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The unavailability of medicines is, for the most part, an international problem, and thus requires international solutions

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Xavier De Cuyper introduces the

Federal Agency for Medicines & Health Products (FAMHP) and the essential role it plays in Belgiumâ??s healthcare regulatory framework since being founded in 2007. De Cuyper goes on to shed light on the organizationâ??s several ongoing priorities which include embracing digital trends, unlocking the potential of big data, international collaboration and leadership, and closer collaboration with related industries and healthcare stakeholders.

What is the role of the FAMHP as the competent authority responsible for the quality, safety, and efficacy of medicines and health products in Belgium?

Since 2007, the Federal Agency for Medicines & Health Products (FAMHP) has been the Belgian competent authority in charge of ensuring the quality, safety, and efficacy of medicines and health products for human and veterinary use in clinical development and on the market. This includes medical devices and accessories, raw materials, blood and blood products of human origin, and human tissue material.

The FAMHP works together with the academic world, the pharmaceutical industry and other related industries, healthcare professionals, other national, European, and worldwide authorities, and

policymakers to provide patients and citizens with the necessary medicines and health products and to help use them correctly.

National competent authorities for medical devices have a significantly different role when compared to competent authorities for medicinal products. In particular, competent authorities for medical devices do not have a direct role in the pre-market authorization or certification of a medical device nor of a manufacturing site. Rather, to account for the vast array of technologies, these pre-market reviews are undertaken on behalf of the authorities by independent certification organizations called notified bodies. At each national level, FAMHP is responsible for designating certification organizations to act as notified bodies for medical devices.

The FAMHP primarily acts as a market surveillance authority to continue ensuring that medical devices continue to perform and are safe throughout their product lifecycle. Increasingly, the FAMHP is reinforcing the nature and extent of these activities and are typically placing focus on planned, proactive market surveillance. In addition, we are responsible for maintaining a vigilance reporting system to process reports of adverse incidents associated with medical devices from manufacturers, healthcare professionals, and patients. The FAMHP manages systems for the assessment of such incidents and ensures that safety issues and risks are appropriately addressed and, when necessary, acted upon by manufacturers.

What are your current key priorities as CEO of the FAMHP?

One of the key priorities the FAMHP has put forward since its establishment is patient centrality. Patients are at the core of our attention, not only in the outcome of our work for making sure patients have access to safe and effective medicines, but also supporting patients and patient organizations in our processes through national scientific advice and clinical trials to fulfil unmet medical needs. In the future, we expect great patient representation in our commission for medicines for human use. We also have a patient platform where patient organizations can put forward their own themes, questions, and points of attention to us.

With regard to inspections, we continue to work on the system of increasing the accountability of stakeholders â?? for example, auto control and correspondence. These principles give more responsibility to the concerned stakeholders and help us define better risk analysis in every step of the process. This has already been implemented quite well in the domain of medical devices where we currently use a unique online portal which facilitates communication with the concerned companies. We are also working to implement similar principles for retail pharmacies. In the future, we aim to introduce such a system for manufacturers and distributors of medicinal products.

As for other priorities in the domain of medical devices, traceability is certainly up there. By summer 2020, the central traceability register will also become operational. This application aims to improve the traceability of implants in Belgium and create more transparency for patients. This system will provide complete traceability of devices to the concerned implanted patients. It will give us the possibility to immediately take necessary action if a medical device presents a risk for a patient. Patients and their healthcare providers will also have the opportunity to review the type of implant which was used and to print an implant report at any time. This is a major step forward in the domain of the patient safety.

What is the FAMHPâ??s evaluation criteria for the market distribution of products?

Recent years have revealed the importance of further protecting the medicines distribution chain. This is why the FAMHP has invested in improving the legislative framework on the one hand and in strengthening its teams of inspectors to control the distribution chain on the other. GDP inspectors have actively contributed to the drafting of a new guideline for â??good distribution practicesâ?• that came into force in 2013, as well as in the drafting of the European Falsified Medicines Directive (FMD), which provides for several measures to prevent the introduction of falsified medicinal products on the market. Finally, we are currently contributing to the drafting of future good distribution practices for veterinary medicinal products.

In terms of personnel, the distribution division was created in 2014 and since then, the number of inspectors has been more than doubled. In addition, given the relatively high number of nearly 500 actors to be inspected, the FAMHP has taken steps to better inform them by means of updated Q&A, news on our website, systematic calls to be vigilant as soon as an alert emerges in the circuit. Finally, we have improved the performance of the inspections by improving the risk-analysis.

Tell us more about the ambition of the FAMHP to spearhead the areas of vaccines and early phase development.

