Dominique Martin â?? CEO, ANSM, France

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CEO of the ANSM (Agence Nationale de SÃ©curitÃ© du MÃ©dicament et des Produits de SantÃ©) provides a fascinating insight into the French process of authorizing drugs and medical products, his commitment to increased transparency and increased efficiency, and the opportunity for France to take the lead in European regulation following Brexit.

You have been at the ANSM for four years now. How would you describe your greatest achievements thus far?

To respond to this, I think it is best to describe the main issues that the ANSM has tried to solve during my tenure, and then to explain what we have done to resolve said concerns.

First, it is important to establish that this organization was founded in the midst of a crisis; there was a crisis in the way that the French medical regulatory intermediaries were functioning, and the patients were not getting a good service under the old system.

The ANSM is ever-changing; it was originally called the Medicines Agency, founded in 1993. Then, as medical devices became more and more prominent, the group changed its name to Afssaps (French Agency for the Safety of Health Products) in order to accurately reflect the expanded role in medtech evaluation. This particular organizational change was not so much a reaction to a crisis, but rather of positive growth to contend with technological evolution in the field. However, as the ANSM was founded in 2011 as a restructured version of Afssaps, it was shaped by myriad political and external forces. It was thereby forced to establish itself, as an organization, amidst many constraints, primarily skepticism and distrust from the French patients themselves, and a changed global environment in the healthcare economy. My predecessor did the best job possible in shaping the ANSM into a functional body, but there was much to be done when I took the reigns.

The ANSM is therefore in the crux of a â??seesaw,â?• having to balance an outspoken, defiant public and a changing healthcare environment. When I took over, despite the good work of my predecessor, the body was in a state of unrest notably due to the Mediator scandal at the time. There was a contemptuous climate and the organization did not have the clear direction or plan that it needed. Moreover, in the European Union, despite being a founding member, we had lost influence as a regulatory body.

So, to get back to your question â?? since I took over, we have both been trying to re-establish ourselves as a preeminent voice in the European regulatory scene and recapture the trust of the public. We have placed a great effort in increasing our transparency.

That said, how have you worked to solve these problems?

To solve these problems, we have had to undertake several projects. The first concerns industry: we have greatly worked to reduce the regulatory delays that used to hinder the development and launch of new products. It used to be that, capriciously, authorization could take months or years to obtain. So, we took the challenge in hand and worked to transparently reduce the regulatory burden for industry. This was a matter of public service, and we have already made radical changes to ameliorate this issue. A lot of this has consisted of refining, or establishing outright, technical procedures in our work. Now we have a better structure, and it only takes a matter of months to get our certifications done. By next year, we should have our processes completely revamped. This has been a radical change.

The second important challenge is to establish trust among the public and increase the transparency of the ANSM. To meet this goal, we have already taken several measures, and we are doubling down on our efforts to be as transparent as possible. We have restructured our communications department, we have provided social resources regarding our vigilance and intervention operations, and we have brought in experts to help us make information available to the public on the internet. Now, when we have meetings, they are recorded and uploaded on the internet. I donâ??t know of too many organizations that do that, and this has completely changed our communications.

We have also changed the way that we handle â??crisis management.â?• As we have learned from the recent problems surrounding Levothyrox, we need to rethink the way that we communicate with patients and healthcare administrators, anticipate crises, etc. With this particular case, you had the unique situation of having three million users of the drug and one sole provider. The provider made a minute change to the composition of the drug, and nobody seemed to notice around Europe â?? no regulatory body said anything about the matter.

At the time, there was plenty of information that was shared to the countryâ??s 400,000 doctors concerning the alteration in the drugâ??s composition. The problem, though, is that the doctors and caregivers were not in the situation to pay enough attention to this information and they subsequently never informed their patients. So, when you get a user population of three million, which is larger than the urban population of Paris, that is quite ill and feels as if its medical regulator didnâ??t conduct its due diligence, you will naturally see a sense of betrayal spread over them. These patients began to associate uncorrelated illnesses and medical complications with the change in the drugâ??s composition, even if there was no real relationship between the change and their medical developments.

Now, this was still a huge lesson for us: the people, regardless of whether or not the change in the drug was harmful, feel betrayed by the lack of transparency in our work. The traditional means of transmitting this type of information is no longer appropriate â?? after all, how can you be sure that 400,000 doctors will reliably inform their patients of this change on the ANSMâ??s behalf? We have instead decided to work on establishing a means of relaying this type of information in a clear, comprehensible format to the patients themselves. We now have to assess a situation not just from a pharmacological perspective, but from a more holistic perspective, keeping public opinion in mind. We also need to work more closely with the drug providers â?? when we find an issue such as this â??after productionâ?? has changed, it is oftentimes too late for the provider to change back to the old formula. Furthermore, we are factoring the time of year into this new system of communication; should we allow such changes in important drugs to occur in the summer, when many doctors and stakeholders are vacationing?

