AN AUDIENCE WITH…

Emer Cooke


Credit: EMA

With multiple COVID-19 vaccines approaching the finish line, and dozens of COVID-19 drugs in development, more eyes are on the European Medicines Agency (EMA)'s decisions than ever before. Emer Cooke, who started as Executive Director of the EMA in November, is ready. Cooke, a pharmacist by training, has more than 30 years' experience in pharmaceutical regulation. During this time, she has seen the system transform: the typewriters and carbon copy are gone, replaced by unprecedented volumes of data and complexity. With prior roles that have included oversight of the regulation of medical products at the World Health Organization, Head of Inspections at the EMA and Head of International Affairs at the EMA, she is prepared for the multidisciplinary nature of the challenges ahead. She spoke with **Asher Mullard** about the speed of progress with COVID-19 vaccines, the potential longer-term impacts of the pandemic on regulatory affairs and her goals for the EMA once the world returns to business as usual.

Before the emergence of COVID-19, what would you have made of a claim that vaccine developers would have multiple candidates poised for licensure within a year of the emergence of a new pathogen?

I would have been a little bit circumspect. I was involved with the 2009 H1N1 pandemic, and there were multiple vaccines for this pathogen in development at that time. But nothing like the number that we've got for COVID-19. Now, there are more than 200 COVID-19 vaccines in development.

What do you say to people who are concerned about how fast these are being pushed through?

Well, I think we can be very positive about the amount and quality of data that are being generated. Yes, the speed is unprecedented, but the crisis is also unprecedented. And the numbers of subjects who have been enrolled into clinical trials are much higher than developers would normally enrol for a new vaccine. In fact, at various times during this crisis we thought — and hoped — that we wouldn't have enough events to complete the trials. But, because of the way the virus has progressed, events did accumulate quickly.

I do think people have to understand that we have a huge amount of data, and really many more data than we would have for a vaccine normally.

I don't believe that even 10 years ago we could have gotten this many data so quickly.

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What about long-term follow-up data? How many long-term follow-up data are needed?

I don't even think you can put a fixed follow-up time on this, because we just don't know enough information at this stage. But we have a lot of data from clinical trials, and they look promising. We have a lot of safety data from clinical trials that also look promising. But we still need to follow patients. And we still need to carefully monitor, once the vaccines are deployed for wider use.

How has the European Medicines Agency (EMA)'s focus on COVID-19 programmes impacted its other regulatory responsibilities — namely, the approval of new drugs?

We are carefully monitoring the impact on our core business. We haven't seen any delays for the moment in terms of the number of applications that are coming in.

So the delta is in the COVID-19 programmes. But we have had to divert resources.

Do you expect the pandemic to impact the quality of ongoing clinical trials, for instance in terms of protocol deviations, incomplete patient visit data and trial suspensions?

I think we will have to be vigilant about this. I'm not seeing or hearing about this. But it's something that maybe we do have to look at.

What longer-term impacts do you anticipate the COVID-19 pandemic might have on drug regulations?

I think it's inevitable that there will be lessons learned that we can use in peacetime as well. But I think you also have to recognize that the people and the systems are under a huge amount of stress at the moment. And there is a lot of desire to go back to normality. I think we have to be careful about expectations that everything will adapt post-COVID-19. There are certain things that obviously make sense that we will try and continue. But I can't say what these are going to be at the moment. And we're certainly not going to be in a position to use all the agility that we have now in a peacetime situation again.

I do hope that we will be able to keep some of the efficiencies that we're trying to bring into the process. But, I don't want industry to see this as a free pass to more relaxed regulations. We still have a very high responsibility, and we need to make sure that we meet that responsibility.

What about in terms of regulatory cooperation? This pandemic has highlighted the value of internationalized, streamlined assessments. But, given concerns around the perceived politicization of the regulatory process in the USA especially, it has also highlighted the value of independent assessments. How has this affected your perspective on the pros and cons of regulatory collaborations?

I'm a great fan of international collaborations, and of this concept that we are all stronger together. But I do think that we have to be very cognizant of the framework within

which we operate. We can use reliance principles, but ultimately we are responsible for the products that we regulate.

