10 percent annually.

When we look at hospital equipment, another medical device division, it is placed within the general healthcare budget, with areas such as labour and medicines. Therefore, it is extremely challenging to know exactly how much is being allocated to medical devices and what is being reimbursed by the NFZ or paid out of pocket by the Polish consumer.

What is the overall perception of the medical devices sector in Poland?

If you look at individual care, the NFZ allocates one euro for medical devices, compared to 13 euros for pharmaceuticals. This is drastically less than other nations, like the Czech Republic and Hungary, which have a ratio of around 1/7, so more needs to be spent in individual medical device care.

Nevertheless, there are four key factors which give great promise to us moving forward. Firstly, the market potential will grow in parallel with the increase of GDP spent on public healthcare.

Secondly, the government is doing a good job in stimulating the domestic economy and we see unemployment at an all time low. In turn, more Poles are paying more tax so there is a greater amount of funds being placed into the national budget; therefore, the overall budget for medical devices will grow.

Thirdly, the ageing population. In fact, by 2020, 18 percent of the Polish population will be above 65, and they represent a large market of the medical device community.

Finally, the overall health literacy of the medical device sector by the Polish population is drastically improving. They now understand what they can have reimbursed and are enquiring constantly with the NFZ. This will have a domino effect and in the end, result in an increase of sales.

What is the strength of the domestic medical device production industry?

We are running a campaign called "Go to brand", where we promote the Polish producer abroad in conferences and in general within Poland, compared to many years ago, the market has many MNC and local manufacturers. Overall Poland as a good site for production with around 80

percent of Polish medical devices exported to the EU, with a large percentage going towards Germany.

What more can be done to promote the domestic industry?

There has been a proposal put forward by the government to focus on promoting the products of medical device companies investing more into Poland. The issue is that European law may prevent this as it does not allow for fair competition, so this process must still be discussed with the MOH and European authorities.

What is the current policy around medical devices?

The policy is aligned with the changes introduced by new EU regulations concerning medical devices and in-vitro medical devices. All EU medical device trade regulations are observed, and Polish market does not differ from any other EU market in this respect. A discussion is being held now in Poland with respect to medical devices advertisement and promotion. The said discussion will most probably end in enacting laws against unfair practices in the field of borderline products. Our Chamber actively promotes a fair approach. In the beginning of 2018, the Chamber has formally introduced the MedTech Code that aims at clarifying all sorts of marketing and commercial activities on the part of medical devices producers and distributors.

Notwithstanding above, long-term reimbursement policy is a bit unclear at the moment. A 2016 draft bill of medical devices reimbursement is discussed ever since its introduction. It seems to us that the bill, which was originally meant to provide wider access to medical devices for patients, is unable to meet this end because of multitudes of technical and conceptual flows. On the other hand, the actual reimbursement system needs to be changed and adapted to the modern needs of patients. We are now in process of discussing potential alternative scenario which could boost efficiency and innovation in the field of medical devices supplied to patients and co-paid by NFZ.

Prices are some of the lowest in Europe within the Polish pharmaceutical sector. What is the pricing situation for medical devices?

Since last year, it is forbidden in Poland to have the price as the only determining factor when making a decision during the hospital tender process. Nevertheless, we have witnessed hospitals still targeting the cheapest products, and there is stiff competition between companies to find a balance between price and quality.

Overall in Poland, there is a big discussion that prices should be lower than in other countries. Polmed's role is to not focus too much on this area, but to ensure that the market conditions are fair for all players, despite their size or them being international or domestic.

What educational campaigns does Polmed undertake?

The main initiative is Medkompas, a compliance program set up by the World Bank and Siemens. Polmed won the tender for 2011 and 2015, and will hopefully win again later this year. This program is designed to help build the relationship between the medical device producers and distributors with hospitals. Our team goes to the hospitals and educates on the ethics, tender process, innovation and technical dialogue.

We aim to teach the relevant personnel how to purchase the correct equipment during tenders and to ensure items are not purchased solely on cost.

You have voiced concerns about the 2016 reimbursement act. What are the three points that most affect the medical device industry?

Firstly, the small medical devices businesses constructing the individual personalized products, can risk disappearing. The government is aiming to place fixed prices and margins on medical device products.

This does not take into account the nature of the different products, as individual personalised items should be looked at as more of a service due to their tailored nature, such as wheelchairs and this takes more time; therefore, the margin cannot be the same. The government has looked at a margin of two percent, compared to the current margin of around 25 percent. Furthermore, this margin is divided between the supply chain, from the shop to the wholesaler, so this means that the shop in some cases has nearly no profit and small businesses will cease to exist.

The second concern is about the co-payment, an interesting idea that needs to be implemented in the correct way. A proposal we are pleased with is for a price limit to be set on products, and if patients wish to pay more, due to an upgrade, they pay the difference. This is an interesting concept and is fair for all parties involved in the transaction.

Finally, any changes to the medical device legislation should be done in three separate bills; individual care products, that are already in a separate national fund, heavy equipment in hospitals and smaller hospital equipment, such as syringes. If these discussions are split, then new reforms have a chance of being effective.

How receptive is the MOH for your suggestions?

We are pleased to soon meet with the new Minister of Health, **Łukasz Szumowski**, and the current MOH is quite open to medical devices and creating an ecosystem that benefits both Poland and the industry.

What do you see for the future of the Polish medical device industry?

I am very positive about it! Poland is a land of great opportunities and potential for investors. The new prime minister, **Mateusz Morawiecki**, has a great business mind and desires to drive forward the business landscape and Polish economy. This is great news for the medical device sector and we are excited for the future that lies ahead!

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