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Tomáš Dolezal, president of the International Society for Pharmacoeconomics and Outcomes (ISPOR) Czech Regional Chapter and director of the Institute of Health Economics and Technology Assessment (iHETA), gives an overview of the missions and goals of these two institutes and the pivotal role of health technology assessment (HTA) in the healthcare decision making process. Whilst analyzing the Czech healthcare ecosystem Dolezal exposes his concerns about the lack of health literacy in the Czech Republic and outlines how the country collaborates with the rest of Europe.

Can you give our audience an overview of the iHETA and the ISPOR and what their main priorities are?

For both iHETA and ISPOR, the main goal is to promote the principle of Health Technology Assessment (HTA), in order for the regulators to know how to base the reimbursement level and to help the decision-making process. The key approach in the era of resource scarcity is to ensure value for money across healthcare interventions.

We are also promoting education. For example, iHETA has ten years of experience in educational programs about Health Economics, Pharma-Economics, and outcome-based research. We deliver these courses to between 120 and 150 people at the beginning of each year. Educating people

from regulatory agencies, insurance funds, academia, patient groups and pharma industry is a never-ending work, but a priority within the association.

We are also trying to support research; this is something significantly missing in the Czech Republic. For instance, at ISPOR Czech Regional Chapter, we publish several peer-reviewed impactful publications every year on different health economics studies and pharma economics studies, among many others. These various publications aim to help the decision-making process and to increase the level of our work.

How do iHETA and ISPOR differ from each other?

Firstly, iHETA is a nonprofit organization that I founded 13 years ago. In this capacity, I have the chance to work with a lot of collaborators in various fields, such as health authorities, research institutes, communication specialists, etc.

Then, ISPOR Czech Regional Chapter is focused on health economics, and is a part of global professional organization ISPOR (ispor.org), gathering people from different institutions, such as pharma companies, MedTech companies, Health Technology (HT) agencies, professional societies, patient groups, etc. Every year we organize a conference to showcase the results and achievements from our focus on developing HTA in the country.

In addition to your duties at iHETA and ISPOR, you contributed to the foundation of the "Open Healthcare" Information Portal. Can you please share the portal's vision of making healthcare better and fairer?

One of the main issues in the Czech Republic is the low level of health literacy. The Organization for Economic Cooperation and Development (OECD) and the European Commission underlined this problem ten years ago already and very little has changed in the country.

Czech patients are not aware of the real cost of the healthcare ecosystem, and the majority of them still think that every service is for free. Indeed, the Czech Republic has one of the lowest levels of out-of-pocket payments.

Thus, this is why we decided to open this New Information Portal. The purpose of this portal is to provide to the Czech citizens complicated data in an understandable form. For example, information about the healthcare system, how it work, who are the key personalities involved, what

are the main decisions, what is the financing, what are the statistics, and how digitalization is impacting them and altering the system.

However, this portal has been quite difficultly to brand as we do not have the budget for PR campaigns. However, we are collaborating with patient organizations and healthcare publications, and next year we will be present on social media.

On the one hand, looking at digitalization, we notice that there is an issue with the eHealth project. Although eHealth is growing among the Czech society, some are not using this technology properly, because they are not able to correctly search for information.

On the other hand, there is a low level of quality information available to the public, which the current Minister of Health promised to address by spreading more information through different channels regarding the quality of healthcare providers, procedures in each hospitals, and different specialties, in order to help Czechs navigate through the system.

How would you assess your relationship with the government and the regulatory body State Institute for Drug Control (SUKL)?

For 14 years, we have been working with the SUKL by providing National Health Technology guidelines that serve as a reference for the implementation of the official methodology and transparency standards of the SUKL.

Thanks to our long-term cooperation with the Ministry of Health (MOH) and the SUKL, we are also involved in the preparation of legislative changes. For example, last year, we were part of a working group which proposed a new law for orphan drugs and their reimbursement, and we were consulted by the Ministry, the SUKL and by health insurance companies. Through this cooperation, we implemented multicriterial decision-health principles which aim to improve patient access for these orphan drugs.

Another example of cooperation with the MOH and the SUKL is through education. iHETA and Czech ISPOR are providing educational programs for people working for health insurance companies, SUKL and the MOH alike.

