Interview with Jakub Dvořáček, Executive Director, Asociace inovativního farmaceutického průmyslu (AIFP)

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Mr. Dvořáček, in 2010, the AIFP commissioned a study on the economic footprint of the innovative pharmaceutical industry in the Czech Republic. Can you begin by expounding the results of this study?

The footprint of the innovative pharma industry in this market is not particularly large relative to other industries, if we look at figures like sales or number of employees. However, an important result that we noted from this survey was our members' involvement in clinical trials. Their focus on domestic research is truly quite exceptional. The clinical trials per capita performed in the Czech Republic are on par with markets like the UK—one of the highest levels not just in the Central European region, but in all of Europe.

Around 300 clinical trials are conducted yearly within the country. The number of patients who participated in trials, and were treated thanks to our companies, was around 85,000 over the four years leading up to the conclusions of the study. Clinical trials covered 3% of the healthcare budget, for instance, of oncology and cardiovascular disease.

The number of doctors who participate in these trials reaches a volume that one would be hard-pressed to find anywhere else in Central and Eastern Europe—or, for that matter, in the rest of the E.U.

What do you believe makes the Czech market so attractive for clinical trial research?

I believe that several factors are involved. First of all, there is a large amount of high-level centers available for trials. The number of trained, skilled doctors that have the necessary background to conduct such research is also high.

The regulatory framework is quite strong as well. We have a good system that ensures validation and other necessary factors. There is, however, an issue with the legislation that deals with the steps after clinical trials—how quickly the new drugs tested in clinical trials can be channeled to the patient. But the trial framework itself is excellent.

The question is how long we can continue to be competitive as a clinical trial hub. How long can we maintain this level of interest from companies? Large emerging markets like Russia are introducing special incentives for companies to run trials within their borders. At the same time, mature markets like Germany and France are pressing the industry to keep the traditionally high volume of clinical trials in their countries.

We will see how long the Czech Republic can retain its attractiveness. But as I said, the situation today is quite good. We do not only participate in Phase III and IV trials, but also in Phase I and II.

Our members invest around 5% of their yearly income back into the market through their clinical research efforts. If we compare the innovative pharma industry to other industries in the country, we find that our members invest 3-4 times as much money into the country as, for instance, the IT, chemical, automotive, and electronic industries. This makes us stand out.

What kind of market share do innovators in the Czech pharma industry enjoy?

Innovators hold approximately 65-70% of the pharmaceutical market by value. This means that compared with other countries, innovative treatment has a high uptake in the Czech Republic. As I mentioned, treatment reaches the patient with some delays, but it does reach them nonetheless.

With the legislation that is coming, there may be some shift in our market share, but I do not anticipate that the shift will be significant. What is important is that the level of investment into healthcare as a portion of the national budget has been stable for the last 6-8 years.

Are you not troubled by the fact that the budget has not grown? Shouldn’t spending increase with factors like inflation and population growth?

Firstly, there is little population growth in this country. Inflation, too, has been relatively low.

Of course, we would appreciate more funds to be allocated to the healthcare sector. However, if we look at the remainder of the CEE, we see that budgets are being cut, and healthcare systems are

collapsing. The fact that we have the same budget today as we did in prosperous years like 2008 is a success.

A challenge for us is the fact that the health budget that is flowing to hospitals, treatment centers, doctors, and etc. is eating a significant, and steadily increasing, portion of the budget for drugs. For instance, the last 2-3 years have seen active discussion regarding the salaries for healthcare professionals. There is high pressure on the Ministry of Health to increase these salaries, while the overall budget remains the same. This will mean that there will be less funds for the authorities to use on drug purchases.

The Czech Republic is a very small country, but despite its size, innovative drugs are available even for orphan diseases. The Ministry currently wants to introduce an HTA—Health Technology Assessment—system, and we hope this will have a real impact. The HTA is not new for our industry; it has been in place for over three years, and impacts all new drugs coming to the market that are considered highly innovative. After some years of temporary reimbursement, the drug markers have to provide a full pharmacoeconomic study for their latest products.

