Interview with Emil Zörner, Executive Director, Česká asociace farmaceutických firem (ČAFF)

03.07.2012

Tags: Česká asociace farmaceutických firem (ČAFF)

Dr. Zörner, can you please begin by introducing our readers to the CAFF (Czech Association of Pharmaceutical Firms), and explicate its key activities and mission?

We represent 24 companies in the Czech pharmaceutical industry that are mainly involved in the generics business. Our mission is to promote the generics industry, and generic products, to both the authorities and the public. We seek to foster a better understanding within the market of the role that generics play in the healthcare sphere.

The last several years have seen a number of major reforms in the Czech pharma industry, which have mostly focused on driving down prices and reducing pharmaceutical expenditure, while introducing new technological elements such as electronic auctions. Can you comment on the major changes we currently see happening in this market, and the effect they have had on your members?

It is true that from a legislative standpoint, we are experiencing many more changes now than we have in the past. This rapidity is something new for the industry, and is a change that came with the appointment of the new Minister of Health.

There are many of laws, by-laws, and regulations that are now being tackled by legal staff at the Ministry with the aim of reform: we are speaking of the drug code, the insurance law, and the marketing code.

These are the major changes now facing the industry. In the past, developments had centered on pricing and reimbursement; for the last six or seven months, there have been no further issues with these elements, as they have been largely settled.

One would assume that the laws on pricing and reimbursement of drugs would be found in the drugs code. Strangely—and this is quite characteristic of Czech legislation—they are instead found in the legislation on insurance. In the Czech Republic, if you are looking for a particular subject, you shouldn't look for it in the place where you would expect it to be!

Whenever a law is in the pipeline, and the Ministry is selling it to the Parliament and to the public, it is said that the law is meant to fulfill the drugs policy of this country. This is a nice sentiment, and indeed the laws always do fulfill the drugs policy—because this country does not have a drugs policy. A policy of this kind should be succinct, and contain very few words: the Australian drugs policy contains ten pages, for instance. Further, the Australian policy is not a legal document, but rather a part of the total healthcare policy. It is not political, and it shouldn't and mustn't be political. It should survive for many years—beyond a single election period. In the Czech Republic, we unfortunately do not have such a document, so anything the authorities do may be claimed to fulfill the drugs policy. It is quite convenient.

And yet, what changed—particularly under the new administration—is that the Ministry now deals with the industry as partners. In the past, directives were handed down from the Ministry without consultation, and would often hit the industry by surprise. I would partly extend this positive statement to SUKL (SIDC – State Institute for Drug Control) —because our consultations with SUKL remain limited. This we expect to improve with the new SÚKL management.—But today, the Ministry is considerably more open. They listen to our suggestions, and incorporate some of them into legislation. In some fields, we have reached good progress.

Returning to the reforms themselves, I do not agree that current legislation being passed in the pharmaceutical sector is more beneficial to the patient. In other areas of the healthcare sphere—that I observe only as a citizen, rather than an insider—some of the new laws are truly creating a better environment for society. The rights of patients, and other healthcare elements, are improving.

Conversely, in the pharmaceutical sector, new legislation regarding areas like medicine accessibility are not improving patient conditions. Medicines take a long, long time to come to this market. Generics take quite a long time to be allocated reimbursement and price if following the normal procedure. And, the declared intention by the government to increase the co-payment for

medicines up to 23% (today we are at 17%) is not beneficial either. In the ‘90s, co-payment was almost zero.

In the Czech constitution, it is written that healthcare must be free of charge. And we are in very particular company in this sense—Cuba, Ukraine and North Korea share this approach. It is acceptable that healthcare should not be free; but the fact that the constitution claims that leads to unnecessary distortions. In the reimbursement system, for instance, if this line did not exist in the constitution, the government could at least be open with the people: “This is the co-payment for this drug; should you chose not to pay this amount, there are other drugs with less out-of-pocket cost.” However, the margin system in the Czech Republic instead incentivizes pharmacists to dispense an expensive product.

In Russia, there is a ‘list of essential medicines’—treatments for particularly debilitating diseases—that is available to all the populace without co-payment. Does the Czech Republic have a similar listing?

We have a different structure. We have groups of medicines—and this is the way that we are able to circumvent the constitution. There are approximately 195 groups, and in each group, at least one medicine is fully reimbursed. In this way, the constitution is ‘fulfilled.’

