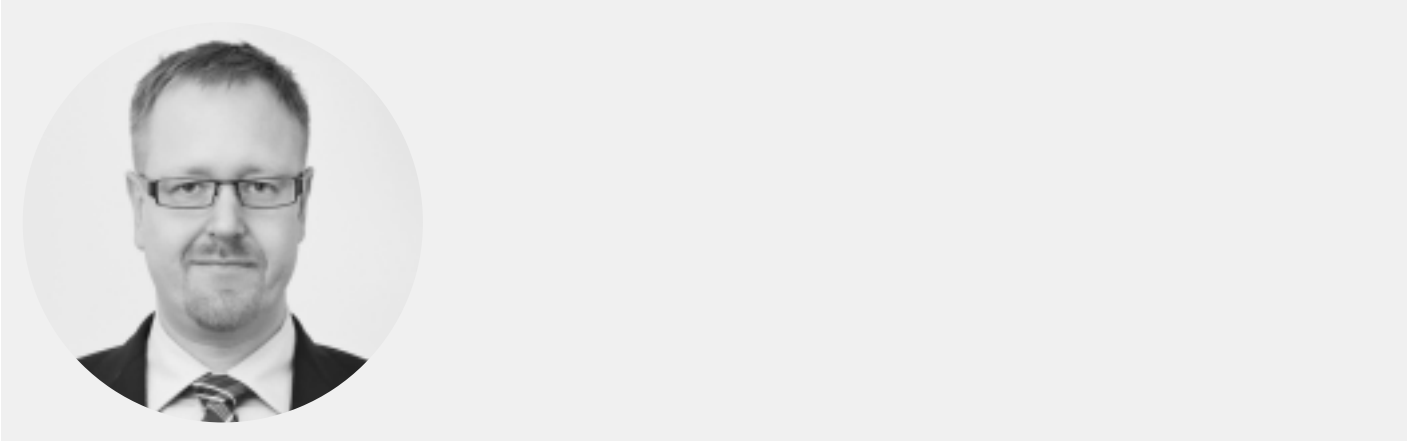
Interview: Jakub Dvořáček – Executive Director, Asociace Inovativního Farmaceutického Průmyslu (AIFP), Czech Republic



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The AIFP's

Jakub Dvořáček explains the recently launched tool for information disclosure between pharmaceutical companies and doctors, highlighting the significance it holds for industry and country. Furthermore, he reviews the Czech Republic's attractiveness as a location for pharma companies.

When we met you in 2012, you named re-exporting and a lack of transparency as core challenges in the Czech Pharmaceutical market. Now the ministry of health plans to implement new legislation by mid-2016 that will limit re-exporting and you recently introduced an online catalogue that will disclose financial relations between pharmaceutical companies and doctors. How satisfied are you with these reform plans?

We established the online catalogue here in the Czech Republic as a tool for self-regulation on a voluntary basis, supported by the scientific society in Prague, the minister of health Svatopluk Němeček, and the deputy minister of health, Diary Lenka Teska Arnoštová. Although on a voluntary basis, this is a major milestone towards enhanced transparency and safety. Achieving that involved a tremendous amount of discussion and facilitation of communication between health professionals

and pharmacists in order to find a solution that was commonly accepted and beneficial to all stakeholders. We established the platform through the participation of the different pharmaceutical and medical associations, rather than on a company-to-company basis. This allowed us to efficiently consolidate the right information while ensuring the healthcare professionals are fully protected. The result is just what we needed: valuable information available to everybody, avoiding a senseless mountain of PDF's. I am confident, that the online catalogue as platform is a natural source of information which significantly contributes to society and the welfare of Czech patients!

Unfortunately, re-exporting is still an issue in the Czech Republic. The new legislation to be implemented in mid- 2016 is a step in the right direction, however is not a sustainable solution to this challenge. Although it will help to avoid dangerous outcomes for patients, it does not ease the situation for the pharmaceutical industry, which is currently fighting to stop the large outflow of medication to neighboring European states.

What needs to be done to stop re-exporting?