HTA will now be applicable not just to drugs, but to the entirety of the healthcare system—technologies, medical devices, prevention systems, etc. I hope that in the future, we will be able to have strong data analysis of all the ‘eaters’ in the system, and thereby increase efficiency. The budget will be much more balanced and we will be able to see what is working and what is not. Funds will be allocated where they are truly needed.

You mentioned the 5% of company revenues that are invested back into this country; you mentioned, too, that the uptake of innovative drugs is quite strong in the market. However, the Czech Republic has famously low drug prices—some of the lowest in all of Europe—because of a referential pricing system. Furthermore, we see pressure from the authorities to further lower price points. Does the government seem to appreciate the value of innovation? Are they paying your members fairly for the added value they bring to the market?

This is certainly an issue for us. We have two systems that are currently limiting prices: one is the maximum price, which is based on an average of the three lowest prices in Europe. The second is the reimbursement system, which too pushes prices down.

Even with the downward pricing pressure we experience from these two systems, we as an industry can survive. The issue, however, is that Czech prices are driving drugs out of the market. I estimate that between 15-20% of all drugs that are distributed through the market eventually leave the country. With the low trade barriers in the E.U., distributors find that it is in some cases

more attractive to sell the drugs to a neighboring market than to sell them here. Parallel export is a growing issue.

We are aware of the situation, and are in discussions with the Ministry. Especially in the case of innovative drugs, the system of public maximum prices is making the sustainability of the pharmaceutical framework quite difficult. We anticipate problems with the flow of drugs to patients. Soon, a large problem may arise wherein some very specific drug that is not easily replaced is simply not available for some period of time. Companies do not immediately receive notice that the drug is not available in the market. When they do find out, it is usually too late. We are quite worried about this situation.

As the AIFP, we hold a dialogue with the Ministry regarding how to revise the system. We would like a system that is more transparent. We know that the budget will definitely not be increased; instead, we need to find a solution to limit parallel export. We cannot limit free trade—hence, we must find another way to make the market sustainable. This will be a main theme of our Ministry discussions in the coming months. If we do not find a solution quickly, we expect major difficulties. We have seen problems arise in other European countries that have such major price pressure.

One positive development in the market that was expressed in our interview with Dr. Zörner of the domestic generics association CAFF was that the government is now much more willing to develop a constructive dialogue with industry members—something that, for many years, was noticeably absent from the Czech healthcare sector.

We too have noticed this shift. We have had a significant chance to discuss all of the legislation that has lately been in development, from the point of drafting by the Ministry. We are a part of the internal process; we are, too, a part of the external process: the official procedure of legislative ratification as bills are passed from the Ministry to parliamentary bodies.

There is, however, an issue here, which lies in the fact that, once the legislation reaches parliament, changes can occur that are not easy for us to predict. In the Czech Republic, the process is as follows: the Ministry develops an amendment to the health law; this amendment is discussed with the industry, with patients, with key opinion leaders in the medical community, etc.; a government legislative advisory board checks over the amendment in light of Czech legislation and European legislation; subsequently, the bill reaches parliament; from the parliament, it goes to the senate, and then returns to the parliament or goes directly to the president.

During the reading in the parliament, there can be changes that come from parliamentary members—and during this very short period, we have low visibility of what will eventually come to

the system. Ultimately, the case is often such that the amendment that is ratified does not represent the full scope of the proposed amendment, and the legislation could actually prove harmful to the system.

This process should be further discussed. Government processes should be transparent and have clear predictability for all stakeholders involved in the amendments. The Czech legislative system is extremely complicated!

As the AIFP, have you had success in the past in actually introducing member suggestions into ratified legislation? Or have you only been a voice?

It depends. For instance, we can look at the last piece of legislation, which was a law on marketing practices. 60-70% of the changes that we proposed were accepted—quite a high percentage.