To give you an example of how this scenario plays out in real life, we can look at, say, hormone therapy for cancer. Two years ago—and this has today been remedied—there was a drug group for hormonal therapy to combat breast and prostate cancer. The breast cancer product was fully reimbursed; if you had prostate cancer, however, your product was not fully reimbursed. Therapeutic groups are often too broad! The fully reimbursed product is, moreover, often not the most advanced product. If you want the latest therapy, in many cases you must take out your wallet.

If full reimbursement is often given to drugs that are not the latest therapy, it seems that this would create an attractive environment—or at least a state of preference—for generics.

I am not sure that it does. Reimbursement, at least in theory, should be the same both for generic and originator drugs (although of course the price may still be different).

I do not believe the current system is particularly attractive for generics. A free market could be better. However, since the authorities do not seem to believe in market forces, we do not anticipate this kind of change.

On the subject of free market forces: the Czech Republic's referential pricing system ensures that it has some of the cheapest medicines in all of Europe. However, free trade amongst E.U. countries often ensures that the cheap medicines available here are sold to distributors in other countries, and the result is that the medicine is not available on the market. What is your view of this situation?

In the Czech Republic, we have two types of price regulation: maximum price, and reimbursement. The maximum price must be an average of the three lowest prices in Europe. The reimbursement is settled according to the very lowest price in Europe.

The Czech Republic has a healthy medium-strong economy—we are certainly not the poorest market in Europe. And yet, we want to have the lowest prices on drugs. To whom do you give the lowest price? To a good customer—the biggest customer; a customer that guarantees a certain volume. But the Czech government, as the customer, provides no guarantee on volume, despite their stipulations of driving down price.

Developed states take their share in paying for research in the pharmaceutical industry—they do so by paying a fair price for drugs. If you want to have the lowest price, you do not want to contribute to drug development. I believe this is unfair.

The people that framed our pricing mechanisms did not foresee that changing just one parameter in the system creates an imbalance somewhere else—and the imbalance was indeed created: we have, as you mentioned, a shortage of products. Re-export from this country is a daily event. You will find drugs that do not exist on this market. For instance, I personally have to purchase a particular product that I need via Internet from Holland, because the drug is not available here. Of course, I must pay full price for it.

It is like the sorcerer's apprentice—conjuring spirits that now cannot be tamed. Intelligent people in the Ministry say, "Price is not our concern anymore; availability is our concern." And yet, the former director of SUKL himself noted that 22% of certain classes of drugs in this market are re-exported. They are exported to markets like Austria, Germany, England, and France.

The authorities are now thinking of how to stop the trend. But you cannot stop the free flow in Europe.

You earlier mentioned the electronic auctions. What these auctions mean to the market is easily explained. When the proposal to introduce the auctions into law appeared in the parliament, one hundred pharmacists applied for distribution licenses—they need this license to export. Today, the

number is closer to two hundred. It is an attractive business to export! Fortunately, the electronic auctions—which in the West would be called tenders—are not in place yet.

According to industry analysis group PMR, the Central European generics industry is set to grow at a CAGR of over 6% between 2011 and 2013—a stronger rate than that projected for innovative drugs, 4%. What is the reality in the Czech Republic?

The growth rate in this market, if we look at IMS figures, has been very mild—somewhere around 1% for the entire pharmaceutical market. As far as volume is concerned, the figures are actually declining. 6% growth is something we definitely do not expect here. We do not see generics growing above the market. The mild price increase is driven mainly by new, highly innovative drugs entering the country—and this itself is offset by continuous price reduction.

Businesses must adjust to the market. I can foresee that there will be redundancies in companies if the Ministry introduces requisites to the doctors—something that is now in the cards. And I am not sure companies have much space to further reduce. If electronic auctions should take place, this event will probably cause many companies to leave the country. However, if that happens, and we are left with a few major companies controlling the market, the shoe will be on the other foot!

Europe has a strong tradition of manufacturing excellence. How competitive do you believe the Czech market is as a manufacturing hub, compared to neighbors such as Poland, Romania, or Hungary?

We have some existing local manufacturers—Zentiva and Teva, for the most part. There are also a few smaller companies with local manufacturing in place as well.

