Interview: Dr. Judit Bidló – Head of Pricing Support, OEP, Hungary

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Providing universal health coverage to the nation's roughly 10 million citizens, Hungary's National Health Insurance Fund (OEP) has one of the most comprehensive and complex structures in Europe. The organization's Head of Pricing Support, Dr. Judit Bidló discusses the current mechanisms governing pharmaceutical reimbursements in Hungary, while also identifying the primary limitations and pressures faced by the system.

As introduction for our readers Judit, can you please provide an overview of OEP's function and scope in Hungary and also describe what you are focusing on now as head of pricing support?

In Hungary, we have a state-owned universal health insurance system called the OEP—completely financed through mandatory tax contributions from employers and employees. Unfortunately, at the current state, these contributions only cover approximately 50 percent of the country's healthcare spending, so the fund has been perpetually underfinanced—leaving the industry to compensate for the deficit.

From a drug reimbursement point of view, we have one of the most complex and comprehensive regulatory frameworks in Europe, which aims to cover all medical and medicinal needs for society—even when it comes to hospital and outpatient care. One of the primary challenges now is

accommodating the growing premiums associated with increasingly innovative therapies and assessing alternative financing methods to introduce them into the system.

Compared to 10 or 15 years ago, the drug mixture has completely changed. The products on the market today are of course much more efficient, but also much higher in price, and correspondingly, it’s become much more challenging for payers to cover them—especially with limited resources. It is crucial now more than ever to define specific outcome criteria and appropriate benchmarks to ensure that drugs admitted into reimbursement perform as expected, else we risk the opportunity costs of not covering other therapies that could’ve save a patient’s life. And of course there are more essential and common classes of drugs such as anti-hypertension or anti-cholesterol, but the majority of them are generic; so, we don’t face as many challenges in covering this product class.

Currently, under the national health insurance framework, what are the primary policies governing the reimbursements of pharmaceutical products in Hungary?

First off, companies can only file reimbursement for those products that already have reimbursement in at least 3 other reference countries in the EU. Countries such Germany and the UK automatically grant reimbursement approval upon receiving marketing authorization, so it’s the third country that might serve as a potential hurdle for some companies. But that also means that level of international experience in dealing with a new indication can be quite limited in certain cases, so we’re constantly in discussions with our counterparts across Europe to help mitigate the lack of information and real-world evidence through cost-sharing agreements.

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The scope of our role as the national health insurance fund is dictated by the health policy, which aims to prioritize certain areas such as oncology or pediatrics. The objectives are specific to Hungary, but of course we can leverage international comparisons to help push our health agenda forward in the right direction and ensure widespread access to the proper medications.

Since there is only one health insurance fund, all the data is centralized, giving us the unique ability to analyze the figures and see how efficient exactly our reimbursement system is. Based on this analysis, we can then reformulate and provide new possibilities in the future.

Speaking of efficiency, what is the average time that a company can expect to wait for a decision regarding the inclusion of a product in reimbursement?

There’s actually a common misunderstanding because we’re not the only ones deciding whether or not products are included in reimbursement.

When it comes to the simplified procedure, which is often the case for generics, the process is quite straightforward and should only take 10 to 20 days—granted the price is in line with regulations.

The first generic product submitted has to be priced 40 percent lower than the original, and if this criteria is met, then we’re able elicit a decision quite quickly.

The extended timelines begin when considering submissions for new active substances, indications, or high-level reimbursement, with decision deadlines officially stated as 90 days, but sometimes taking more time.

We have 2 major reimbursement categories: normative and indication-based. The normative says that in every registered indication, every doctor can prescribe it within the certain reimbursement level that we defined in the regulation. Whereas, for indication-based, the Department of Pharmaceuticals and Medical Devices within the Ministry of Human Capacities dictates the doctors who can prescribe these products, usually specialists, and also sometimes the centers as well. This aspect of the process is where delays can occur—particularly when considering more complex areas such as oncology or hematology. To put things in perspective, 80 percent of the applications going through the non-simplified procedure last year required ministerial decision.

We have a publicly available tablet on our website that every applicant can use to follow their product after we send it to the Ministry within the 90-day deadline. But because of the more variable and uncertain decision timelines after this point, many companies have begun utilizing an alternative route called the Named Patient Program, where the patients themselves file for drug reimbursements on an individual basis. This actually creates a huge hurdle for the OEP. For example, last year alone, there were 10,000 applications for the Named Patient Program. And its always much more difficult and resource constraining to elicit decisions on a case-by-case basis pertaining to only one patient at a time, as opposed to implementing one centralized reimbursement approval for one drug that appeals to the masses.

What are some of the main factors that might either delay a decision or ultimately deny a product from reimbursement completely in your experience?

