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20.11.2019

Tags: [Czech Republic](#), [Pharma](#), [Association](#), [Regulatory](#), [Pricing](#), [Reimbursement](#)

Martin Mátl, executive director of the Czech Association of Pharmaceutical Companies (

ČAFF), shares the key priorities and challenges of the association and its members; assesses the Czech generics ecosystem, and gives insight into the importance of generics in providing a sustainable healthcare environment with ready availability of medicines for patients.

Last time we spoke in 2016, you were strongly focused on two areas: making sure that your member companies followed the Ethical Code of Conduct and changing the public insurance law in the context of medical pricing and reimbursement. What have been the key achievements and milestones of the association since then?

We have completed the implementation of two new elements of the Code of Conduct. The first one is certification of employees of our members who are in contact with healthcare professionals. The second one is disclosure of transfer of value between our members and healthcare professionals and healthcare organizations.

The Act of Public Health Insurance has a big influence on pricing and reimbursement, and this is a crucial factor for our members. Since 2016, there has been an attempt to tighten the entry of generics and biosimilars to the market in terms of deeper price cut.

Unfortunately, and probably unintentionally, it was bound with repeated application of price reduction on every subsequent generic or biosimilar. This could cause serious market difficulties and ultimately jeopardize the availability of pharmacotherapy to patients. We were successful in our efforts to convince all relevant stakeholders, and the law was repaired before any serious damage occurred.

Back in 2016, we were close to starting the implementation of the Falsified Medicines Directive (FMD) legislation. In 2017, we became part of the Czech Medicines Verification Organization (NOOL) and we have participated in the successful establishment of a Czech Medicines Verification System (CZMVS). Now, with the stabilization period of the above-mentioned legislation ending shortly, we are about to reach a very important milestone.

How has the focus of the association shifted over the years?

Our main priorities are still the same: to ensure sustainability and increase predictability in highly regulated market conditions. It is obvious that we are focused on topics related to pricing and reimbursement, regulatory framework, ethical standards and increasing positive awareness of generics and biosimilars. Last but not least, we deal with issues related to FMD implementation.

The Czech pharmaceutical market grew by 6.9 percent from 2017 to 2018 and now has a total value of around USD three billion. How important are generics and biosimilars within this?

IQVIA data states that generics represent 54 percent of the pharmaceutical market share in terms of volume and 23 percent in terms of value.

The whole market currently stands at CZK 70 billion (almost USD three billion) and distributes 163 million packs.

Based on these figures, we can say that generics represent a less expensive spectrum of pharmacotherapy, which is not a surprise. They are essential to make pharmacotherapy available to a wider range of patients and to control public spending on medicines.

Christoph Stoller, the recently appointed president of Medicines for Europe, has highlighted medicine shortages as one of the key issues of his presidency. What is the current situation in the Czech Republic around shortages and how do you think it can be dealt with?

Shortages are indeed an important topic throughout Europe. While the Czech Republic, as part of Europe, shares many of these issues, there are some factors behind Czech drug shortages that are specific to the local market. This is largely due to the fact that prices here are lower than elsewhere in Europe.

Due to high pressure on prices and the fact that the Czech market is relatively small, there are problems in the supply chain, forecasting the amount of medicines needed in the country, and so on. This is the main issue now and it will continue to be in the future.

You recently attended and participated in a conference on Health 2020 - National Strategy for Health Protection and Promotion and Disease Prevention. The strategy was presented by the former Minister of Health Svatopluk Němeček in 2014. Where does this stand now? Is it still relevant in the healthcare ecosystem?

Even though healthcare receives a lot of attention in the Czech Republic, especially before any election, and there are a lot of conferences about different strategies, I do not see a clear path.

A current hot topic is healthcare providers' wages. Thanks to the relatively good shape of the economy, healthcare funds have some reserves and there is pressure to take these reserves and increase wages in the healthcare system. This will be a problem in the upcoming years for a number of reasons, including that the share of personal costs in our hospitals accounts for 80 percent of total spending. People from other fields do not believe this to be true. If the growth of the economy does not continue to be as positive as it is now, the Czech healthcare system will be in trouble.

Another factor causing pressure on the budget is innovation, with the expenditure on innovative technologies and medicines growing year by year.

Given that generics and biosimilars have brought savings of billions of crowns to the Czech Republic in areas like rheumatoid arthritis and Alzheimer's (CZK 1.6 billion (USD

70 billion) and CZK 2.5 billion (USD 11 billion) respectively), is the new Ministry of Health receptive to facilitating biosimilars into the healthcare system?

Although we have already held discussions with healthcare funds in the last couple of months and they have stated that they would like to increase the spread of biosimilars, there has not yet been much progress made. Some complications related to the procurement law have been encountered and the competition in the market is also a difficulty. Changing hospital rules are challenging.