Frankly speaking, I don't think that there is a solution to this problem. In comparison, the GDP per capita in the Scandinavian countries and Germany will always be stronger than the GDP per capita in the Czech Republic; these countries will always be able to pay a higher price for drugs and treatments. The only way to put a complete halt to re-exporting activities is to significantly raise the prices in the Czech Republic which will not happen in the foreseeable future. The problem of high re-exports is two dimensional: firstly it can place the lives of Czech patients at risk, and secondly can incite pharmaceutical companies to not register their products in the Czech market anymore, as is would contradict EU-regulations; an issue which is already observable in Romania for instance. The scope of re-exporting is dependent on differences in price, which is why authorities in the Czech Republic have to handle the pricing very sensitively and avoid pushing them too low.

Having said that, my recommendation is to focus on maintaining the good conditions in other areas and seize available opportunities to fine-tune these areas for the benefit of all Czech stakeholders. My colleagues here are already doing exactly that. They navigate around the price pressure by enhancing efficiency and transparency, identifying the best pathways to the hospitals and pharmacies in order to help and protect the patients.

Despite drawing attention to the shortfalls of the new legislation to limit re-exporting, I would like to highlight that I believe that this is a step in the right direction, which showcases the tremendous effort of the regulatory authorities to create a sustainable healthcare environment. Additionally, it

is of relief to me and my colleagues, that the legislation change should put an end to avoidable, life threatening situations for Czech patients.

The two tier reference system in place in the Czech Republic heavily squeezes margins of innovative pharmaceutical companies. Does that limit the attractiveness of the Czech market for innovative treatments?

Unfortunately it does. The maximum price is the result of the average price from the three lowest prices within Europe. The process to eradicate countries from the referencing basket takes tremendous effort and a lot of time. We succeeded in eradicating Romania and Bulgaria from the reference basket, however, countries such as Greece are still part of it, thus creating a rather challenging pricing framework.

Despite the challenges of pricing methodology I am happy to be able to say there are other factors that very much enhance the attractiveness of the Czech market! Market access, for instance, is one of the best in the region. In recent years, the time needed for an innovative treatment to reach the patient has been significantly reduced. There is also a special pass for innovative treatments called the ‘temporary reimbursement and statute of highly innovative medicine’, granting swift market access for highly innovative treatments needed by the patient, only limited by numbers and public budget. After three years, pharmaceutical companies then have to re-proof the result of their clinical trials and defend their product; if defended successfully, it will be included in the classical reimbursement procedures. This procedure is well accepted by the pharmaceutical companies and allows patients access to needed innovative treatments.

How would you assess the overall availability of innovative treatments in the Czech Republic?

I believe there is always room for improvement, however the waiting lists for treatments are not an issue in the Czech Republic. When patients are diagnosed they receive the needed treatment swiftly, in particular the number of patients receiving the latest treatments is increasing. The ministry of health centralized specific areas of innovation in specialized care units, greatly enhancing efficiency in granting access to medical and pharmaceutical innovation for Czech patients. The sole flaw that I identify in this system is the time delay of patient transfer from general practitioners to the special care units, the communication between these entities has to be improved in order to maximise the positive result on the overall healthcare.

Market access of innovative treatments is one of the most important aspects for pharmaceutical companies and, of course, for patients. How does the Czech Republic

compare in market access time to other countries in the region?

I am confident that in the Czech Republic we have the right balance between sophisticated regulations in terms of transparency and quality, while being one of the fastest countries in the CEE region to grant market access. Efficiency and effectiveness is combined to a level that provides maximum quality and security for the patient while offering a stable and predictable environment for pharmaceutical companies. The only dimension of attractiveness for pharmaceutical companies in which neighboring countries can outcompete the Czech Republic is pricing.

A positive notion you gave in 2012 was the development of PPP (public-private-partnerships), in which the Ministry of Health and relevant regulatory authorities would increasingly seek dialogue with the pharmaceutical industry. Now that there is a new governing party, and a new health minister in place, how would you describe public-private-partnerships now?

The degree of PPP under the minister of health, Svatopluk Němeček remains just as excellent as it was under the former minister of health, Leoš Heger. We can address our concerns and the risks we identify as an industry to the relevant regulatory authorities, and the ministry, in tandem with the state institute for drug control, reviews these appropriately and, more often than not, collaborates with us in the aftermath for the benefit of the overall healthcare sector of the Czech Republic.

