Pedro Facon – Deputy CEO, NIHDI, Belgium

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Speaking exclusively to PharmaBoardroom, Pedro Facon outlines the scope and aims of the new medicines roadmap that NIHDI has recently presented to the Belgian Ministry of Health following extensive stakeholder discussions in 2022. In a wide-ranging and in-depth conversation, Facon describes his hopes for tackling the growing number and length of managed entry agreements in Belgium, the hot topic of budgetary confidentiality, and the increasing importance of data collection and analysis.

For those that are not familiar with the Belgium healthcare system, can you share what NIHDI is and what its functions are?

The National Institute for Health and Disability Insurance (NIHDI) (*Rijksinstituut voor Ziekte- en Invaliditeitsverzekering* (RIZIV) in Dutch, *Institut National d'Assurance Maladie-Invalidité* (INAMI) in French) is a Belgian social security institution, founded after World War II. As a social security institution, rather than a classic public administration body, NIHDI's governance is conducted by a board featuring representatives of employers, employee organisations, as well as public health insurers/mutualities. It is the second largest social security institution in Belgium, after pensions, and manages a sizeable EUR 50 billion budget across health insurance, (EUR 40 billion) and disability insurance (EUR ten billion).

It is interesting to highlight in the actual context that while disability insurance has traditionally been the ‘little brother’ to health insurance in terms of NIHDI’s operations, the growing number of people who are not able to work for long periods of time due to disability mean that this is an area of increasing importance. NIHDI provides replacement income to these people and enacts a series of policies to reintegrate them in the labour market.

In terms of how the EUR 40 billion health insurance budget is allocated, EUR ten billion goes to doctors, with smaller portions for hospitals and their functioning, nurses, and medicines which accounts for around EUR six billion.

Another characteristic is that unlike in many other sectors, part of this medicines budget is returned to the state by industry via clawbacks when the budget is exceeded. Additionally, there have been a growing number of contracts/managed entry agreements in recent years, whereby risk is shared between government and industry. These agreements, primarily for innovative medicines in areas like cancer and immunology, already account for EUR 2.5 billion of the EUR six billion medicines budget. Is important to remark how this has become a challenge – having so many of these early-on agreements outside of the standard permanent reimbursement model.

Is it sustainable for NIHDI to have such a large proportion of the medicines budget dedicated to these managed entry agreements?

We remain supportive of managed entry agreements in principle. Innovation is coming online more and more quickly and NIHDI aims to give our patients rapid access to this innovation. However, we are frequently confronted with reimbursement procedures that leave unanswered questions regarding both outcomes and budgetary impact.

Managed entry agreements, in and of themselves, are a good tool to diminish uncertainties and prepare fundamental discussions on the permanent reimbursement of medicines. However, several issues have been raised from both NIHDI and the Belgian Health Care Knowledge Centre (KCE), the country’s health technology assessment (HTA) body.

Firstly, these contracts are rapidly growing in number, now accounting for almost half of total medicine expenditure, which poses questions about how they, and our classic reimbursement procedures, are managed.

The second issue is the length of the contracts, which diminish uncertainties, but can lead to NIHDI being trapped in a deal for a possibly less effective product for a long period of time. As a payer,

we want assurances that these uncertainties will be diminished and that data collection and evidence gathering are done so that we are able to exit these contracts if necessary and as soon as possible.

The third point, which is the cause of much discussion on both societal and political levels, is the confidentiality of the budget chapter of these contracts. A degree of confidentiality is important, given Belgian prices' role in reference pricing systems across Europe, but the increasing negotiated prices are understandably leading to a debate as to the level at which their confidentiality can be accepted.

Fourthly, there are improvements to be made around data collection and analysis. NIHDI has a small expert group of just three people negotiating managed entry agreements, despite the giant budget of EUR 2.5 billion that they represent, meaning that our resources are stretched as this team concludes new contracts while also following up on existing ones.

These four points all form important parts of the *new medicines roadmap* that NIHDI has recently proposed to the minister following thorough stakeholder discussions in the second half of 2022. While some stakeholders feel we should simply stop these contracts altogether or do away with confidentiality agreements, this would be a foolhardy move without a pan-European agreement. European-level solutions are under discussion, but our first priority on a national level should be to ensure financially acceptable access to quality innovations for our patients.

What kinds of reforms to the current managed entry agreement system is NIHDI proposing within this roadmap?

We have already taken certain measures, including the fact that the Belgian Parliament's Supreme Audit Institution can, under certain limited conditions, analyse the confidential parts of the contracts.

