EUROPEAN MEDICINES AGENCY: WHAT’S AT STAKE?
Drug agency relocation talks divide old and new EU members

The debate over where to relocate the London-based European Medicines Agency (EMA) after Brexit has divided the remaining 27 EU member states, despite calls for an urgent decision from the drugs industry and patient groups.

Newer EU members from Central and Eastern Europe have called for “geographical balance” in the relocation decision while older states say the primary concern should be ensuring its “business continuity”.

In June, European Council President Donald Tusk and European Commission chief Jean-Claude Juncker presented the procedure for relocating EMA and the European Banking Authority (EBA) after Brexit.

EU-27 leaders then endorsed the procedural arrangements at the June European Council summit.

The EMA is an EU regulatory authority which ensures that medicines available to more than 500 million citizens across Europe are appropriate and safe. The agency is currently headquartered in London but will have to move once the UK leaves the EU.

Hosting the EMA brings considerable economic benefits to the host city as the service employs more than 1,000 people, paid by the EU.

Around 20 countries across the bloc have already stated their intention to host the EMA, so competition will be tough and proceedings complicated.

Member states have until the end of July to submit their bids to host the two agencies, based on particular criteria. The Commission will then review the bids by 30 September.

The final decision is expected in November and, according to the rules, a Eurovision-style voting process will take place. For many, this was the most suitable option considering the high

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number of candidate countries.

Commission sources have stressed that the UK would have no say in the process but would have to facilitate the transfer of the two agencies.

THE QUESTION OF “DECENTRALISATION”

The agreed upon EU document states that the relocation decision will be a combination of objective criteria and the “desirability of geographical spread”.

The accessibility of the location, the existence of adequate educational facilities for the children of EMA staff, as well as job opportunities for their family members, are among the objective criteria.

Some member states already host one or more EU agencies. Others, especially the newer members from Eastern Europe, have no agencies on their territory.

GEOGRAPHICAL EQUILIBRIUM

In the 2003 Joint Statement and Common Approach on Decentralised Agencies, EU leaders recognised the need to give priority to new member states when distributing the seats of new agencies that may be set up in the future.

In the case of the EMA, the Commission paper acknowledges that the procedure concerns relocation, rather than a new agency. However, it states that “the spirit of that leaders’ agreement should be taken into account”.

“A judge looks at both the letter of the law and the legislator’s will,” an EU diplomat commented.

Diplomatic sources from newer member states stress that they had initially hoped that bids from countries without any EU agencies would be given priority.

“Don’t Gamble with Patients”

But some older member states underline that the EMA is an existing EU agency and should be treated as such. “When the initial discussion for the location of the EMA took place years ago, some states that are now members of the EU weren’t even there,” a source said.

In addition, a Western diplomat said emphasis should be placed on “business continuity”, ensuring the “continued functionality at the existing high level”.

“We have to focus on the role of the EMA, which is essential for health systems. It’s an expert field, one cannot gamble with the EMA,” the diplomat said, adding that EU leaders should avoid a scenario in which patients pay the price for political games.

“Almost 20% of the work is being carried out by the British regulator […] If it ultimately goes to a country whose regulator does not have the capacity, then what happens if something goes wrong?” the diplomat warned.

The Commission has also called for a quick decision on both the EMA and EBA, as the two regulatory bodies must continue to “function smoothly and without disruption beyond March 2019”, when the UK is due to leave the bloc.

PATIENTS AND PHARMA

The pharmaceutical industry and patient groups also agree that a quick relocation of the EMA would be in everyone’s best interest.

In April, three patient groups (European Patients Forum, European Consumer Organisation and Rare Diseases Europe) sent a letter to the EU’s Brexit negotiator, Michel Barnier, and European Commissioner for Health and Food Safety Vytenis Andriukaitis, urging them to impress upon the Council the need to be “extremely vigilant in deciding on the optimal location”.