From the start in 2007, is was our objective, in addition to the effective performance of basic tasks, was to pay special attention to a number of â??centers of excellenceâ?• or spearheads. Meaning fields in which our agency wishes to excel and be regarded as the FAMHPâ??s visiting card in a European context. It is important for the FAMHP to stand out in a number of areas from the medicine authorities in other EU member states. Our main focus nowadays is on two spearheads: vaccines for human use and early phase clinical development.

The main criteria on which basis these domains have been selected are their importance for public health and access to innovation, Belgian research activities and expertise, speed of knowledge acquisition within our agency, potential for development, power of differentiation compared to other national competent authorities (NCAs), and industrial activities in Belgium. Some critical success factors are the amount of rapporteurship and scientific advice at national and European level and the number of clinical trial applications received within those domains of excellence.

What opportunities do you see for collaboration with the pharma industry to ensure the population the optimal use of the medicines and health products?

It is indeed one of our main goals to enable access to innovation for Belgian patients. Besides the active role that the FAMHP takes at the European Medicines Agency (EMA) in for instance the Scientific Advice Working Party (SAWP) and the Committee for Medicinal Products for Human Use (CHMP) (the rapporteur for prime dossiers), the FAMHP takes the lead at a national level in cooperation with the FPS Public Health, Food Chain Safety and Environment and the National Institute for Health and Disability Insurance (RIZIV-INAMI) via a program called â??Parallel Access to Innovationâ?•. Different projects have been defined such as the strengthening of centers of research, early temporary authorization and early temporary reimbursement, synergy in regulatory and Health Technology Assessment (HTA) for medicinal products and devices, mobile health and lots of other projects. It goes without saying that the pharma industry will be an integral actor in these projects.

In addition to innovation, the FAMHP also pays particular attention to ensure sustainable access to existing therapies. The problem of drug shortages has grown in recent years and the FAMHP has

therefore deployed additional resources to prevent and mitigate drug shortages, in a very close collaboration with the concerned stakeholders.

A number of important measures have already been implemented, such as the strengthening of the delivery obligation, the reporting of shortages by the companies, and the systematic evaluation of the criticality of each reported shortage so that appropriate measures can be taken. The FAMHP attaches great importance to transparent communication with health care professionals, companies and patients and therefore launched an online application, www.pharmastatus.be and enabled the integration of the information on shortages in the prescribing tools. However, further measures are still necessary, and the challenge will be considerable in the coming years as evidenced by the fact that the subject is high on the agenda of the new European Commission.

As for medical devices, 2020 will be an interesting year. In April 2017, two new regulations on medical devices and in vitro diagnostic medical devices were adopted. They entered into force in May 2017 and will progressively replace the existing directives. The new regulations will be fully applicable in May 2020 for medical devices and May 2022 for in vitro diagnostic medical devices. As the Belgian authority, we welcome the adoption of these two regulations which establish a modernized and more robust European regulatory framework to ensure better protection of public health and patient safety while still ensuring flexibility to guaranty to people access to the best, most innovative medical technologies and devices that can be life-saving or life-changing.

Our communication with the medical technology sector in this recast of the legislation was fruitful. We have tried our hardest to make sure that the sector will be prepared by proactively informing them by organizing multiple symposia which were very well attended and gave the sector the opportunity to have their questions answered, for example.

However, the decrease in the availability of notified bodies to review devices, particularly in higher-risk classes, will delay product approvals and slow devicesâ?? entry to the market. Additionally, with notified bodies now being required to review a greater volume of data, timelines will be lengthened. This potential bottlenecking could lead to market shortages. We are closely monitoring this issue with the European Commission and other competent authorities to adopt a common approach. We also hope to this challenge into an opportunity to collaborate more effectively with the whole sector so that patient access will be unaffected.

What objectives do you have for the FAMHP looking forward?

Making data publicly available and linking large data sets with clinical and research data will enable the integration of data analysis into the assessment processes to improve decision making. The acceptability of evidence from big data for regulatory decision-making is still uncertain, but novel technologies and the evidence generated from big data will potentially benefit public health by accelerating medicines development, improving treatment outcomes, and facilitating earlier patient access to new treatments. For instance, data analysis will facilitate pharmacoepidemiologic studies to monitor medicines safety and measure the impact of regulatory decisions on patient outcomes. The FAMHP participates, on national and European level, in initiatives regarding this topic.

Lastly, but perhaps most importantly, we need to keep building and reinforcing the European network. We really need to harmonize important domains and themes. Every country has similar problems and tackles broadly the same issues. For example, the unavailability of medicines is, for the most part, an international problem, and thus requires international solutions. For those domains, a strong Europe, as one of the most important players, will handle those problems more efficiently than all countries independently each searching their own solutions.

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