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Simplifying procedures and adapting to changing times is essential

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Diane Kleinermans leads the reimbursement commission at Belgium's medicines payer, the National Institute for Health and Disability Insurance (NIHDI). With Belgium currently undergoing a landmark reform of its reimbursement procedure, Kleinermans discusses the access picture in the country today, international HTA collaborations, and the delicate balance between maintaining the stability of the country's social security system while ensuring access to necessary treatments for all patients.

Could you please share the different roles you currently cover within the Belgium healthcare sector and in the NIHDI?

I am currently serving as the President of the Commission for the Reimbursement of Medicines in Belgium. My role involves overseeing the process of accessing and reimbursing new medicines, which I have been doing since the end of 2020. Additionally, I am President of the BeNeLuxA initiative [a cooperation between health services in Belgium, the Netherlands, Luxembourg, Austria, and Ireland on health technology assessments (HTAs), horizon scanning, exchange of strategic information and price/reimbursement negotiations – Ed.], which is an important aspect to note. I am also actively engaged in the reform of the reimbursement procedure, which goes beyond just the Commission for the Reimbursement of Medicinal Products (CTG). This ongoing

discussion and reform are crucial for the future of healthcare in Belgium.

Although I hold the chair position in the CTG, I personally do not conduct evaluations. The evaluation process is carried out by the internal experts of the National Institute for Health and Disability Insurance (NIHDI). However, I am heavily involved in the negotiations of managed entry agreements (MEAs) being a member of the working group responsible for these negotiations, which is another significant aspect of my role. MEAs allow a temporary reimbursement while collecting additional information about the health technology in question.

Prior to this position, I had extensive experience as an internal evaluator, conducting HTA assessments for the NIHDI for many years. Additionally, I served as an advisor to Maggie De Block, the former Minister of Health, specifically in drug policy, which provided me with a comprehensive understanding of the reimbursement process itself.

What are the most significant challenges that NIHDI's Drug Reimbursement Commission is currently facing and how might this upcoming reform help alleviate them?

Speaking about the reform, it is essential to note that the current procedure has been in place for over 20 years, since 2001. Although there have been amendments and additions to it over time, the procedure has become quite complex. It was adjusted to address new market challenges and emerging technologies. However, its design did not fully anticipate and accommodate the challenges we face today. We need to review and simplify the procedure to ensure it is capable of effectively addressing these challenges, including providing early access to patients in need, particularly for new types of technologies such as cell and gene therapies (advanced therapy medicinal products (ATMPs) as defined by the European Medicines Agency (EMA)) and combination therapies, which our current procedure does not adequately address.

Another important consideration is the "patent cliff" and "biocliff" phenomena in Belgium, where there is a significant decrease in drug prices when patents expire. We are nearing the end of this process, and it is crucial that we improve our ability to respond to this challenge. Funding is necessary not only for innovation but also to ensure comprehensive treatment options can be financed. Simplifying procedures and adapting to changing times is essential, as the current complexity makes it difficult for individuals to fully comprehend and navigate the details of the procedure.

Many of our interviewees have voiced concerns about the excessive length of the reimbursement process in Belgium which is far greater than many other EU countries with similar incomes per capita. What would you consider to be the primary causes of this phenomenon?

The lengthy reimbursement processes in Belgium are a result of factors that are partly beyond our control as an authority. The timeline for the procedure is clearly defined by law and typically takes a maximum of 180 days. However, this timeline can be extended by an additional 120 days if a management entry agreement is pursued due to inherent uncertainties. In other cases, the procedure may take longer because companies can request “clock stops” at different time points, which can last for a maximum of three months. These clock stops are initiated by the company and are not under our control.

Another factor contributing to the length of the reimbursement process is the introduction of a request for reimbursement, which is solely determined by the company. Once a medicine receives market authorization, it is up to the company to decide when they will submit a request for reimbursement in Belgium. Although we cannot influence this decision, we sometimes proactively reach out to companies to inquire about the delay in their request for reimbursement, particularly when there is a demonstrated medical need or when the medicine is of significant importance. However, the final decision to submit a request lies with the company itself.

If we compare this with the reimbursement scheme in the US where the first winner takes all, what kind of approach does NIHDI take in Belgium when it comes to distributing reimbursement funds?

In Belgium, our approach to distributing reimbursement funds is different from the “first winner takes all” scheme commonly seen in the US. While being the first in a particular class can provide advantages in terms of market penetration, it does not guarantee automatic reimbursement in Belgium. When we receive a request from a company for a new product with the same indication as an existing medicine on the market, we evaluate it based on certain rules. We assess whether the new product offers any added value compared to the existing medicine and in the absence of added value, we ensure that the budget implication remains neutral in terms of reimbursement. Therefore, it is not solely based on being the first, but rather on demonstrating possible added value and otherwise budget neutrality.

Do you consider the EMA's 'Horizon Scanning' to be a tool that can be utilized in reimbursement decision making or does it serve a more informative purpose? And might that change in the future?

At the moment, *horizon scanning* is primarily used as an informative process rather than a tool in reimbursement decision-making. However, the results of horizon scanning are considered during our evaluation process, especially when there are additional products expected to enter the market soon. We incorporate this in our decision-making process, although it is not yet well formalized. As part of the ongoing reform, we aim to improve the utilization of horizon scanning.