As we address these factors, we should be able to maximize our sense of transparency and limit the suspicion among the public.

If you look at how far you have come in this rebuilding process, where do you consider there to still be gaps?

It depends on the topic. If we are talking about the public service side of things, wherein we have reduced regulatory burden, I would say that we have largely accomplished our task. What remains is to establish stability, but I would say that we are about 80% of the way there. Itâ??s a small gap.

If you look at the other aspect, regarding the communication and transparency issues, I would say we have a lot of work ahead of us. We need to figure out how to be transparent with our documents and our processes. We have discussed this a few times with our European colleagues, but this issue

is uniquely French â?? our public is simply more demanding of its government in this realm than are the populations of other European countries. Logistically, it will take us some time to find a way to implement transparency measures within everything that we do. We will need a new IT system that can export all of our documents to a public database and website and a new behavior model within the organization that centers in on transparency and public awareness. It is not easy to implement a new logistical, cultural and behavioral paradigm into an organization of this size (950 people).

You have mentioned that the ANSM has lost its prominence in Europe. With Brexit, we are seeing the MHRA falling in influence â?? does Brexit present an opportunity for the French regulatory system to regain some standing in Europe?

It is a big chance for us. We started our â??comebackâ?• plan about three years ago, before Brexit took place. We have modified our indicators and have become more active in giving scientific advice.

> On Brexit. â??We really cannot let this opportunity to retake the lead in Europe pass us by.â?•

How this situation will unfold depends largely on the nature of Brexit itself; will it be a hard or a soft Brexit? Will it be a hard Brexit, in which the UK will be left completely out of the EU and Europe will have to fill the void left by the prominent British regulatory bodies? Or it will it be a soft Brexit, wherein the UK will essentially rejoin the union in a matter of years? Regardless, we do have a window of opportunity opening. Our problems in capitalizing on the opportunity are budgetary constraints and the fact that, following a change in status in 2011, the ANSM can no longer interact with industry.

In order to prepare ourselves for our Brexit strategy, we will need to work with the other government ministries. We may also need to consider having special â??additionalâ?• terms for certain members of government; these additional terms are special extensions to specific mandates, implemented to help navigate the Brexit process. We may have to reorganize certain roles, focusing on our strengths. For instance, we are very good at oncology and vaccines. We need to fortify and prioritize our strengths in these fields, regardless if they are in industry, academia, or wherever. We have also worked with other countries, such as Italy, Belgium, and the Netherlands. It may be in our interest to follow the lead of our Spanish colleagues, who have a system in which the European Medical Agency (EMA) gives them funding for their portfolio of projects. The French system, as it stands, is not designed for such financial cooperation, but I think it could be beneficial as we regain footing in the European regulatory ecosystem. We need to create a â??virtuous circleâ?• in which we can increase our access to financing, use the funds to invest in the quality of our regulatory work, and so on.

During the 8th edition of the Strategic Council of Health Industries (CSIS) last July, the French government revealed a plan to revitalize industry and increase inward flows of investment. How can the ANSM help the cause and make France more attractive to industry?

We worked very closely with the CSIS and have gone through great lengths to reduce the delays in the clinical trials process â?? we have already met the goal of reducing the average time to clinical trials from 60 to 45 days. We have created a special process for approving Phase I trials, and we have also implemented a process through which we can quickly consult external experts on a variety of matters.

However, we do face one obstacle that is omnipresent in Europe; we are not the only regulatory body that has a say in authorizing drugs and therapies. The CPP (ComitÃ© de Protection des Personnes) must also give a prior notice on the conditions of validity of any research implied on the human person for all authorizations. As it stands, it is cumbersome to organize collaboration with the proper ethics committee, so we will have to find a way to streamline the process. To do this, we will need to work with the other regulatory branches in France (like the HAS, or *Haute AutoritÃ© de santÃ©,* and CEPS, or *ComitÃ© Ã©conomique des produits de santÃ©*). Increased collaboration among government agencies will help us better handle the authorization of new, innovative products. The ANSM is not strictly a science agency, after all â?? in order to assess the truly groundbreaking advancements, we need to pull together the brainpower from many French government bodies.

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