In June, the European Federation of Pharmaceutical Industries and Associations (EFPIA), which represents the pharmaceutical industry operating in Europe, expressed its concerns regarding the EU leaders’ decision to postpone the talks on the EMA’s relocation.

The uncertainty over EMA’s location should end, “ensuring that transitional arrangements are in place for issues that may impact patient safety and patient health,” EFPIA said.

“It is a serious concern that the heads of states’ deliberations on the Agency’s future have not resulted in an early decision on its relocation: in the event of an obstruction or eventual failure, Europe possesses no backup option,” the industry group added.
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]

INTERVIEW

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

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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.
Member states are being urged to unite around the issue of relocating the London-based European Medicines Agency (EMA), rather than bicker in public and give the UK government cause to believe the EU cannot cooperate properly, diplomats told EURACTIV.com.

The European Commission has announced six criteria the candidates need to fulfil in order to become the drug agency’s new home. Member states have until the end of July to submit their bids to host EMA and the European Banking Agency but the political discussion has already heated up.

The Commission has tried to downplay the political angle of the talks. It has stressed that the relocation of the EMA is not part of the Brexit negotiations but a consequence to be agreed amongst the remaining 27.

The executive has also made clear its intention for a quick decision about the transfer.

But the member states admit that the decision is a big test for them and for the EU as a whole, on a political and communications level.

According to diplomats close to the talks, there is a deep divide between the old and the new member states. The first camp suggests that the relocation does not concern a new agency but an old one, while the second camp is pushing for a “geographical balance”.

There was also a proposal to split the EMA’s several departments across Europe but it never took off due to the high number of candidacies.

In addition, EURACTIV.com has learned that some countries have also raised some concerns about the “objective” criteria.

“One cannot argue that the new EMA location should depend on the number of flight connections with the rest of Europe,” a source said, underlining that this automatically excludes certain member states from the periphery of Europe.

SHOWING COHESION

Another crucial element of the

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recent EU Council talks was that the EU leaders decided “not to give the wrong message to the UK government and to the public”.

A diplomat said that a deadlock or intense public discussions among member states could show a lack of unity and, above all, inability to reach the first Brexit-related decision.

“Indeed, we have thoroughly discussed this issue and decided to have a quick and effective relocation; otherwise we risk to send a wrong message that we cannot cooperate [...] obviously, reaching a deadlock in that would not look good in the eyes of the public opinion, both in the UK and the EU,” the diplomat warned.

The diplomat added that a public dispute among the member states could also be seen by the UK government as a weakness on the EU’s part ahead of the crucial Brexit talks. That line of thinking is mainly endorsed by the member states that have not expressed an interest in hosting the agency.

PARIS AND BERLIN WANT TO CHANGE THE RULES

At some point, there were rumours that France would support Germany in its bid to host the European Banking Authority (EBA), while Germany would in return back Paris’s wish to have the EMA relocated to Lille.

But EURACTIV was told that the plans have changed. France now appears to be in favour of getting the EBA because it would help attract more banks to Paris.

“At least Frankfurt should not get the EBA,” diplomatic sources stressed, stating that if it did, it would deal a blow to the French banking sector.

Before the official vote in November, each country will present its bid in October and the Commission will then assess them.

EURACTIV has learned that Paris and Germany will push for an EU Council agreement and not a Eurovision style votings, which they claim won’t work.

“All 22 candidates will vote for themselves in the first round, and then in the second round for irrelevant candidates, so in the end, the winner will get very light support and no legitimacy,” the diplomatic sources said.

“Tusk has pushed for the Eurovision system to calm down Eastern countries which were totally upset, but Germany and France are pushing for an agreement in this discussion at EUCO, before the voting process,” one diplomat said.

THE SOUTH

Several southern members, including Spain, Portugal and Greece, have stated an interest to host the agency.

Barcelona’s intention to host the EMA is nothing new. In 1992, the Catalan capital offered to take the agency but narrowly lost out to London.

“Many years after that, we are obviously much more prepared,” said Carlos Parry Lafont, an adviser for the Spanish Ministry of Health.