The pharma market in the Czech Republic is one of the most regulated markets in Europe - one of the latest regulatory changes being the January 2017 amendment to the Pharmaceuticals Act. What does the regulatory framework look like today?

The Czech state regulates almost everything: from prices to reimbursement. The majority of medicines have a regulated maximum price despite the fact that there are a lot of competitors on the market.

In the Act of Public Health Insurance, there is an annex which has 180 groups described and there is a rule that in each of these groups there must be one fully reimbursed product. For example, we have the basic rule to distinguish between regulated and non-regulated products: if there are four products from four marketing authorization holders on the Czech market, this product should not be price regulated. But there is a second rule: if the product is relevant to set up reimbursement in the group according to annex number 2, which should be fully reimbursed, all these medicines should be price regulated.

As a result of these two rules, we have almost 8,000 stock keeping units (SKUs) in the system, 6.8 thousand of which are price regulated, which is the vast majority. As a consequence, this creates pressure on pricing, as we have an external reference system that includes countries like Denmark and Sweden in the basket, and the tender price is set as a reference, influencing the price in the Czech Republic for a long time.

How do you advocate for improved market access for your members' products?

We are advocating for change mainly in terms of price regulation. We do not find it necessary to regulate the price when there are a lot of competitors on the market and are dealing with the

Ministry of Health to adjust this. However, the Minister fears that prices may increase too much.

There is a stronger driver that is also threatening our members: price agreements between companies and payers. If one of these agreements is lower than the external price, it will be considered a reference price for setting the reimbursement for the entire group.

Even though there is a rule that the reference product for the group must account for at least three percent of market share, if a company decides to make a price agreement with a healthcare fund, it is automatically used as a reference price despite the fact that the company does not have any market share. It is very difficult to negotiate or to advocate to stop this because it is an effective tool for healthcare funds.

The Minister of Health Adam Vojtěch signed the Reimbursement Decree for 2020 earlier this month with a record increase in reimbursement being allocated to all segments of healthcare: a total of CZK 35 billion (USD 1.5 billion). What does this mean for the generics and biosimilars ecosystem?

This Reimbursement Decree is crucial for budgeting for hospitals and healthcare providers and will have a big impact on biological products, but not for medicines dispensed in pharmacies because they are not counted in this budget.

For historical reasons, as most of our members' focus is on medicines in pharmacies, this Decree is not crucial to the association yet, but with the growing importance of biosimilars, this is changing and will also be our priority in the future. It will give centers the opportunity to treat the same or a higher number of patients than in the past, so it is good news for patients and biological products.

Some of your member companies produce drugs locally, and some simply have sales offices. What makes the Czech Republic a good country to manufacture in, what are its biggest challenges, and how do you continue to support your members?

There is a positive balance between the costs and the effectiveness of the production sites. Furthermore, we have a lot of educated and skilled people in the Czech Republic, making it a suitable place for such kinds of production.

I would say that Zentiva, Teva, Promed or Glenmark, to mention a few, have the same problems within the Czech market as members that are not producing here. A lot of products which are

manufactured here are devoted to export. It is logical – it is unrealistic to run a production site exclusively for the Czech Republic considering the size of the market.

In terms of support, at the association we are trying to build a positive picture on generics – about their benefits, how they are reinforcing the decrease of budget on medicines, and how important they are to ensure the availability of medicines. If a given company is lacking an active substance for whatever reason and there are more than four competitors, the availability of that active substance is ensured.

Moreover, we are dealing with the Ministry of Health in every piece of legislation. We are trying to keep the environment as sustainable as possible. It is not easy, but we are trying to improve the environment not to be threatening, to support the sustainability of the business, to make the conditions on the market attractive for companies to launch new products.

As we see a shift in the dynamics of the pharmaceutical landscape worldwide, what are your key priorities for the association moving forward?

Moving forward, we would like to focus more on data to be able to explain to stakeholders what is going on in the market. As politicians do not focus on the details, we need to help them to understand what is positive and what is negative for the availability of medicines.

Our members would like to see our support in gaining bigger market share, in leveraging generics and biosimilars, and in striving for a sustainable environment.

Another of our goals is to show the Ministry of Health, the Ministry of Industry and Trade and other stakeholders the importance of companies of the likes of Zentiva, Teva, Promed and Glenmark manufacturing here. They are very successful in their production and that should not be taken for granted. Even though everyone knows that we have such production sites and companies in the Czech Republic, it is important to repeat it.

What is it that motivates you to give your best day after day at the association?

I am interested in the system and I like to understand how decisions are made, what the reasons behind them are and how things can be changed. I enjoy working for, and being part of, positive change.

As the generics industry, we only have a comparatively small hammer. We need to keep smashing the glass and being persistent.

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