We have the International Horizon Scanning Initiative, which is a spin-off from BeNeLuxA. It has established databases and high-impact value reports in specific therapeutic domains. These reports help us assess the value of a drug, identify alternatives, and understand the uncertainties present at the time of reimbursement request. This information significantly influences the reimbursement decision and the level of reimbursement. Higher levels of uncertainty may result in the need for a managed entry agreement, which impacts the accepted cost of the drug based on the level of uncertainty.

As part of the reform, we want to establish earlier and more significant dialogue with companies based on the assessment and horizon scanning results. This dialogue would focus on addressing uncertainties through managed entry agreements. We would discuss potential approaches such as utilizing real-world data, additional clinical trials, or patient registries to address the uncertainties identified. This dialogue needs to happen early in the process to ensure timely resolution within the duration of the managed entry agreement. Starting these discussions towards the end of the reimbursement procedure is too late.

There seems to be a larger than average (or than acceptable) number of managed entry agreements being utilised in Belgium. What are your thoughts on this? Do you think the current levels of MEAs are sustainable going forward?

There are several factors behind the increase in the number of managed entry agreements in Belgium. Firstly, the early introduction of new technologies to the market has led to higher levels of uncertainty and limited data availability at the time of reimbursement requests. This makes it more likely to opt for a managed entry agreement. Additionally, there are significant budgetary and financial uncertainties, as well as a rise in the prices of medicines. Managed entry agreements serve not only to provide early access to promising medicines but also as a tool to control budgets

and ensure the sustainability of the healthcare system while meeting patient needs.

However, one weakness of the current managed entry agreement system in Belgium is the process of exiting these agreements. Initially, these agreements were intended to have a limited duration of three years, with the possibility of extension. However, some companies have found ways to prolong their presence in these agreements, using it as a strategy to maintain their official prices. They argue that they cannot exit the agreement due to the potential impact on their pricing compared to other European countries. This situation poses a challenge as it prevents a drug from transitioning to the regular reimbursement system.

In my view, this is a flaw in the current system. Discussions are underway as part of the reform to find a solution to this problem. It is important to address this issue because it is not reasonable for a drug to remain under temporary reimbursement for an extended period when there is no longer any significant uncertainty. The classical reimbursement system should not be temporary but rather provide a definitive and sustainable approach.

Earlier you mentioned the importance of data in reimbursement decisions. What is your view on how well constituted the data coming through in reimbursement dossiers is?

The quality of data in these instances can vary significantly. As the chair of the Commission for Reimbursement of Medicine (CRM), I review all the HTA evaluation reports prepared by our internal experts. We consider the quality and robustness of the data during the assessment process. Uncertainties in the data can arise from various factors. For example, a company may request reimbursement for a broad population, but the data provided may only be based on a specific subgroup. This raises uncertainty about the generalizability of the results to the broader population.

The long-term effects of a drug are also a source of uncertainty. We need to consider whether the efficacy and safety will be sustained over an extended period. Additionally, there may be uncertainties related to the eligible population for the drug. All these elements are evaluated during the HTA assessment, and comparisons are made with existing alternatives to determine whether the new drug offers better, equivalent, or inferior outcomes.

Accelerated pathways for drug approval present a challenge for reimbursement decision-making. These pathways often involve drugs that address significant unmet medical needs but have lower levels of evidence compared to traditional approval processes. This creates difficulties for payers in

ensuring the effective use of the budget. As part of the ongoing reform efforts, we aim to establish a better early access system in Belgium. Although we don't have all the answers yet, we want to review and improve the current system, prioritizing patient needs while also considering risk-sharing arrangements with the companies.

Ultimately, the patient's well-being and access to necessary treatments remain our priority throughout the reimbursement decision-making process.

When it comes to clinical trials, one possible decision criterion for the industry in selecting a location is how quickly reimbursement might be granted post-trial. Do you see a correlation between the reimbursement decisions made by the NIHDI and the new therapies in clinical trials in Belgium?

The industry's consideration of reimbursement timelines in selecting trial locations is a known argument amongst regulators. While I understand the importance of the pharmaceutical industry to the economy and employment in Belgium, as the CRM, our evaluation must remain objective. We cannot factor in such arguments during the evaluation process. The CRM provides a recommendation based solely on the objective evaluation of data.

However, it is worth noting that the final decision on reimbursement is made by the Ministers of Budget and Social Affairs, and they may consider various factors, including industry considerations, when making their decision. But within the CRM, our role is to maintain objectivity and base our evaluation solely on the available data.

Is there any final message you would like to deliver on behalf of the NIHDI?

I believe it is crucial to acknowledge that we are currently in a dynamic period of medicine and therapy development, presenting exciting opportunities. However, we also face the significant challenge of maintaining the stability of our social security system while ensuring access to necessary treatments for all patients. It is important for patients to understand that the decisions made regarding reimbursement are based on the best available information and aim to optimize the allocation of the budget to meet patient needs. While we strive for excellence, we recognize that perfection is elusive. Nonetheless, our commitment remains strong in using the resources at hand to serve the best interests of the patients.

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