Frankly speaking, it is about minding the system itself over individual needs. We have to live within the sphere of the system—harming this sphere would be a mistake. Our goal is to improve the system together with all stakeholders for the benefit of Czech patients; and all stakeholders must align in adopting this goal! If the patients' needs are satisfied, so will those of the ministry of health, the state institute for drug control and, of course, the pharmaceutical industry at large. Having said this, it becomes obvious that there really is no rationale for any of the stakeholders to take opposition to one of the other stakeholders. Communication is key! For every proposal I plan to announce, I always consult the ministry of health and the state institute for drug control prior to doing so. Together we create synergies that benefit Czech patients, and I am glad that this is the case.

Three years ago you were proud to mention that clinical trials were on par with markets like the UK and Germany. How has this developed?

This country is—fortunately so—a country with a significantly high percentage of clinical trials; more than 400 were launched in 2015 alone with great support from hospitals and patients. Over

recent years, the quality of clinical trials conducted in the Czech Republic has increased significantly, as has the number of patients participating. Of course we notice strong competition from western Europe, however we are in the pole position to become the clinical trials hub in central and eastern Europe (CEE): a recent directive, jointly established with the ministry of health and the hospitals, creates the perfect environment for clinical trials: the speed and transparency the Czech Republic offers is unique in regional comparison and we're a society in which the cooperation of industry and medical professionals is of the highest standard!

How has this impacted domestic innovation capabilities?

There are numerous cooperation initiatives within the industry itself and local academia. We have a memorandum of understanding with the Czech academy of science, as well as the Czech technology agency. Together we publish all possibilities of cooperation through the Czech academy of science linking the industry with local scientists. We have already established four consortia's focusing on neurology, multiple sclerosis, muscular dystrophy and on ebola research. We witness growing interest within academia to cooperate with the industry, we established a partnership with the Charles University and the University of Brno focusing on exceptionally well performing PhD- and postgraduate students actively communicating the benefits their work in the industry can have on society and Czech patients.

What are your proudest achievements that showcase how you and your members have improved the overall health situation for Czech patients?

We really had an impact on patient organizations. As the patients are our main concern, we sensitively improved the role the patient organizations inherit, hand-in-hand with the ministry of health. Not in a way to steer or direct the patient organizations, but to enhance their self-capacities, so as to enhance the benefit for the patients!

What's more, I am confident that we found a way for the whole system to become more transparent; in particular through the online catalogue. Furthermore we focused on developing an internal communication strategy to further create synergies in between all my colleagues, significantly contributing to creating a stable market! Internally it supports 'seeing the light at the end of the tunnel', we can now live with all remaining obstacles as we achieved to establish a framework in which the time needed for market entry and market access is predictable and allows analysis of the number of patients that will benefit from the innovation, which is to be brought to the market.

The minister of health introduced the Health2020 vision at the beginning of his term. How can innovative pharmaceutical companies support ministerial efforts to raise overall public health?

We will contribute in two main areas: prevention and providing better healthcare in the context of the demographic change we witness in the Czech Republic. We aim to find a balance of in between all stakeholders that will fit into the national strategy on health 2020; that includes further developing scientific societies and patient organizations so that all voices are heard appropriately. As mentioned earlier, all stakeholders follow the same goal—the benefit of the patients—and I strongly advocate that together we can achieve more.

The recently launched counterfeit directive will consume a significant amount of our capacity. It foresees us to directly intervene between pharmacists and patients. That’s a first in our industrial history – nonetheless a topic of top priority to us!

Another major concern for us is to further enhance transparency of the system. What we have been learning in the process of establishing the online catalogue is, that we need to further include medical professionals in our negotiations and our pathways of finding a solution for transparent healthcare. An excellent self-regulation platform, analogous to the one established in the Netherlands, is my dream and my ambition! The difficulties we encountered in achieving the current disclosure of information was the result of insufficient communication.

Overall I look positively towards the future, I am confident that we can achieve our goals and ambitions aligning with health 2020, thus further helping Czech patients!

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