Manufacturing here is today fully at GMP level—which was not the case in the early ‘90s.

With this said, I am not aware of any special incentives—tax holidays, etc.—given by the government for attracting production investment from pharmaceutical companies. We do find such incentives in other industries, but I do not believe the government prioritizes this form of investment from our own industry.

To what degree do local Czech companies play a role here, relative to the usual international players?

Traditionally, Zentiva is well known by doctors here. Zentiva was purchased by Sanofi, but retains its identity in the country as a local Czech and Slovak company.

Teva purchased a Czech site from a local company that was known as Galena. They have an excellent production operation, which supplies not only the local market, but also the worldwide market.

What is on the agenda of the CAFF for the coming 1-2 years? What battles will you fight for your members, and what reforms would you like to precipitate in the market?

As I earlier said, we seek to develop a friendly environment for generics, and to foster understanding in society about the importance of generics. We want to develop a mechanism wherein the pricing evaluation for generics is different from originator drugs. We want a shortened evaluation—as required, incidentally, by Brussels!

We would very much appreciate a transparency directive, which does not seem to be forthcoming. Such a directive would require SUKL to adhere to the statutes already required by European and Czech law. The law states that within 90 days, the generic product must be on the market. If the transparency directive moves ahead, it will be 30 days. If not, the authority will be fined, and pay damages to the company.

We already have some elements in the new law that allow for a shortened procedure, but we would considerably appreciate the addition of transparency.

We would also very much appreciate a better structure within legislation: for legislation to be more logical, and for it to promote a better environment for all stakeholders. There should be only one way to interpret a law, and legislation should not be ambiguous.

We are troubled by the fact that the situation in the country is very much linked to the people sitting in the Ministries. For instance, I mentioned that the Health Ministry is today much more open to speaking with the industry. But this is perishable—if the people in the Ministry are changed, the reality may become quite different. In Germany, the officials will stay even if the political direction changes; this is not the case in our country. One of our priorities is the following. This is an extremely regulated market, and we have different regulations for pricing and reimbursement. The main regulation for these mechanisms, however, does not work. It does not produce the expected results, and it does not produce them on time. There are delays. For the same product, we see company A getting a reimbursement of 100, and company B getting a reimbursement of 1500. The excessive evaluation in the market is counterproductive, and precipitates inconsistencies.

Two years ago, the parliament agreed on flat cuts in drug pricing of 7%. By European law, such a statute cannot exceed one year in timeframe—but last year, the law was repeated, and cuts of 7%

were introduced again. It was nonsensical, anti-constitutional, against domestic law, and against European laws. At the same time as the authorities cut prices by 7%, in the same time period, VAT was increased—it is robbing Peter to pay Paul! The 7% cut, moreover, was agreed under a shortened procedure as an emergency legislation. This is the inconsistency we see in the law.

This should disappear. It is, slowly, disappearing—although our new system still only obliges SUKL to make a pricing review once every three years, rather than once every year, as it should. But generics are entering the market faster than they once did. The new law also allows greater stability in reimbursement, even as margins change.

We should also structure our pricing system in such a way that the pharmacist can be motivated to dispense a cheaper product—we touched on this briefly earlier in our conversation. Today, the opposite is true. We would also not mind if the prescribing doctor is motivated similarly. But we are very far away from this—unfortunately, I do not see it moving.

What is your final message to our international readers?

The positive message is that over the past years, there was always money made available to pay for Czech healthcare, in general—for treatment, for doctors, for the improvement of equipment, and for drugs. I, as a citizen, have no problems receiving treatment in my country.

I am not sure that I have a positive note, however, for the industry. I listen to more than 20 country managers, and typically, they are quite worried. I do not remember them saying, “I presented my plan at headquarters, and it was a robust plan.” Instead, I hear them saying that they had to explain why things are done a particular way in the Czech Republic, and why there is this level of uncertainty in their planning.

The industry still can work here. But for small companies that depend on a very small portfolio, I believe the future is not that bright. We see companies withdrawing from Hungary. We are not there yet, and perhaps this is the positive—we are doing better than some of our neighbors! Companies stay here because they are committed to the market. The country managers are committed, and the employees and committed. This is why they put up with difficulties, and try to find a reasonable way to maintain a sustainable operation here.

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