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Pharma companies in the Czech Republic grow by double-digits every year. At first, they encounter many difficulties to access the market, but once they achieve that, they grow very fast

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Jakub DvorÌ?aì•cÌ?ek, CEO of the Czech Association of Innovative Pharmaceutical Industry (AIFP), describes the thorough review of the reimbursement scheme the association has worked on alongside other key stakeholders in Czech healthcare and evaluates the major change this will bring in terms of access to innovative medicines for patients. Furthermore, he emphasizes the significant role of an open platform for discussion and negotiation whilst sharing some of the outcomes of the â??Innovation for Lifeâ?• study, which portrays the major benefits that pharmaceutical innovation can bring to the Czech Republic in the long run.

Having been CEO of the Association of Innovative Pharmaceutical Industry (AIFP) for over eight years, you deeply understand the Czech healthcare ecosystem. What do you identify as its main problems and priorities?

From the board of the association and our member companiesâ?? insights, we realized that the system was not suitable anymore to get new therapies to the market. For this reason, we spent the last two years working jointly with the Ministry of Health, the State Institute for Drug Control (SUKL), medical scientific societies, payers and patient groups to review the system and create new legislation that will enable innovation to reach Czech patients. We are currently at the end of the inter-documenting procedure with the MoH and are moving to the final discussion before the

proposal reaches the parliament.

At the moment, besides regular reimbursement, there is the option of reimbursement on an individual basis for innovative products. This way, even without the new legislation in place, patients can get the most advanced treatments. The problem is that these need to be approved one by one, generating a disbalance in market access.

Usually, highly innovative treatments are not considered cost-efficient by the regulatory agency and are therefore refused. Consequently, the Marketing Authorisation Holder (MAH) stops the process. However, companies can go back to payers for a special agreement, and with this agreement in hand, to the SUKL, who will accept the treatment even though it is still not considered cost-efficient. After the 2+1-year temporary reimbursement period ends, there is the possibility of receiving permanent reimbursement.

Within the â??Innovation for Lifeâ?• study, which focuses on nine therapeutic areas that illustrate the development, progress and impact of innovative treatments, you emphasized that pharmaceutical innovation brings major benefits on an economic, demographic and social level. Can you highlight some of the studyâ??s further outcomes?

We designed the â??Innovation for Lifeâ?• study combining data from the Institute of Health Information and Statistics of the Czech Republic (Ã?ZIS), run by Professor Ladislav DuÅ¡ek, data from our statistics department, from the Czech Statistical Office, and the Ministry of Labour and Social Affairs. The outcome is a very detailed review that shows that innovative medicinal products cannot be seen as a one-off expense, but rather as an investment. New therapies free people and the system from special assistance, disability grants, and so on, and bring them back to work.

Ten years ago, there were fears that biologics would destroy the system by monopolizing all the funds and resources in the healthcare system. It did not happen. On the contrary, they brought advantages to people with serious diseases, enabling them to get back to living a normal or semi-normal life.

What is the scope of innovative pharma companies in the Czech Republic, i.e. what benefits do they find in the countryâ??s ecosystem?

Pharma companies in the Czech Republic grow by double-digits every year. At first, they encounter many difficulties to access the market, but once they achieve that, they grow very fast.

Patient access is relatively high, the centres are well-funded and, despite it being a slower process than the European average, innovation is here. Furthermore, there is centralized care, which covers the areas of oncology, dermatology, and neurology, and has been growing by more than 10 percent annually for the last ten years.

Of course, it would be great to be in Germanyâ??s position, where the drug takes 100 days to reach the patient, but our GDP is lower, and our economy is weaker.

How do you support your member companies to reach agreements with health authorities?

Each company needs to find its way to reach the agreement. We are here to shape the system. Our role is to work on the methodology and the legislation. Yes, it is a demanding process. Nonetheless, the system provides even the most innovative treatments to patients.

The goal is to simplify the scheme to accelerate the process of market access for orphan drugs and some special therapies. However, at the moment, even if it is not in a regular system, patients can receive treatment through Paragraph 16, and this is what matters the most. This is how breakthrough therapies such as CAR-T reach the Czech patient.

How has this dialogue evolved since Adam VojtÄ?ch was appointed Minister of Health?

Mr VojtÄ?ch has a unique and refreshing way of thinking and working. He is not a doctor, nor has he worked for a hospital before. By profession, he is a lawyer, and he gained understanding about the system whilst working for some time as a healthcare specialist for the Prime Minister. This allows him to work alongside all stakeholders without any prejudice and to create an open platform for conversation and negotiation. He is very aware of the fact that in the end, we all work for the patient.

What have been some of the biggest changes since we last saw you in 2016?

A lot of investment has happened since then. Companies like Novartis, MSD or Pfizer invested in establishing local hubs here in the Czech Republic â?? not only as service centres but for R&D activities, too. Novartis and MSD have recruited around 2,000 and 1,500 people respectively in the last few years.

How would you assess the Czech clinical trial landscape?

Per year, CZK 1.7 billion is invested and 21,000 patients are being treated through clinical trials.

The approach is positive and the percentage of clinical trials per capita is high. However, the number of patients, as well as the amounts invested, are slightly declining.

The number of clinical trials â?? which is still seeing constant annual growth â?? needs to accelerate to compensate for this decline.

What are some initiatives fostering innovation in the Czech Republic?

Some Czech universities and hospitals participate in the Innovative Medicines Initiative (IMI), a public-private partnership that aims to speed up the development of better and safer medicines for patients.

For the second round of calls for proposals, led in cooperation with the National Academy of Sciences, there are ten research projects for which the local scientists are involved in research with big pharmaceutical companies.

What keeps you motivated after all these years at the AIFP?

It is an extraordinary opportunity! This job is like riding a rollercoaster: you never know what the next curve is going to be. It gives me the chance to combine management, analytical work, public affairs, and public relations, as well as to speak to all stakeholders of the system directly.

Besides, seeing results is very gratifying. If the new legislation gets approved with effect at the end of 2020, I will be completely happy.

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