Pharma expert: EU drug agency should be 'easily' accessible to all

Adrian van den Hoven: "Our main fear is that the Brexit is going to lead everything slowing down, all the important projects." [Sarantis Michalopoulos]

This article is part of our special report European Medicines Agency: What's at stake?.

Any country that wants to inherit the European Medicines Agency (EMA) from London has to be easily accessible. Candidates will also need to increase their national agency's resources, as staff are expected to move to the EMA, according to Adrian van den Hoven.

Adrian van den Hoven is the director general of Medicines for Europe, which represents the European generic, biosimilar and valued added pharmaceutical industries.

Van den Hoven spoke to EURACTIV.com's Sarantis Michalopoulos.

Let's start with the Brexit negotiations. What are the main challenges the health sector is facing?

Brexit will have a significant effect on medicines. Our industry is the biggest supplier of medicines as 62% of the medicines are actually generics today. One of the main challenges that we have is that a lot of the licenses for the registration of generics are actually held by the UK medicines agency, the Medicines and Healthcare products Regulatory Agency. As a result of the UK leaving the EU, logically those licenses can no longer be held by the UK agency. These are held by the UK agency for the rest of Europe, or licenses held in European agencies for the UK.

It's about 8,000 medicines in total. It's a huge number. The difficulty is that the industry needs really some certainty about whether or not those medicines can remain in the UK agency – which we would prefer through some transition agreement, whether they need to leave and therefore be transferred to an agency somewhere else in Europe. What is important here is to make sure that if they need to be transferred then the European agencies have the resources to do that because currently, they do not. As a result what is happening is companies taking precautionary measures and transferring licenses out of the UK to Europe. The system is becoming very slow because the agencies do not have the capacity to absorb those transfers.

The big concern we have is that the regulatory network, which is coordinated by Europe but actually done by national agencies, risks freezing up because of the work related to transfers.

Do you have a particular example in mind?

Yes, we actually see that things are slowing down. For example, there is a very big problem with an IT project for medicine, which is basically a project of EMA to identify medicines electronically. It's called Identification of Medicinal Products (IDMP). That project is now delayed by six months or even a year because of the fact that the agencies do not have enough resources to do it.

This is really negative for the industry which has already invested in its own internal IT systems to do this. If we don't develop the EU IT system, we will face difficulties with a lot of regulatory issues to manage.

And that's basically our main fear: that Brexit is going to lead to everything slowing down, all the important projects because people are basically trying to manage the Brexit situation. We want to make sure that we have a good dialogue with the regulators in the EU and the UK so that we can manage this process.

We want that dialogue to be with the regulators not with the trade negotiators. We fully respect them, but they don't deal with the day-to-day implementation of the regulation. We need the trade negotiators to give the regulators the authority to do so, which is not the case currently.

So, you are saying that trade negotiators should take a step back because they politicise a technical discussion?

I don't know if they are politicising the talks. I think what is happening, which is normal in a trade negotiation, is that everything is kind of centralised to the trade negotiators, to the team of Mr Barnier in the EU and Mr Davis in the UK. The difficulty is that this is not a trade negotiation. Every single day our members have to interact with regulators for day-to-day business to make sure they can keep supplying the medicines that people need.

We cannot leave everything to politicians and trade negotiators for whom this is very technical. We need to be able to continue to work with the regulators including in the process of separation of the UK from the EU market or transition or whatever is finally agreed. We would prefer transition.

Regarding the EMA relocation, the initial EU member states are clear. What should be the priorities in your view?

It's important that the staff, which is more than 900 people, will have the right conditions, access to schools in their language etc. Most major European cities have international schools and the proper facilities. I think all the special conditions need to be taken care of.

But the main issue for us is that the location needs to be accessible from all countries in Europe. That practically means that one could take a plane or train to get there relatively easily. That's because of the fact that companies and trade associations spend so much time in the EMA. Just to give you an indication, our association – just the people who work here – spend 100 days a year at the EMA.

If you multiply that with 2,500 companies then we have a huge number of people that have to go to the agency for one reason or another.

All the national agencies also have to able to fly or take a train and get there. So I think that accessibility is really vital because if one needs 1.5 days to get there then that's a challenge.

The second key point for us are the resources of the local agency. It's important the resources of the national medicines agencies are increased. What will happen when the agency moves is that some people from the local agency will move to the EU agency. For them, it will be an exciting opportunity to work in the European context.

The risk is national agencies losing a big part of their staff as well and this has to be planned by the country that will host the agency. The scientific work is actually done by people from national agencies as they do the assessments. The EMA coordinates it.

I assume this will exclude the countries hit by the crisis.

That's not exactly true because most agencies are financed by the industry. So, a few of them are financed by taxation, that's true. But the majority of them are financed by industry fees.

Even countries under severe financial stress can be effective. Just as an example, in Portugal, which has been under financial scrutiny for quite a while, they have a reasonably strong agency which is self-financed.

Do you fear that this five-month delay in the relocation decision will disrupt the market?

I don't know if it will disrupt the market but I would say though that the fact that we don't have clarity on EMA or transitions on anything on medicines is a problem.

As I said already, very important regulatory projects are being frozen. And this is not good news for patients and public health. We want to make sure that the industry will be able to keep supplying medicines that it won't cost too much because there will be some costs. Particularly for generic medicines, the price we sell them is very low and any additional cost will need to be factored into generic prices.

It's of absolute importance to get a clear view on where the UK and the EU go on medicines. Medicines are very different from the financial or the car sector. I am not saying that these sectors are not important. But if this affects access to people's diabetes or chemotherapy medicines you have a very serious problem. No government, neither the UK nor the EU wants this Brexit to lead to problems regarding the supply of medicines. No one wants to deny the UK medicines or vice-versa. Even in war situations, we have a special treatment for medicines, so I think for Brexit we also need it.