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Judit Bidlo, deputy director general of price support at the Hungarian National Health Insurance (NEAK), shares her insights on the healthcare system's developments over the last three years, the rationale for the restructuring of the organization, its ongoing collaborations with pharmaceutical companies and other institutions, and outlines the strategic objectives for the future.

Can you introduce the rationale for changing the name, and how this has shifted the responsibilities of the organisation (formerly known as OEP)?

The change in nomenclature conveyed an internal reorganization and shift in governance. To solidify this, the OEP was changed to incorporate "national", to outline a more impactful role within the country, thus NEAK.

This was part of a complex, large-scale reorganization of the regulatory bodies and all government institutions since 2016, of which, not just the epidemiological, pharmaceutical centres and OGYÉI was affected, but other authority tasks as well – even including the issuing of new ID cards. Furthermore, the national health insurance has a closer relationship with the Ministry of Human Capacity, as some functions are integrated with them. The change was most pertinent in the administrative functions and the relationship with the people. These functions have been centralized, which previously were in separate organizations. Hence, in rural areas, regional

governmental offices have become more streamlined.

How has the healthcare landscape evolved in Hungary or any big major trends that can be seen?

The most noticeable change is the speed of information sharing by companies and the amount available to the patients. This has improved transparency within the healthcare ecosystem. As soon as there is a new product registered in the EU, within days, patients who are eligible for this treatment are made aware of it. Inadvertently, the velocity and scale of reimbursement processes have increased as well. This is a key challenge: NEAK needs to find solutions to reconcile the number of new products registered with a reimbursement system that can adapt to this new influx of registration.

The government implemented a three-step procedure to improve the healthcare environment: reorganise the institutions, invest in infrastructure, and increase salaries of medical professionals. The hospitals have different needs and challenges than NEAK. Through the European Union, there are funds available to reinvest in infrastructure and equipment. However, this unfortunately has no impact on the salaries of medical practitioners or the centres of Hungary, as the investments necessary are more substantial. The third step was to raise salaries to curb the brain drain Hungary is experiencing and incentivize medical professionals to stay in the country.

What challenges is NEAK facing with reimbursement and innovation?

Under the auspice of NEAK, medical devices, as well as medicine, are registered and reimbursed. Roughly 10-12 years ago, medical devices were a more convoluted subject in the context of reimbursement. There was a bigger gap between a bandage and a bionic arm, than aspirin and a cardiovascular drug. However, with the advancement of medicine and the healthcare trend moving to personalized care, that gap has increased. Nowadays, the medicinal field with the onset of gene therapies and molecule discoveries has become more complex. Additionally, the distinction between medical devices and medicine in certain areas are blurred, which creates incongruities.

Hungary’s insurance system is state-owned which needs to cover social and healthcare needs, ensure horizontal and vertical equity while managing taxation. Patients are immediately aware of these new therapies and devices’ availability and want to have them reimbursed by the state. However, because everything runs through a singular system this slows down the process by which

innovations are categorized. For each drug there is a different reimbursement system: biologicals are classified differently than high priced, hypertension, or oncology drugs.

Next to the normal reimbursement process for drugs and medical devices, there is also the individual patient-based reimbursement system. A patient can request personally a repayment on a certain medication. This has been introduced as a relief system, but now this became a pre-reimbursement category, which grants patients much earlier access to these drugs than the reimbursement application from companies. This compassionate use of products is financed by the pharma companies themselves.

How do you ensure different medical technologies' know-how is analysed and transmitted?

NEAK collaborates closely with different authorities and committees comprised of doctors. There is a defined process that starts with the evaluation of the dossier submitted by the company to apply for reimbursement, which is then engaged by the medical chamber, assessment of the product and technology with OGYÉI, and the ministerial decision being the final stage. If it is a generic or a low-priced drug, NEAK will publish it. However, if it is more complex or high priced, the reimbursement publication will be done by ministerial decree.

