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pharma.be is the association of the Belgian R&D-based pharmaceutical industry, representing over 42,000 employees at 130 companies. CEO Caroline Ven outlines the crucial role that pharma.be and its members played in Belgium's COVID-19 response and recognition of the role that innovative pharma plays in Belgium. Ven also outlines the persistent market access issues facing the industry in Belgium and the legislative changes needed to resolve them and ensure that patients in Belgium continue to have access to lifesaving medical breakthroughs.

Can you begin by outlining the role that pharma.be and its members played in Belgium's response to the COVID-19 pandemic?

We played multiple important roles. Firstly, the significant clinical trial footprint that pharma.be member companies have in Belgium was extremely useful for the development of both vaccines and treatments for COVID-19. Several companies which have a strong clinical trial footprint in Belgium, were vital in this push.

Secondly, our members were at the forefront of the production and distribution of COVID vaccines to the rest of the world. Smaller companies implanted in Belgium that produce active pharmaceutical ingredients (APIs) also played a pivotal role. There was a huge and rapid upscaling to serve enormous global demand, leveraging both our strong manufacturing facilities as well as the country's top-notch logistics partners such as Brussels Airport, Liege Airport, and the Port of

Antwerp. These facilities are fully cold chain certified and were able to deal with the specific conditions at which some of the new products coming online had to be transported.

Thirdly, we were able to move quickly thanks to our excellent relations with the Belgian authorities, including both the Federal Agency for Medicines and Health Products (FAMHP) and the National Institute for Health and Disability Insurance (NIHDI). For example, pharma.be members managed to strike agreements to start clinical trial trials in just a couple of days, whereas that process normally takes weeks.

The fact that Belgium has a full life sciences ecosystem in place covering R&D, production, and distribution, ensured that our COVID response was relatively robust and that things went as smoothly as we could have hoped. Additionally, our ecosystem being multistakeholder was a real benefit in this time of crisis and common purpose.

Has the pharma industry's role in fighting the COVID-19 pandemic led to an improvement in its reputation among the broader Belgian public?

Despite our robust pandemic response, where pharma fulfilled its duties to public health and also side-lined many potentially more lucrative projects in favour of developing COVID-19 treatments and vaccines, there remains work to do in terms of our reputation in Belgium and sharing our impact with the public.

Firstly, while Belgium is best known internationally for beer and chocolate, the number one industrial sector in our country is pharma. Our economic impact is sizeable, which we continue to underscore in our dialogue with politicians. From employment to R&D, and especially productivity – which is high on the European agenda – pharma is a leading industry and perhaps the only sector to have combined productivity growth with value added and employment growth over the last ten to 15 years. We create both highly qualified jobs as well as short-skilled ones that make up around a third of our total employee base. Moreover, in terms of R&D, Belgium is considered by the European Commission to be a leading innovator. This is largely thanks to the pharmaceutical industry, which spends more than EUR five billion on R&D annually, and its collaborations with universities.

The public recognise our impact and the career opportunities that pharma can bring. However, as for-profit organisations in an environment of predominantly non-profit organisations like hospitals and sick funds, challenges will always arise, even though all these stakeholders have the same

goal of helping patients gain health. Vaccine hesitancy crept up in Belgium during the pandemic, although not as badly as in some other European countries, and pharma was accused of just wanting to sell vaccines rather than make people better. There needs to be a greater recognition of the economic cost of a pandemic and people not being able to work versus the costs of vaccines, which is far lower.

For these reasons, pharma.be is attempting to engage in more open dialogue with all stakeholders and to explain both our mission and business model. We need indeed intellectual property (IP) protection, for instance, to make sure that the incentive to invest in a very risky business over a long period of time prior to a positive outcome remains. When we are criticised on this point, I point to the fact that no other actors within the health system are stepping up and doing this; it requires long-term shareholders as it is a long and expensive process with no guarantee of success. Unlike playing up pharma's economic benefits – which is more straightforward and easier to understand – there remains a need to build trust via dialogue about our role in the health system.

How is pharma.be attempting to raise awareness of the pharma industry's role and impact within Belgium?

We have launched a new health talks initiative whereby different stakeholders are invited to engage in Chatham House Rules discussion about a certain issue in the healthcare system. This open dialogue is not aimed at coming to a consensus, but rather at getting to know each other better. While COVID restricted our ability to hold such events in 2020 and 2021, there now seems a greater willingness for stakeholders across the healthcare ecosystem to come together and discuss topics that are relevant for all. pharma.be now has a much stronger relationship with Belgium's generics association, Medaxes, for example, and there is clearly much more that unites than separates us.

What are some of the highlights of pharma.be's recently published *Report to Society 2022*?

