Interview with Xavier De Cuyper, General Administrator, Federal Agency for Medicines and Health Products (FAMHP)

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Mr. De Cuyper, can you start with a brief introduction to the federal agency for medicines and health products (famhp) and its role within the Belgiumâ??s complex regulatory environment?

We are the regulatory authority for medicines as well as for medical devices in Belgium. Although many of our counterparts across Europe tend to have separate agencies for medicines and devices, in Belgium we combine the two. I believe that this is the right path to follow as I am confident that there is an even increasing interconnectedness between these two domains. Indeed, within the network of agencies across Europe (HMA) discussions are on-going on how to bring these two fields closer together and preferably under a unified agency as EMA exists for the evaluation of medicines or in a common network as HMA.

As a relatively young agency, the famhp is responsible for a wide scope of activities and this continues to grow into new sub-domains. When we were established in 2007, we were composed of nearly 200 employees and this figure has more than doubled since. However, I must admit that right from the beginning we started with a rather negative image as a public authority, industry having dubbed us the â??agency of back-logsâ??. Fortunately, this is now a thing of the past since we were able to overcome those issues in as little as 2 or 3 years and we can certainly be proud of our improvements and achievements since.

How would you explain that the creation of the famhp happened so late in a country such as Belgium with such a strong presence of the pharmaceutical industry?

Of course there was a regulatory authority within the department of public health prior to the creation of the famhp. However, for reasons of administrative and managerial simplification, there was a need to create an independent body assuming the responsibilities. Key in this discussion is the way the Agency is financed, namely almost entirely funded by the fees charged to industry. Of course, such financing is far easier managed as an independent organization. In fact, meanwhile almost every Member State in Europe has set up such an independent regulatory body for medicines.

Your website states that despite budgetary constraints and a difficult context, the agency has achieved good results in its 5 year history. Can you elaborate on these good results and highlight its most notable achievements?

Broadly speaking, we identified six strategic objectives that we wanted to achieve. Of course, one of these was to be recognized in all of its competencies as the competent authority, extending far beyond the issues of back-log but also for providing the public with accurate and reliable information on all types of medicines and health products in development and on the market. So far, this has proved to be a great success. Several initiatives (media campaigns) were launched to educate the

public on the proper use of medicines as well as warning them about the dangers of purchasing drugs online.

A second objective is to source the best possible expertise so that they can provide us with the appropriate evaluations and opinions on products applying for market access. Unsurprisingly, this is something that is rather difficult to achieve especially when you consider the very wide scope of therapeutic areas we deal with. In addition to the effective performance of the basic tasks, we decided a number of years ago to focus special attention on a number of spearheads. These include vaccines, oncological treatments, proactive vigilance policy and early phase development. Although we yearly re-evaluate our spearheads and consider other possibilities, the basic idea here is to create a mutually beneficial situation with the industry and allow them the opportunity to approach us with their concerns and avoid having them taking the wrong direction. Overall, it is my feeling that the industry generally recognizes our efforts and is happy with our progress so far. Nonetheless, our work is far from over since there certainly is room for improvement. This is something we will constantly strive to achieve.

What is your position with respect to the level of integration of the various agencies across the European Union? Is there room for improvement?

It is my conviction that there should be to an increased amount of integration and networking among the respective European agencies. It is not very useful to have the same, if not overlapping, expertise in the entire scope of activities and therapeutic areas we are responsible for. Such an integration of these cross-border activities would certainly contribute towards a more rapid and effective evaluation of important medicines while also helping to lower administrative costs.

Personally, I think that being able to provide patients with access to innovative and effective medicines is a priority and I think the capacity to do so could be effectively enhanced by working in close cooperation with our European counterparts. Not only will patients gain earlier and easier access to potentially lifesaving medicines, but an increased level of cooperation can help to restore the EUâ??s leadership in research and development which in turn will contribute towards the industryâ??s reinforcement. I firmly believe the time has come to make this change and I think that todayâ??s economic climate may act as a catalyst providing the push needed to realize this opportunity.

