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Martin Balada and Kateřina Podrazilová from the Association of Health Insurance Companies of the Czech Republic (SZP ČR) give a thorough insight into the current dialogues surrounding pricing and reimbursement, set to deeply impact access to highly innovative and orphan drugs in the country. Furthermore, they evaluate the uniqueness of the Czech multi-insurance structure and reflect upon the complexity that lies in finding the balance between accessibility, efficacy, and sustainability in the Czech Republic.

Could you introduce our audience to the Association of Health Insurance Companies of the Czech Republic (SZP ČR)?

Looking backward, the association was first established in 1993. Back then, there were many insurance companies in the country which required a platform to facilitate communication between them. In 1997, the name of the association was finally settled as the Association of Health Insurance Companies of the Czech Republic (SZP ČR), as an evolution from the first association in

1993.

While we used to have over ten members, and in 1995 we had as many as 17 members, today we have six, including all of the country's insurance funds except the General Insurance Company (VZP), which is independent from the Association. Through these six insurance funds, we cover 42 percent of the market of the Czech Republic, which is roughly 4.7 million clients.

The multi-insurance system is a particularly unique structure in the CEE region. Can you discuss the impact it has on the Czech healthcare system?

It is a unique system indeed. We think that, even though it is more complex to govern than other European systems, its robustness makes up for this. It is effective and works for Czech citizens. Despite there being pressures to lower the number of funds, among some other governmental interventions, we believe that it is less fragile than systems with a single insurance company. Proof of its competitiveness is its stability: it has been running for over 25 years.

What are the association's current priorities?

There are currently two major topics that stand out and occupy the majority of our time. Firstly, we are in discussions with the Ministry of Health regarding reforming primary care as well as other care services. Secondly, at the end of each year, the negotiations for next year's Reimbursement Decree need to be finalized. Some big changes are being implemented in Act 48, which is crucial for insurance companies.

Moreover, an important part of our agenda are the proceedings between the association's drug committee and the State Institute for Drug Control (SUKL). Additionally, there are risk-sharing negotiations for newly reimbursed drugs, discussions about bringing new molecules to the Czech market, and conversations with manufacturers around innovative therapies such as gene therapy.

What changes will the amendment of Act 48 bring to the system?

Although the final wording is not ready yet, several changes are expected.

One of the main concerns for insurance companies is the so-called "Rights of the Clients" section, which refers to a special process in terms of non-reimbursed care – Paragraph 16. In this context, the process will revolve around providing extra services for our clients.

Moreover, there will be amendments to the current pricing and reimbursement process, which we have had for approximately ten years and is not suitable anymore. It needs to undergo robust changes.

Within the pricing and reimbursement law, we are putting together a new appendix about medical devices.

Cooperation is the key to advancement. The Ministry of Health has the leading role in this, supported by insurance companies, care providers, manufacturers, and patient groups. These changes will deeply impact all the clients of our insurance companies.

How do you advocate to defend the common interests of the insurance companies and their clients?

Our role at the association is to advocate for our six member companies. The majority of our member companies operate all across the Czech Republic, while two have more regional positions.

While we do not directly advocate for the clients of the insurance companies — that is the role of the insurance companies themselves — we make sure to help them in finding those who can assist them.

We take care of any problems related to legislation or that require communication with the media. Sometimes, as one may imagine, it is difficult to find consensus: the approach and size of our six member companies are different, and thus, their problems too. We act as a platform of discussion, trying to get a better understanding of their issues and, once we find consensus, we express it as one joint opinion from all the member companies.

What are the most crucial factors shaping the dialogue around pricing and reimbursement with the authorities, particularly with the State Institute for Drug Control (SUKL)?

The most fundamental factor today is a new vision on how to finance extremely expensive care.

We have special rules for highly innovative drugs, which is an exceptional legislation within Central and Eastern Europe. In the Czech Republic, highly innovative drugs get 36-month-long temporary reimbursement. After that period, the intention is for the product to get permanent reimbursement, which is challenging from a pricing perspective.

The desired adjustment for this drug segment is to lengthen the temporary reimbursement period to five years. The first step to achieve that is to gather more in-depth information regarding the patient volumes, how long they stay on the given medications, and so on, in order to get a 360-degree view on the needs to be addressed. For this, as the information available now is far from enough, we need evidence from registries. The data we can retrieve from there might not be broad but is surely significant.

In addition to this, a new approach for orphan drugs referred to as a “third way” is being discussed to tackle the lack of progress here. Orphan drugs are expensive and aimed at a limited number of patients. However, medical necessity is very high. Today we have less than 30 orphan drugs in the Czech Republic, half of which get reimbursement regularly. This means that regular reimbursement is not an unrealistic nor unreachable goal.

The issue lies in the patient volumes. Taking cystic fibrosis (CF) as an example, we see that there are very few patients — just over 600 in the Czech Republic — and medicines are extremely pricey. Nonetheless, we need to find a solution to these kinds of cases. It is not only about one illness: there are over 6,000 rare diseases. For some of these diseases, therapies can extend the patients’ lives and, in some cases, even cure the disease; for others, therapies can only improve symptoms. The broad range of orphan illnesses that there are brings even further complexity into the equation – from those that can end the patients’ lives to others that one can live with despite it being unpleasant. To apply the same process to such singular circumstances is difficult.

The new legislation for orphan drugs proposes the existence of an expert committee with the right to judge the importance of a certain medicine being reimbursed based on the highest interest for society, something touched upon in paragraph 17.2 Act No 48 of the Czech law. Public interest covers three pillars that are particularly difficult to balance: accessibility, efficacy, and sustainability. If the legislation is put into place, which we expect to happen in 2021, it will be the task of the commission, formed by experts, patient groups, the Ministry of Health and the insurance companies, to weigh the different pillars and make a decision.

Can you share any success stories about how cooperation between insurance companies and the association has contributed to accelerating access to treatment?

It is very expensive to treat spinal muscular atrophy (SMA), and, shortly after registration, the drug must go under proceedings to get reimbursed, which takes time. The patient, of course, wants and needs the treatment as quickly as possible.

After dialogues with the expert committees that took into account the patient’s profile and the level of urgency of providing the treatment, we got back to the manufacturer to negotiate the price, the exchange schemes, the financial caps, etc. and succeeded. This was a difficult situation. However, we managed to deal with it within a few months – faster than the State Institute for Drug Control (SUKL), where the request for pricing and reimbursement remains untouched.

All our negotiations and decisions are based on public interest and considering the before-mentioned critical pillars: accessibility, efficacy, and sustainability. In this sense, we have to be careful as it is hard to predict what the system can absorb. The question that arises is: should we pay an extreme amount of money for one patient or the same amount for diseases that affect many people? It is tough to rate.

Even though we have a system for setting pricing and reimbursement for medicines, we believe that it is important that we keep seeking ways to bring care to our clients as fast as possible.

What is your vision for the association moving forward?

In the Czech Republic, it is mandatory to pay the health tax and, while citizens have to pay even when they are healthy, this ensures that quality care will be there if they ever require it.

We have faced challenges when it comes to enabling innovative and expensive therapies. Thus, our vision for the future is to keep looking for solutions to finance new drugs that can add value to the Czech healthcare system and, hence, save and improve the lives of more patients.

We think that the competition between insurance companies is the motor to move forward and to continue to strengthen the system.

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