Transparency, and a high ethical standard, is something that we are really pressing for today. The image of this industry is not very positive in this country, due to some incidents that occurred in the past. The media always focuses on negativity, of course. But, I believe that even in this field, conditions are improving. And it is not just about our voice—it is about our arguments. If we are able to offer strong arguments based on data and reality, we are able to convince the government of our positions.

We always emphasize that the greatest interest of the innovative pharma players in this market is to have a sustainable, predictable system. We do not want to see temporary fixes, and then renewed regression. We want a fully balanced system, that will be predictable not only for us, but for the remainder of the healthcare sector.

We want to live by the same rules as other healthcare stakeholders as well. This is currently a problem in the Czech market. The pharmaceutical industry is under strict regulation here. This is something that we are used to from our experience in other countries. However, in other countries in Europe, we see similar rules governing the work of pharmaceutical players, medical device companies, and the other players in the health system. We are trying to promote a similar framework for everyone.

I had mentioned this notion earlier in terms of budgetary decisions. As pharma companies, we can make our contribution to savings and efficiency; but we expect that other healthcare players will have to participate in these savings as well. For instance, we would like for hospitals to seek greater efficiency.

We expect the same of patients. Patients are supposed to have access to the latest treatments, but they must understand that capital is limited. We also need to find a greater transparency in the flow of drugs. We will be able to ensure that drugs are not used improperly, or, say, removed from a pharmacy but never used.

Do you believe that the market is headed toward this ‘fair and balanced’ system?

I see that the vision of the Ministry is indeed to create such a system. However, the way that the authorities are implementing changes could be more efficient. There are many stakeholders involved, and everyone tries to ensure that their interests are a bit more protected than the interests of others. The only way to solve this dilemma is to have the same conditions for everyone.

If we look at the amount of money that flows into healthcare in this country, I believe that it is enough—it is enough to have a very strong standard of care for all citizens. But we need to use our resources better, in all segments of the system.

A particular difficulty in the Czech Republic is that drug approval takes up to three years longer than neighboring countries like Austria. What is your view of the ease of market access for your member companies’ products?

The issue is that a new drug can only be introduced on the Czech market after two other countries introduce it in Europe. Hence, we must always wait. My question is, why? What constitutes the major difference between the Czech Republic and a neighbor like Austria

Our perspective is that a patient should receive a new treatment—especially if it is highly effective—as soon as possible. If the patient can be treated faster, the greater expenditures of the government are lowered. The government will save money if drugs with proven efficacy can reach society, and the people are able to continue to work and contribute to the economy.

We would like to see faster drug access in the Czech Republic—especially because of our contribution to clinical trials.

If we evolve a strong, transparent, HTA-based system, which will not limit the access of innovative drugs, I will be more than happy. I hope we will be able to re-open this discussion with the Ministry soon. I believe that the country should contribute back to the industry, just as the industry contributes back to the country. Again, we are looking for balance!

The Czech Republic is a challenging pharma market. What do you believe it takes to be successful here?

We have to do more to promote the added value of our new drugs. The industry has voiced the positive effects of particular products on particular diseases; we need now to speak more about the greater social value of pharmaceuticals—the value that I have just mentioned. When the population is healthy, budget savings occur across the board. If our companies are to be successful, we must really highlight this added value, and show the payers that if they spend the same amount, or a bit more, on innovative treatment, then we will see savings in the social security system, because we will be able to bring people back to work sooner than with drugs that are out of patent.

We as the healthcare industry have to cover quite a long period post-retirement and provide our pensioners with a high quality of life. This is something that we bring to society: the people are more healthy, and they can live longer, with a higher quality of life both before and after retirement.

What do you believe makes the Czech market attractive for your members?

This is quite a small market. However, what is attractive about the Czech Republic is that it is one of the increasingly few countries in Europe with a sustainable budget. Economic conditions are not declining; we may not be growing at a high rate, but we are not deteriorating either. Our members can build long-term businesses here.