Parry told EURACTIV that Barcelona’s new bid is not only based on the city’s natural advantages but also on its potential for biomedical research and high investment in clinical research “besides the guarantee Spain can give for the continuity of EMA business without any disruptions”.

“Almost 40% of the pharmaceutical companies located in Spain are based in Barcelona,” Parry explained, adding that the local pharma industry is a leader in clinical trials in oncology.

Asked whether the plans to hold a second independence referendum in Catalonia in October could derail Barcelona’s bid, Parry replied: “That is not on the agenda and the best proof is that the Spanish government is leading the bid, working together with the Catalan government and the Barcelona municipality”.

The Spanish government official also said that after years of strong and painful reforms the Spanish economy has been through, giving the EMA to Barcelona “would send a strong message”.

“It would reward the efforts the Spanish people have made all these years,” he emphasised.

In the meantime, the European Commission said this week that the process of Catalonia’s independence was not a criterion to determine whether or not Barcelona could host the EMA.

“The criteria for choosing the new headquarters of the European agencies are already known and I do not remember that this is one of them,” Commission spokesman Alexander Winterstein stressed.

Analysts suggest that Madrid is trying to send a dual message. Domestically, the government is showing Catalonia support in an effort to mend relations, while at the same time putting indirect pressure on Brussels to help stabilise the EU’s internal political landscape, thereby helping itself.

For Lisbon, it is common sense for the EMA to go south. In a recent interview with EURACTIV, Portugal’s State Secretary for European Affairs Margarida Marques said that southern cities are in a better state to host the agency.

“Officials from the EMA prefer to go to the south more than the north because the weather and the food are better. You also find good facilities to integrate your family and your children. It is not a scientific argument, it is common sense,” she claimed.

Crisis-hit Greece, which is currently hosting the European Union
Agency for Network and Information Security (ENISA), has also joined the race to get the EMA.

Greece’s Alternate Minister of Foreign Affairs, Georgios Katrougalos, has highlighted the low cost, the local growth potential and the country’s strong pharmaceutical sector.

Diplomats also claim that the EMA could offer great opportunities for local Greek businesses as every year it invites thousands of scientists, supports conference tourism and brings customers in hotels and throughout the catering industry.

“We are interested in taking the agency for our own national reasons but also because we are Europeans and we want to ensure its operation as is the case now,” Katrougalos told EURACTIV.

**FOCUSBING ON “BUSINESS CONTINUITY”**

Northern European countries such as the Netherlands, Denmark and Ireland are focusing on the need for a smooth transition.

“The Netherlands guarantees the full business continuity of EMA should it relocate to the Amsterdam Metropolitan Area,” a Dutch government document noted.

“This will allow the EU’s pharmaceutical sector to safeguard human and animal health in the EU,” the document states.

The Dutch also claim that their country has one of the strongest national medicines regulatory agencies in the EU and that it will increase its scientific capacity to take a larger share of EMA’s work.

For Copenhagen, the EMA should be placed in a location that is attractive to staff, new recruits and all other involved parties.

“Hopefully, in our view, Copenhagen has an environment that has an academic level and tradition of good governance that will increase the likelihood that EMA will continue to function as well as it does in London,” Danish government special EMA envoy Lars Rebien Sørensen said.

Ireland believes that its cultural and geographical proximity to the UK is an advantage for EMA staff.

Irish Minister for Health Simon Harris recently said he opposed a politicised discussion over the relocation and pointed out that EU leaders should focus on the “objective criteria”.

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EU leaders should make a patient-oriented decision on the relocation of the European Medicines Agency (EMA) from London and ensure “minimal disruption”, according to the pharmaceutical industry and consumer groups.

The discussion about the relocation of the EMA has kick-started and EU leaders are expected to make a final decision in November.

More than 20 member states have already expressed their interest in hosting the EU drug agency. Analysts say the talks have inevitably been politicised.