New propositions include putting the type of risk-sharing agreement we make with the firm in the public part of the contract. This would not include figures, but rather concepts like the architecture of compensation mechanisms. NIHDI is also looking to publish a more profound annual analysis of the way we use these contracts. This involves the creation of a new trial and real-world evidence platform to drive better research design, data collection, and data analysis in collaboration with the KCE and the Federal Agency for Medicines and Health Products (FAMHP), Belgium's drug regulator. Unlike some of the other proposals on the table, this is supported by the pharmaceutical industry

and is something I am also keen to discuss further at a European level as Belgium takes on the presidency of the EU Council in 2024.

Will the creation of this trial and real-world evidence platform mean that the job of collecting data still sits with companies? How will stakeholder responsibilities evolve?

As well as aiming to support the work of the contract negotiation group and the Commission on Reimbursement of medicines, this platform also aims to support companies. They will get feedback from the FAMHP, NIHDI and KCE experts represented on the platform who are very familiar with data research and techniques.

Significantly, we will also include the new Health Data Agency that is being launched. This will be an important tool in strengthening the way that real-world evidence research is designed, how the data is collected, and how it is analysed.

All of this inter-stakeholder effort should hopefully lead to a more value-based discussion on reimbursement, beyond budgetary constraints alone. Today, we often lack the data and insight to really pinpoint value. Companies often complain about being paid too little for their products, but we can also see that reimbursement is being granted to products which finally do not have excellent real-world data despite promising early trials.

Do you think that payers like NIHDI need to be better equipped in terms of staffing and resources to keep pace with the innovation that the industry is bringing through?

Like most public administrations around the world, NIHDI is subject to budgetary constraints and Belgium is not always able to invest a lot into its capacity. However, NIHDI has been able to reorient some of its resources towards pharmaceuticals and has negotiated with the government for investments in some specific profiles such as health economists. We also join forces with the KCE, with academic institutions and industry via working groups on, for example, real-world evidence, where we share ideas and find common ground on methods and techniques.

The reinforcement of NIHDI’s capacity is not necessary because we are antithetical to private industry, but rather because we are being confronted with information asymmetry. The decision on whether to grant reimbursement lies with NIHDI, as does the responsibility to explain to citizens and patients why we have taken certain decisions, including rejecting products that patients are

asking for on the basis of a lack of cost-effectiveness.

Belgium spends around 11 percent of its GDP on healthcare, one of the highest ratios in Europe. Could this spending be better allocated to ease some of the pressures that the system is facing?

Belgium's public healthcare spending as a percentage of GDP is actually about average for high-income countries in Europe and in line with the likes of France and the Nordics. However, there is pressure on this spending, with competition between different sectors of healthcare like doctors, pharmacists, and healthcare providers to secure public funding. Moreover, outside of healthcare, domains like security, climate transition and education are also pushing for a bigger share of state funding. There is increased competition everywhere, leading to increased scrutiny about how the money that is allocated is spent.

Coming back to contracts, the industry often tells us that we negotiate well and that we would pay more without such strong negotiation, but we do not know this for a fact. I often ask my colleagues in both government and industry to imagine a leak of material regarding all these contracts across Europe which revealed that the Belgian authority had negotiated very badly. This would spell the end of the trust in NIHDI and the Minister of Health but would also be damaging to the industry in the long term.

Although the industry is profit-driven, we should expect them to take some social responsibility and not ask for more than is reasonable. A short-term focus is good for short-term profits, but in the long run, this undermines the trust of citizens in the reimbursement of medicines and can damage the legitimacy of the entire healthcare system.

One way of reapportioning existing funds could be to build specific therapeutic area-based budgetary targets, creating epidemiology-driven plans or programs …

Belgium has had a few specific pathology plans, including for cancer and HPV, over recent decades. While these areas were highlighted as priorities, there are no sub-budgets or sub-objectives within the overall medicines budget. However, the country has defined that expenditure on health insurance should be more driven by healthcare objectives. NIHDI established a process to determine these healthcare objectives which is now being anchored in the law. At the end of each legislature period, a commission of health objectives is established which creates reports that are

transmitted to the healthcare decision-makers who should then take them into account in their policy choices.

How useful have you found the EUnetHTA initiative and the move towards joint clinical assessments across Europe?

Historically, Belgium has always been a champion of international and European collaboration. We are continually active in the EUnetHTA initiative along with the FAMHP and the KCE and are also the originators of the BeneluxA initiative in collaboration with counterparts from the Netherlands, Luxembourg, Austria, and Ireland. Other key international projects in which Belgium plays an important role include the EU Innovation Network of national competent authorities, the OECD and the Oslo Medicines Initiative.

Joint clinical assessments under EUnetHTA will start in 2025 and we are working closely with the FAMHP and the KCE to give our input into the process and shape it.