Belgium serves as an excellent destination for clinical studies, particularly in early stage studies partly due to the rapid approval processes. However, the new EU proposal on clinical studies is set to level the playing field and harmonize its procedures across the EU, posing a direct threat to the industryâ??s competitive advantage. What is your position on the matter and how do you think Belgium can preserve its leadership in clinical studies?

I think that whatâ??s important for us as European citizens, and potential patients, is to ensure that we have access to the best medicines available and am therefore a proponent of EU wide integration and harmonization measures. I believe that a big change was already achieved in 2009 with the launching of the Voluntary Harmonized Procedure (VHP) within the network of agencies (HMA). Although it was a voluntary measure, as the name suggests, it shares many similarities with the EUâ??s proposed regulation on clinical trials. This indicates that to some degree, such developments were to be expected and that industry had consequently begun taking action some time ago. Though, I believe that clinical trials will remain to be a central activity for us in Belgium given the years of experience and knowhow that the industry has accumulated as well as the infrastructure including research centers and hospitals of academic centers.

On the other hand, I believe that a bigger challenge will probably be the enhancement of the centralization of ethics committees. This represents another area where we can realize and achieve greater procedural and administrative efficiencies. The idea is not to have a centralized body on a European level, because thatâ??s practically impossible. The idea is more to have for each country one body that is able to provide unified recommendations or opinions on clinical trials. Specifically, the challenge here is how to make this model workable. If we are able to achieve this in the Belgian context, it will certainly contribute towards our ability to maintain the countryâ??s leadership position in early phase development.

Taking a few steps back in order to gain a global view of the situation, how would you rate the effectiveness and sustainability of the current healthcare system in Belgium and what contributions can be made by stakeholders towards its improvement?

In order to support the sustainability of the system, we are essentially active in providing good and timely services to the industry. Similarly, in order to make the local environment more attractive to the industry, we also try to simplify as much as possible all the procedures and processes for our stakeholders. Although this might seem trivial, our stakeholders certainly appreciate such reforms and this represents only one of the range of measures that the authorities are taking to improve the overall situation. Itâ??s simply a question of better organization practically without extra cost.

In addition to this, the Belgian government has made significant efforts towards creating the right environment to ensure healthcare access to its citizens. Nonetheless, there is still room for improvement since there are still certain classes of people that are unable to afford the costs of social security and therefore are not encouraged to seek proper healthcare when required. Another challenge we are facing in Belgium relates to the diversity of the competent authorities responsible for the research industry and the economy in general. For this, the government has recently attempted to create a platform that combines all of the relevant partners extending beyond stakeholders. So, the goal is to maintain Belgiumâ??s capacity and strength in research and development of innovative medicines by creating identical incentives across the country.

What is on the agenda of the FAMHP for the coming 1-2 years? What challenges do you wish to overcome, and what reforms would you like to realise?

This is difficult because we are only one element in the European network. As I mentioned earlier, my ambition is to be an important player in the European network and to strengthen Belgiumâ??s prominent position in the pharmaceutical and healthcare industry, particularly in terms of clinical trials and research activities.

We also recently observed an increasing number of reputable centers that research and develop the use of blood, cells and tissues for medical use. These technologies and knowhow are evolving so quickly that I am certain that we will have to incorporate the evaluation or control in a matter of just a few years. This is comparable to what is happening with medical devices and the increasing difficulty in making a clear distinction between medical devices and medicines. However, I think this will be difficult because the decision makers of the European commission do not share my enthusiasm to enable an increased level of integration between both sectors. Why should we not encourage a better organization within the European medicines agencies by way of an improved scope of activities? It seems to be a political issue and unfortunately it represents one of the ways in which we can address the issues of personalized medicines and make them a reality. Rather than being a challenge, we should face this as an excellent opportunity to further develop our reputation as a direct partner of the sector.

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