However, the pharmaceutical industry and consumer groups are urging EU leaders to focus on business continuity and avoid potential risks for patients.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) has said that the main priority is to put an end to the uncertainty over the location of the EMA, as well as to ensure transitional arrangements are in place for issues that can impact on patient safety and health.

“Scientific recommendations, new medicines approvals, pharmacovigilance and safety monitoring activities are vital elements of the ongoing effort to provide EU citizens with effective, safe and high-quality medicines,” said Elizabeth Kuiper, EFPIA’s director of European affairs.

AVOIDING DISRUPTION

EFPIA has expressed concern that any delay in relocating the EMA will have an impact in several areas. Kuiper noted that EU leaders should avoid unnecessary and potentially risky delays to the effective functioning of the EMA.

Alan Morrison, chair of the EFPIA Brexit Task Force and vice-president for Europe and International Regulatory Affairs at pharmaceutical company MSD, noted that the criteria laid out by the Commission are “objective and correct”.

“From our standpoint, the biggest issue is business continuity, the

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pharmaceutical assessment workload, maintaining the speed, quality, and efficacy of the regulatory process,” he explained.

Asked about the “geographical balance” criterion pushed by newer member states which do not currently host any EU agencies, Kuiper replied, “It’s one of the criteria, of which there are six in total.

But he insisted about the necessity to come to a decision quickly. “We need a quick decision and we appreciate the fact that all six criteria should be taken into account,” Kuiper said.

Politics, however, is making some nervous that the decision could be delayed.

Ilaria Passarani, a member of the EMA management board and head of food and health at the European Consumer Organisation (BEUC), said that “unfortunately” the process is likely to be made political.

“We call on member states to put the interests of European patients before their own,” she told EURACTIV, emphasising the need for a decision as soon as possible to ensure minimal disruption.

“Any delay could hamper the agency’s ability to monitor the safety of medicines on sale and swiftly remove the harmful ones from the market,” she warned, adding that if it takes longer for the Agency to approve new medicines, consumers might struggle to access the treatment they need.

“To avoid these negative situations, the decision must be a swift one,” she said.

UK’S POST-BREXIT ROLE

Another important element of the ongoing discussion is the role of the UK in the EMA’s activities after Brexit.

The UK currently contributes around 20% of the scientific rapporteurs that lead many of the agency’s assessments. The pharma industry believes there are mutual benefits to be gained from the UK remaining a member of the EMA, not least that the EU will continue to benefit from British scientific expertise.

For the pharmaceuticals industry, the continued alignment between the UK and EU regulatory regimes is essential in order to maintain current capacity, processes and time-frames for the introduction of new medicines for patients.

“Avoiding divergence and duplication of regulatory standards and practices is therefore critical,” Kuiper stated.

For Morrison, the collaboration on a technical level post-Brexit could work well.

REPLACING BRITISH SCIENTIFIC TALENT

The EU’s centralised procedure for authorising medicinal products includes a scientific assessment by the EMA’s scientific committee and a decision-making process by the Commission.

According to Morrison, the UK could continue to participate in the scientific assessment process in future.

“Essentially, even if the ultimate post-Brexit decision-making is separate, the process of gathering the evidence and scientific assessment could remain collaborative, allowing citizens of both the UK and the EU-27 to benefit from the expertise in the UK.”

Asked by EURACTIV whether the 20% UK contribution could easily be replaced by another national agency, Morrison replied, “Probably yes, but it will definitely take some time to build on that scientific talent.”

He explained that the reason why the EU originally put in pace a centralised procedure in 1995 was because of the recognition that the scientific talent in Europe was spread across the community.

“I am sure, over time, everything can be replaced but it’s challenging to replace this talent in the short and medium term, that’s why we support the business continuity to preserve this level and quality of scientific talent,” he said.

Speaking in April at the Biovision World Life Sciences Forum 2017 in Lyon, Virginia Acha, executive director of the Association of the British Pharmaceutical Industry, said that for her sector the development of medicines should not be seen as something on which to “wait and see”. She emphasised the need for “practical and pragmatic planning from now”.