To what extent is NEAK collaborating with the industry to find solutions for reimbursement pricing?

Due to the setup of the healthcare system, the only way to have successful reimbursement pricing is through risk-sharing agreements. Hence, NEAK is collaborating with the industry frequently and has become proficient in setting these agreements up. It is also important to have a transparent reimbursement cycle that is communicated to all stakeholders and to increase savings with generics or biosimilars. The accrued savings will allow innovations to be included in the reimbursement system.

If the generics and biosimilars are proven to be effective and safe for patients, by the registration authority (in most of the cases by EMA), NEAK must make them available and reimburse them. There is a need to create competition with the generics and biosimilars environment to create a competitive market. Furthermore, spending is a long way from being optimized as 90 percent of pharmaceutical spending is allocated to 15 percent of patients. Comparatively, there are no pricing

policies defined by the EU, whereas Hungary uses at least 11. Year on year there has been an improvement to include innovations, and through engaging all stakeholders, this process allows the availability of new drugs for patients.

The reimbursement policies need to be separated from the economic governance. Pharmaceutical companies should invest in new drug development, as this benefits the whole ecosystem. However, within the reimbursement framework, the efficacy of a drug takes priority. The Ministry of Innovation and Technology are responsible for formulating a strategy for reimbursement of innovations through the governmental system and not the healthcare system. In the case of the generics, we cannot privilege certain companies, based on characteristics, if there are similar or better-suited drugs available in the market.

Does NEAK contribute to raising awareness with doctors about the generic and biosimilar products and their importance?

NEAK is engaged with doctors and spreading information about generics and the reimbursement process. For biosimilars the main process is through tenders. In the case of biosimilars, doctors need to be made aware of the characteristics and the benefits of these new products compared to existing ones. Through conferences, we update doctors on the newest biosimilars, and each field of expertise has a different adoption rate. Gastroenterologists committees were first willing to use biosimilars, haematologists followed suit shortly after, but oncologists are still sceptical. There are still some challenges ahead in this field and some good deal of convincing to do.

Is there a possibility to create a value-based healthcare system in Hungary?

It is not a possibility, but a necessity. The European Union published recommendations on how to implement this, which is a great step forward as there is no ideal reimbursement system in place: no one knows how to manage it perfectly. However, the biggest challenge with such a healthcare system, rather than cost-based, is defining and quantifying value. The added value in oncology is easy to measure, as the efficacy of the drug is linked to the prolongation of a patient’s life. However, this is more difficult to establish in the field of rheumatology for instance. Therefore, it is important to define whether incremental innovation can be considered as value or only a significant improvement of the survival chance can. These are questions that are at the heart of this new healthcare system, and which have severe ramifications for the patients but also the

supporting ecosystem’s governance framework.

NEAK has made huge investments in databases and has the second largest in the country, after the tax authority. At his stage, it is quantitative rather than qualitative, but it remains extremely valuable as it produces real-world data and efficacy. This tool will be further developed and help implement the added value healthcare system. There is an ongoing project to create a unified health record with the collaboration of AAEK. The electronic health record will be combined with NEAK’s database to create a cloud-based central registry which can be accessed by all healthcare stakeholders.

What are NEAK’s priorities in the upcoming years?

The main priority is to increase the life expectancy of the Hungarian people, as it is still on average five years lower than other European countries. This requires investing more efforts into improving the data analysis regarding real-world evidence for medication but also hospital treatments: define the areas of improvement and understand what is effective with more accuracy. Additionally, there needs to be more discussion regarding the expectations and the needs of patients, but also industry players and medical professionals, from the insurance and reimbursement authority. Especially when defining which high priced medication, which are aimed at small patient groups.

What is your final message to the healthcare industry stakeholders in Hungary?

It is important to identify and define the areas of unmet needs, which are the basis of value. In collaboration with the industry and companies, defining value will not only help to create a value-based healthcare system, but the insurance and reimbursement systems will be better understood and implemented.

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