Has the COVID-19 experience highlighted any collaborative opportunities for you?
One thing that maybe we will develop further is how to involve non-EU regulators in the regulatory processes. For remdesivir, we involved Health Canada in the assessment. We've opened up the assessment process for COVID-19 vaccines to observers from other countries. And, to the extent that we can do this without a huge amount of additional resource, I would look to continue that work.

How do you think about the EMA's role when it comes to transparency and communication during this pandemic?
The whole area of community communication, transparency and ensuring trust in the regulatory system is an area about which I feel very strongly. I believe that we are accountable to the population. And we need to be able to explain what we do to the person on the street. I think we're making great strides in the communication area. But we're in a world where there's a lot of misinformation. So we have to maybe see how we can reach out to be the definitive source of information on regulated products. And we have committed to proactive publication of the data from our COVID-19 applications.

The EMA has already been publishing clinical reports for newly approved as well as withdrawn drug applications since 2016. How is that work going?
We've been working to publish a lot of information proactively, including clinical data. That is part of our policy now.

We also respond to any access to information requests. But, a lot of the requests that we get are actually from industry, about other people's products. And you know, I don't think that was what we were trying to do with this policy. So, maybe we need to think about whether we have missed a public need here?

I remember somebody saying to me, "well, we ask for data, and then you give us too much". And it is too much. They want us to pick out the good bits. We haven't really focused on this as much as we would have, because of the diversion of resources to COVID-19. But I think it does merit looking at again.

Once COVID-19 is behind us, what are your priorities for the EMA?
There are a number of areas where I would like to see change. I'd like to see us embrace digitalization to make our processes more efficient, and also to use the new developments in artificial intelligence to inform us better about the products that we're regulating. I'd like to see better connections between the regulatory system and the health records held in health systems. Because, you know, when people were setting up these systems, they weren't thinking about the interconnectivity, because it was so far away from what they could do at the time. But now it's a possibility. And, think about how much better we could regulate products if you knew how the products were really being used, and how the patients were reacting, as opposed to waiting for the traditional regulatory mechanisms to feed information back to us.

I think the potential of digitization cuts across a lot of different areas though, including process efficiency, trying to look at repetitive tasks and how you can automate them, and more. The electronic package leaflet is a potential link with the health-care systems, for example. And in the USA, I believe they're looking a lot more at links with claims data, which again wouldn't really have been part of the regulatory system.

How do you expect this will affect drug developers?
I don't think that we're there yet. I think that we still need to learn a lot about how we can really use these tools in ways that can help us to do our business better. And I think we need to have a greater understanding as to what the benefits and potentials are, as well as the risks.

The volume and complexity of regulatory information has exploded over the course of your career. Will digitalization and increased interconnectedness drive another explosion?
I don't know whether we can bear a lot more complexity. I think what we need to be thinking about is really how we get the right information out of all the information that's out there. More is not necessarily better. But we need to assess whether more is a pathway to getting better information.

> I do hope that we will be able to keep some of the efficiencies that we're trying to bring into the process. But, I don't want industry to see this as a free pass to more relaxed regulations

With additional tools, we might be able to pick out the information that really makes the difference.

You've also highlighted antimicrobial resistance and access to medicines as priorities for your time at the EMA. These are often considered to be market issues. As such, what regulatory tools will you use to address these issues?
I agree that these are essentially market issues. And the EMA's role is regulating the safety, quality and efficacy of the interventions, so there are limits to what we can do. But the type of interventions where we can contribute in terms of antimicrobials is on the consumption and sales of these products. We're doing some monitoring on that. We can play a role in the use and inappropriate use of existing antibiotics. And then the big challenge is encouraging the development of new antibiotics that we don't want people to use: we want to have them, but we want to save them. It's a very, very strange market dynamic. And it needs economic thought beyond the regulatory system to really get this. But I am encouraged by strategies where policy makers are looking at potential incentives for drug developers. This is something that, for me, regulators play a small role, but an important role in.

Do you think that the global experience with COVID-19 has driven home the risk of antimicrobial resistance, and raised political capital to address it?
I think it's given a momentum to research. Okay, very targeted research at the moment. But maybe some of what we will have learned can also be applied for antibiotics. What COVID-19 has taught us is that there is a lot of potential that doesn't necessarily come to the fore until you have a crisis.