To put it briefly, the level of uncertainty is perhaps the primary driver. If there is a new oncology treatment, for example, which can add 2 or 3 weeks to the current therapy with a slightly bit higher price, it is always very risky to have a decision whether we will reimburse it or not. I think the

Hungarian population is a little bit special in that aspect that if we start to reimburse something, there is no possibility to stop it. Hungarian people are very active in advocating for certain treatments, even if all other countries have chosen not to reimburse them. This is why the regulatory authorities have to very carefully evaluate cost-implications, therapeutic benefits, and also measure the potential health impact before making a decision. Essentially, we need information and some sort of financial guarantee that expenditure on a product will not exceed a certain threshold—particularly important from a budgetary standpoint.

On the other hand, there have been very successful financing programs for specific therapies previously, for example, hepatitis. The leaders in the area are AbbVie and Gilead, and all of their products are included in reimbursement, which are also supplemented with a countrywide register. The reimbursement inclusion happened within 2 months, mainly because if there's a treatment that can cure a patient within 12 weeks, then there is simply no question as to whether or not we will reimburse it. The questions start to arise when treatments have only incremental value, both in terms of price and therapeutic benefit.

Is there an appeal process if an application is rejected by the Ministry?

No. However, there is a rule that if it is denied because of the impact on the health budget, then there is an opportunity to resubmit the application without any fees. This is mainly because there is a possibility of more budgetary support at later stage that may or may not be able to accommodate a company's product submission. If the application has been refused or denied because it is not cost-effective or efficacious, then, unless in court, an appeal is not option and the company must start the process over again.

From OEP's perspective, what are the main considerations when negotiating the price of reimbursed products with manufacturers?

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We always first try to benchmark the prices against reference countries in Europe. In Hungary, the regulations stipulate that companies must price their products in accordance with the lowest prices across these reference countries. We then try to evaluate the product against other therapies within the same therapeutic area. If it is more of a "me-too" product than a real innovation, we directly compare it with other therapies already available on the market. If it's a real innovation and has real added benefit, then we conduct an extensive technology assessment to help us to define an appropriate price level. And we have an exceptional health technology assessment center that conducts comprehensive analysis on those types of submissions.

One of the challenges you mentioned before right now is introducing more high-level and innovative therapies into the system. How exactly can this be achieved?

We have different types of agreement and of course we are aware that there is an international price comparison in lots of the countries here in Europe. I know it's not the best way but it's very useful that there are some hidden agreements that can provide us rebate and hidden discounts which are not published in the website, so at the end we have to pay less to a certain product. Of course it is very directly linked to the population and we will provide this medication so if we will provide it to more patient, then we will have more discount but we can solve it in a hidden way so the other countries will not be aware.

Clearly the system is quite comprehensive as it is, but I'm sure it's not without its challenges. What would you consider the current limitations of the regulatory framework, and what is being done to address these limitations?

In instances where expenditures on a particular medicine exceed the planned budget, we cannot stop the financing, simply due to our obligation to the patients and ensuring a continuity of access. As policy makers are expected to adequately define the pharmacuetical budget in line with the populations' real needs, they usually plan the budget a little bit lower than expected.

The other limitation lies in the lack of flexibility in the budget act. Currently, we have separate budgets for outpatient drug reimbursement, tendered products, and hospital care, with absolutely no possibility to reallocate funds in between them. For example, if a new treatment came on to the market that could cure appendicitis, it's likely that we would not be able to immediately finance it through the limited drug budget. The hospital budget, however, still has some savings that cover this therapy, but we would not be able to utilize it for that purpose.

The government recently announced its intentions to integrate the OEP into the Ministry of Human Capacities. How will this impact the decision process?

There won't be any real changes because the task would remain. Somebody has to do the work—whether that's the Ministry or separate state agency. The standards of operations would of course change if we were dealing with a partially private entity, but that is not the case here—OEP will still be state run and owned.

What factors ultimately motivated you to work on behalf a state agency, as opposed to maintaining a career within the industry?

Previously when I was working within industry, I was typically only covering a handful of products at one time. Now, in my current role I'm dealing with over 2,000 products—each one of the same importance with a varied story of its own. So, the sheer complexity of this job and the breadth of experience that it entails have intrigued me. One day I could be dealing with oncology and then diabetes the next, while touching upon asthma in between. Working at a health insurance fund that has responsibility over an entire population's wellbeing requires approaching every day with a clear and tactile mind to look past the marketing message and evaluate in-depth whether or not these products have real value and can in fact improve patients' health outcomes.

Do you have a final message for not only all the industry stakeholders in Hungary but also our audience of international readers?

At the end of the day, the OEP strives to be transparent in all decision processes, maintaining clear and direct communication channels with all the pharmaceutical companies in Hungary. We certainly have many tools that we've implanted to provide as comprehensive coverage for Hungarian patients as possible, while also promoting a healthy and competitive business environment. Negotiations are never easy, but we incorporate a multitude of consideration factors before making any decision, without ever sacrificing the integrity of our system.

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