Is the relatively low generic penetration in the Belgian healthcare system something you are looking to address to leverage the savings that generics can bring to the system?

We are neutral in terms of technology; what matters to us is competition. To this end, NIHDI has developed a series of techniques to lower prices in the off-patent market, for example. Whether a drug is an originator or a generic does not matter, and the past challenges surrounding the recognition of the quality of generics are no longer an issue. What matters is sustainable competition. We feel that we are reaching the end of what price reduction mechanisms can offer and that more and more we need to be working on volumes rather than prices.

The topic of biosimilars is different because these are ‘similar’ products rather than molecular copies. Prices can be lower than for originator products, but these are still biologics with all the research and production costs that they entail. Belgium has had problems with biosimilar uptake, some of which were addressed in the first Pharma Pact through monitoring and prescriber guidelines, and we are now reinforcing this. Most importantly, the regulatory framework for the tendering process for off-patent products in hospitals, especially with regard to biologics and biosimilars, has been strengthened. A series of criteria have been imposed that dictate that within a certain period of time after a biosimilar hits the market, the hospitals need to issue a tender and

the tenders cannot have a period longer than three years. We also have defined which criteria they cannot use in the tendering process to prevent anti-competitive actions. A thorough evaluation of the market dynamics is also foreseen.

Belgium has historically been one of Europe's leading clinical trial destinations, but the rollout of standardised clinical trial legislation across the EU may serve to diminish the country's competitiveness. Moreover, if the products being trialled are unlikely to eventually reach the market, or will be subject to a long wait before market entry, industry sponsors may think twice about locating trials in Belgium. What do you see as NIHDI's role in addressing these issues?

Belgium has a historical advantage in clinical trials, but the new European regulation will be something of an equaliser. Our *new medicines roadmap* attempts to help maintain Belgium's competitiveness and attractiveness. The country still boasts solid fundamentals, including the quality of our clinical centres, hospitals, doctors, and training programmes. That said, from the point of view of the payer, it is true that we need to think long-term about early and fast access. The roadmap is not about clinical trials alone, but we need to contribute to a continuously attractive landscape.

The FAMHP is the key stakeholder in this push, but NIHDI is also implicated and impacted by it. In our roadmap, we are proposing some actions on early and fast access which will also give the signal that we really want the products that address unmet needs to ultimately gain reimbursement. It is our ambition that there continues to be R&D in Belgium as well as production, as is the case for vaccines, for example.

At the EU and Belgian levels, we defend new financing mechanisms to give the signal that we want the firms to file for reimbursement. While industry stakeholders will point to Belgium's low positioning on the EFPIA's WAIT Indicator and that Belgium is losing its position as an innovation hub, I have a nuanced view. While we have to be cautious that Belgium does not lag behind on reimbursement, many firms do not file in Belgium in the first wave or even do not file in Belgium at all.

This is a worry, but I believe that NIHDI offers attractive, legitimate, and correct conditions for the pharmaceutical industry. I am always open to discussion, but the aforementioned information asymmetries, whereby figures are withheld from us by big companies, mean that the process is challenging. Our aim is not to be too strict or bureaucratic and the roadmap contains a series of

propositions on streamlining and shortening procedures to do things more quickly.

Do you have any specific messages for the pharmaceutical industry in this regard?

Firstly, all stakeholders need to orient their activity and investments towards unmet needs. Belgium will bring this topic to the table in its EU Council presidency in 2024, as it needs to be reinforced.

Additionally, Europe needs more strategic autonomy and to be less dependent on other regions for both raw materials and finished products. However, if good fiscal incentives to this end are put in place, we need to be certain that companies will file their products here.

Finally, I want to diminish information asymmetries regarding R&D and production costs, because if the pharma industry wants to have a discussion on value, we need more insight into their real costs. There should be a shared responsibility for population health. Firms, of course, are not public administrations and have to satisfy their shareholders, but since their income is so heavily dependent on the expenditure of reimbursement authorities, they are a stakeholder and cannot consider themselves mere consumers within the system. I believe that strategic partnerships between authorities and industry have a lot of potential, but there is work to do on both sides.

What is your final message to PharmaBoardroom's international audience?

All societies are confronted with many costly challenges, from climate to security and healthcare. In healthcare, shared leadership is vital and the industry will be an important partner in the transformation of the healthcare sector and health insurance system. Their ideas, experience, and expertise in creating value through products is one important element, along with overall organisation, professionals, and digitalization.

All stakeholders should step up to the serious challenges we have today, whether budgetary or otherwise. A sense of urgency is needed to transcend our classical positions and roles. As the COVID-19 pandemic showed, we were able to work together as one team with shared responsibility and respect for everyone's missions. This is something that can be improved at a national, European, and global level.

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