When our members invest in R&D here, moreover, we build strong links with the medical community. And the medical community in this country is quite special: very well-educated doctors, good hospitals, and medical centers that are of higher quality than many other countries in the region. If all parts of the system work, it will be good for society, good for patients, and good for the industry. I believe this is the reason why we are here. If this country is to be competitive against other markets in the future, we must have a healthy population. This is what we work towards! Unfortunately, we are not always viewed in this light; some people believe that the industry is only out for profit. People in this country are used to having healthcare provided for free. For 50 years of the communistic period, healthcare seemed free but of course it was not: the system paid for healthcare, and the people paid the system.

Now things are changing, and the people have to contribute more from their own pocket in the form of co-pays, in addition to the taxes they pay to the system. I understand, however, why the Ministry introduced co-pays: the people must be responsible. They must understand that healthcare is not free. Of course, the system must cover the majority of expenditure, but when the people pay some small additional fee, they are better able to see the value. This fosters a different viewpoint within society.

And yet, the people consider this somehow unfair: they see that they paid their whole life for the public health insurance, and now they have to pay additional monies for the co-pay. But this additional amount is peanuts! I believe it is a positive change, and people will start to understand the value of medicine, the value of innovation, and the value of their own participation in healthcare.

We as an industry should contribute to this ideological shift, and help the people understand that they are responsible for their own health. People should focus on prevention. If the system can save money in the budget in this way, we will have more money to bring innovation to the market.

On the point of R&D, are companies bringing earlier stages of research to the country, or only clinical stages?

So far, only clinical trials. But this is something that we would like to change. We are looking at channels like the IMI program, which is a major private-public partnership program in Europe. This platform tries to build a bridge between public R&D institutions, small and medium enterprises, and so-called ‘big industry.’ There is 2Bn EUR allocated to major projects: half from the European Commission, and half from the industry. This is complimented by national funding, as well.

Before the IMI, there was no clear system that pushed academia to work with the industry. We would like to highlight the possibility of such collaboration in the Czech Republic as well. There are ways for our academia to reach the R&D processes of the industry and commercialize their ideas. We can go beyond clinical trials, and initiate basic research here. We can find ways to be closer.

The European Commission put a great deal of investment into building three large centers—ICRC in Brno, the Mayo Clinic joint project, and the biometric center in Olomouc.

Are your members involved in these centers?

Our members are not involved at this time. These centers of excellence were a joint effort between academia and the European Commission. However, I believe that the opportunity is really there to create a close connection between the industry and these new centers. The sites have the latest equipment, and well-educated people with industry experience. I believe it is a win-win situation for both industry and academia to create these new links.

For years—maybe generations!—academia here performed R&D, and performed basic research, but always kept it on the shelf. In very few cases, this R&D transferred to the product. This needs to change. We need to change how people within academia see the industry. We need to show scientists that when they find something interesting, if they work with the industry, they can bring

their projects to fruition and bring a benefit to society.

The requirement put forth by the authorities is that these new facilities will have part of their income come from the industry. There is hence pressure from the Commission, and the IMI project as a tool of connection. We want to promote understanding. Again, if we are to be competitive in this country, we must have these links. In Germany, in France, and in like countries, these links already exist. We must ensure that they exist for our members here in the Czech Republic, as well.

We are at the starting point of something great.

Do you see that the Czech market is attractive as a manufacturing hub for innovators?

Actually, none of our members have manufacturing facilities here. Only generics are produced in the Czech market. I do not believe the Czech market is competitive in this area—I am quite well aware of the investment incentives offered in this country, and I do not see that they are appealing for pharmaceutical production. We see that generics players are too shifting East—to countries like China and India. I do not anticipate investment in the close future.

What is your final message to our international readers?

I believe that in the long run, we can be a very interesting region, which can bring considerable added value for R&D and for the reputation of the industry. We are considered a country that is open to innovation. There are still some changes that we must make, but we have started to be successful.

We are a small region, but we have specifications that you can hardly find elsewhere.

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