There are many items to highlight, including the fact that our huge clinical trial investments have remained at a high level. Most interestingly there is data on all the new medicines we have brought to the market, up from 76 in a COVID-affected 2020 to a record 133 in 2021, including 27 innovations with added therapeutic value. This means that many patients now have a treatment

available for their illness for the first time. There were also 17 approvals for orphan diseases, 44 new indications, and 45 me-too products, which are also important.

The industry has also created compassionate use programmes, bridging the access gap for patients with unmet medical needs and no authorised drug available to provide our products for free.

Belgium's legislative framework for compassionate use has long seemed unfit for purpose; do you now sense a governmental willingness to address this?

We are currently discussing a big reform of medicinal policy with the Minister of Health, one of the most important items of which is the implementation of a more effective early access programme. A form of early access programme does exist in Belgium, but uptake has been low due to the lack of adequate rewards and its complicated nature. However, via dialogue with MoH we have reached an agreement that we hope will foster early and rapid access to promising medicines that patients need. We hope to follow the lead of the French early access system, which has been highly successful, and are hopeful of implementation before the end of 2023, ahead of national elections in 2024.

How do you assess the access scenario in Belgium more broadly?

Patient access can be a challenge; for example only just over half of recently European Medicines Agency (EMA) approved medicines are currently reimbursed in Belgium. The evaluation methodology is not always clear, but the new framework for medicinal policy that the MoH is preparing should lead to a big improvement. There will be much more external expertise in the evaluation of medicines, greater use of real world evidence (RWE), and a move towards a value based evaluation rather than a narrow focus on price alone.

The recent creation of a Health Data Agency will also be helpful in this, granting companies access to RWE that has previously been siloed with clinicians in the hospitals. The current low levels of RWE utilisation lead to greater uncertainty and the requirement for companies to pay higher rebates. Greater RWE use will make it possible for promising medicines to prove their value, and for less promising products to be scrapped, fostering higher levels of certainty throughout the entire process.

Belgium is one of the biggest spenders on healthcare as a percentage of GDP in Europe at 11 percent. Do you think this level of funding is sufficient and being used effectively?

Healthcare expenditure is a broad umbrella with a lot under it. In a country with high living standards like Belgium, the high wages of our healthcare professionals (HCPs) naturally make up a large proportion of this. Pharma is not the cuckoo's egg in the healthcare budget and in fact medicines make up just 16 percent of the total budget, a share that has been declining in recent years.

While pharma is often criticised for the price of its new therapies, this is not reflected in the figures. In fact, innovative medicines have done more to move the dial on life expectancy and treatments for diseases like cancer and hepatitis C than any other healthcare system intervention in the past 20 years. The societal benefits that medicines bring are not adequately reflected in the budget allocation.

Will the new medicines policy being brought forward by the MoH lead to an increase in the medicines budget?

There are various chapters in the new medicines policy, including access to promising innovative medicines as well as a shift from the authorities from being a payer for medicines to being a buyer of medicines. There will be a prioritisation of where we as a country do, and do not, want to invest, which could be a slippery slope to refusing to purchase medicines that certain groups need. When resources are limited, there is a need to prioritise and I understand the desire to focus on the therapies that have the biggest potential impact on population health, but this will be a delicate balance to strike.

From January to June 2024, Belgium will hold the rotating Presidency of the Council of the European Union. Is there anything on the health agenda that you hope the Belgian government will bring from Belgium to Europe?

Honestly, we are yet to have a discussion with the MoH on his priorities, but we think he will put discussion of unmet medical needs on the agenda. This links into the wider agenda priority of greater European cooperation on health policy. As the pandemic showed, each country looking out

solely for itself policy-wise is not a wise course. For this reason, vaccine contracts were negotiated at the European level, for example. Greater collaboration will be a priority, and we already see that a common ground for health technology assessments via EUnetHTA is being established. We welcome the use of joint clinical assessments, which creates better reusability of data and outcomes than if every country did its own.

The EU's Pharma Strategy for Europe covers topics including affordability, access, manufacturing, clinical trials, and maintaining competitiveness; how do you see Belgium's role in the continent evolving within this context in the coming years?

It is vital that our leading position in Europe across the value chain is maintained and even reinforced. The fact that Belgium has not only R&D, manufacturing, distribution, but also a strong network of hospitals and universities is our unique selling point and something we want to continue to share and foster. However, this all becomes less relevant if we are not able to ensure early and rapid access to medicines for our population.

On a European level, Belgian pharma – like our equivalents in other countries – is concerned about the EU Pharma Strategy fostering access at the expense of IP rights. As an innovative country, we have a lot to lose if these rights are weakened.

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