“We are looking for as close a line to the EU regulation as we can arrive at,” Acha said. “The partnership with Europe has been productive,” she added, stressing that the main priority is to ensure that the UK will have no problem in delivering medicines the day after it leaves the bloc.
The European Medicines Agency (EMA) is not a toy to be played with by politicians, Edith Schippers told EURACTIV.com. The decision on the agency’s relocation should be based on the European Commission’s assessment, she argues in an interview.

Member states have until the end of July to submit their bids to host the European Medicines Agency, which is currently in London.

The European Commission will then review the bids by 30 September, based on six criteria. A final decision is expected in November in a Eurovision-style voting process.

Edith Schippers is the Minister of Health, Welfare and Sport in the Netherlands.

She spoke to EURACTIV’s Sarantis Michalopoulos in a telephone interview ahead of the official presentation of the Dutch bid today (11 July) to host the EMA.

What would be the main advantages of Amsterdam hosting the EMA?

Amsterdam is a very nice city to live in. It’s in the top 10 of the most loveable cities in Europe and we basically have a multicultural community. The economy is flourishing, we have a high-skilled multilingual workforce and of course, the Schiphol airport. It has the highest number of direct flight connections with the rest of the EU.
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So, in our plans, the distance between Schiphol and the EMA location will be less than 10 minutes. In addition, our regulator is ready to take over the operations of the EMA, which is in my opinion very important as the EU drug agency is not just an authority. It’s the authority which many patients across Europe are dependent on.

20% of the EMA’s work is currently done by the UK national agency. Will your regulator be able to continue this work?

I’m convinced about that. We will invest more in this scientific work because we find it really important. The full details on that will be presented this afternoon.

What is your opinion about the discussion over the need for “geographical balance”?

It’s obvious that geographical balance is very important. But this is not just an institution. If you start building an institution or an authority then you start from scratch. This is a fully operational and very important authority. It is important to have geographical balance, but the EMA is one of the cornerstones of the EU’s health system.

As a minister of health, I find it quite significant to decide on its relocation based on objective criteria. It’s in the interest of EU patients that we will take care of the continuity of the agency’s work.

The decision will be based on objective criteria but many admit that it’s still a political decision. Do you think that a decision based on politics could put the business continuity criterion at risk?

I know that it’s a political decision. But I think the assessment of the European Commission should be taken into account in this decision. Otherwise, why does the Commission make an assessment?

The political decision has to take into consideration the Commission’s evaluation.

There are candidate countries that are backed by the pharmaceutical sector to host the EMA, is this a disadvantage for the Netherlands?

There is a misunderstanding here. The EMA is not about the pharma sector in the first place. The EMA is for patients and its main objective is to provide safe and effective medicines to 510 million people in Europe.

Having said that let me point out that in the Netherlands we have an important bioscience sector, which is responsible for many innovations in drugs and treatments.

But let’s be clear. The EMA is for patients in the first place, not for the pharmaceuticals.

Do you fear that the EMA relocation will split EU countries? Could this be a negative political message ahead of the Brexit negotiations?

Even after Brexit, we remain 27 countries and of course, these countries can have different opinions and political views. This is also the case with the EMA relocation. It’s very good to have discussions in Europe also after Brexit, we have different opinions but in the end, I am sure we will reach a conclusion with EMA.

The EMA talks won’t be the last discussion we will have among the 27 member states after Brexit. It’s not wrong to debate within the EU, but in the end, of course, we have to come up with one policy.

Talking about conclusions, do you agree with the so-called “Eurovision-style” voting process for the relocation of the EMA?

The EMA is not an entertainment. It’s very important for the life of people and we should not treat it as an entertainment. So, the assessment of the Commission is truly vital and the political decision will have to consider its assessments.

So you disagree with two or three rounds of voting.

I am in favour of a decision in which the assessment of the Commission will be the basis.

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