In terms of outcome-based research, how is this shaping the dialogue around pricing and reimbursement with the SUKL?

Outcome-based research is also included in the HTA process for drug submission, especially regarding the data coming from the clinical registries. Moreover, since 2008 it is possible to grant conditional reimbursement, which is called Managed Entry Agreements (MEA). If the drug is highly innovative, and is not fulfilling the requirements for cost effectiveness thereshold, then it becomes possible to get temporary time-limited reimbursement. To benefit from this, the company has to collect the data, which is called Coverage with Evidence Development (CED), a topic currently discussed extensively at the European level. In the Czech Republic, we already implemented this approach ten years ago. This kind of process can enable a lot of new and innovative medicines to reach the patients faster.

Moreover, the registries are also a reliable source of information. These value-based outcomes are often incorporated in some of the biggest disease registries in the Czech Republic, which are regularly collecting data from around 50,000 patients. In addition, there are also several small registries, for example rheumatology, dermatology, etc. which are also reliable sources, and that iHETA is trying to showcase though our different publications.

What are the main concerns that the healthcare system has when it comes to the implementation of new treatments and technologies?

Firstly, the problem is the legislation barrier. Our system has been totally rebuilt in 2008 with a simple idea: “one size fits all”. There is one procedure for all types of treatments. However, the Ministry of Health is now trying to change this system with a new legislation proposal aiming to implement specific pathways for specific types of drugs. For example, orphan drugs are not individually treated, but under this proposal, a special pathway would be created, and the patients’ voice carry more weight. This legal barrier has also been observed for the implementation of new oncology treatments, such as gene therapy and cell therapy, which are extremely expensive treatments. Over the last two years, the Czech Republic has achieved big advances in terms of patient advocacy, and we should influence other CEE countries in this movement.

The second problem is budget scarcity; indeed, these highly innovative yet costly medicines are quickly increasing the country’s healthcare expenditure. Looking at healthcare financing in the Czech Republic, the healthcare budget is based on yearly negotiations where all the stakeholders of the healthcare ecosystem are involved, and everyone is striving to increase their own budget. So, the implementation of new innovative medicine is viewed as a strange animal. There is a huge pressure from traditional institutions and healthcare stakeholders (i.e. hospitals) to decrease the

budget for financing innovation. The big issue is also that in the Czech Republic the healthcare and social care budgets are separated.

Another problem is that there are no long-term outlooks. We are not able to do prospective planning in our health and technology assessments as there is no horizon scanning implemented. We do not look at the next three to five years in terms of technological prospective, even though these procedures for horizon scanning are often implemented by HTA agencies across Europe.

How does the role of the HTA in the Czech Republic compare to that of other CEE countries, and how do you collaborate to with your neighbours?

From the perspective of a mid-sized European country like the Czech Republic, we are not much involved in the global planning of clinical trials. However, we have effective and high-quality infrastructure, so we can deliver high-quality outputs which makes us attractive for clinical trials. Nevertheless, the Czech Republic is too small to be used by global pharma at early stages of clinical development before the European Medicine Agency (EMA) or the Food and Drug Administration (FDA) are approached.

That is the reason why iHETA supports the common joint assessment project at the EU level stemming from the EUnetHTA initiative, aiming at more common cooperation between the different HTA agencies across Europe. This should lead to a common clinical evidence assessment as well. To that aim, we are already working with our sister association in Slovakia in order to have a bigger voice on the matter of HTA principles during the decision-making process.

We already cooperate with ISPOR Slovakia Chapter, and more broadly with the ISPOR of the Central and Eastern Europe (CEE) countries, but I would like to see more cooperation at the European level.

Another example of strong regional cooperation is the BeNeLuxa initiative. In the same way, the Czech Republic, Slovakia, Poland and Hungary should work together because these countries face a similar situation and this regional cooperation might encourage horizon scanning, for instance.

What aspect of the Czech Republic’s healthcare system would you say you are the proudest of?

The high level of availability and quality in our healthcare system should be showcased better. However, we are not yet measuring the quality of our services regularly, which should be a big part

of the picture and future challenge. We have quite an intense network of hospitals and physicians, which are readily available. Everyone can benefit from universal healthcare, which is essential, and a big achievement in the region.

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