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‘We Need Help,’ Says EMA Chief Amid COVID-19 & Burgeoning Workload

by Ian Schofield

COVID-19, resource constraints and a forthcoming expansion of its responsibilities are piling the pressure on the EU regulator.

The executive director of the European Medicines Agency has made a plea for more staff and financial resources to help the agency face the challenges posed not only by COVID-19 but also by other work such as dealing with access to document requests and publishing clinical trial data – not to mention the proposed expansion of the organization's mandate as part of EU plans for a “European Health Union.”

“We need help. We definitely need help,” Emer Cooke told a 30 November hearing of the European Parliament’s environment and public health committee (ENVI).

Since 2014, she said, “we have increased our activity by 43%. And during that time, apart from specific short-term tasks, or indeed the extended mandate, our actual establishment plan has been reduced by 10%. So you can see immediately that there is a mismatch there between what we're required to do and what our establishment plan, our staffing plan, allows us to do.”

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The EMA has been under financial and staffing constraints since it moved from London to Amsterdam following the UK’s 2016 decision to leave the EU. Asked how it was coping with these

constraints and its growing workload, a clearly exasperated Cooke said: “I think that's a very important question, and it's a very human question. It's not just about money. This is about how we as a system are coping and I think we have to recognize that everybody is under severe pressure here.”

In a presentation that had a distinctively personal flavor, she noted that, having first been relocated after Brexit, the agency’s staff had “moved into the COVID-19 crisis, and they then had more and more workload on them. So it’s not an easy time for anybody and I think we really have to appreciate that.”

Cooke said that the agency had a “very, very motivated staff,” and that it had had to prioritize a lot of the COVID-19 work. “People are working around the clock. Every time we think we've got to the end of a wave, we breathe a sigh of relief, and then another new challenge comes ahead of us.”

Requests For More Staff Rejected

Additional human resources were needed, Cooke said. “We need to be able to do not just the COVID-19 work but also all the work that allows us to publish the clinical trial results, that allows us to do the access to document requests, that allows us to ensure that we protect the personal data of any subject in any transfer of data, that we can ensure that we're making the right decisions on confidentiality of the data submitted.”

She said the agency was therefore “disappointed that the 20 posts that we had asked for our work program for 2022 were not accepted.” She told members of parliament (MEPs) on the committee that “we would very much like to draw to your attention to the need to ensure that we have consistent and sustainable staffing to allow us to do our work.”

The executive director also highlighted the mental health impact the situation was having on the agency’s staff. “I do want to bring a little bit of a personal note into this because… we don't know the implications of COVID-19, but we do know that working in different situations for some people causes additional health and mental strain and this is something we're also seeing from our own staff. We have increasing number of staff on long-term sick leave, which again, as executive director, that's something I have to be very concerned about.”

Concern Over Expanded Mandate

Cooke also expressed some worries about the agency’s ability to carry out the added responsibilities that it will be taking on as a result of the draft EU regulation that will expand its mandate, particularly in terms of monitoring medicines shortages.

On 28 October, the parliament and the Council of the EU reached a provisional agreement on the draft regulation, which has been drawn up as a result of the supply chain problems that were

experienced during the COVID-19 pandemic. (Also see "*EU Bodies Agree On New Drug Shortage Monitoring Platform*" - Pink Sheet, 29 Oct, 2021.)

The idea behind reinforcing the EMA's role is to monitor and mitigate actual or potential shortages of medicines and medical devices that are "considered to be critical" in dealing with public health emergencies, and to ensure the rapid development of new, high-quality and effective products that might be needed in emergency situations.

Among the novelties introduced by the parliament into the draft regulation was a new shortages monitoring platform to be set up and managed by the EMA.

> ***"We're hopeful that we do have the resources but we need to address the delta between the original commission proposal and what will be finally adopted" – Emer Cooke, EMA executive director***

Cooke generally welcomed the expanded mandate. She said it would give the agency "new tools to tackle many of the challenges that the medicine system is faced with, from coordination national responses to medicines to shortages of critical medicines, to supporting innovation, particularly in crisis situations, but also in preparing for other health threats including antimicrobial resistance, the silent pandemic which is also a cause for concern."

The regulation, she told MEPs, was "one of the building blocks of the health union and is setting the stage for even more structural ambitious reforms under the pharma strategy next year."

Cooke acknowledged that the extended mandate package originally proposed by the European Commission came with an additional 40 staff over a seven-year period and an additional €100m over the same timeline.

She also noted that MEPs were "very interested in the shortages platform," and "we really appreciate the work that went into putting a very comprehensive proposal on the table to better deal with shortages."

However, she said, this differed from what was in the original package. "So we don't know. We still have to evaluate exactly what the resource consequences of that will be." She added: "We're hopeful that we do have the resources but we need to address the delta between the original commission proposal and what will be finally adopted."

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COVID-19 Clinical Data Publication

Another of the EMA's new responsibilities is the rapid publication of clinical trial data on all COVID-19 vaccines and therapeutics that are approved at EU level – another resource-intensive task.

"We have published the clinical trial data, we've done that very quickly following the authorization, and we are committed to doing that," Cooker told the ENVI committee. "Now this is an area where we are under resourced, so in terms of moving this to every product that's coming through, this is causing us some challenges at the moment."

HERA

She also addressed the ongoing debate over the role and responsibilities of the new Health Emergency Preparedness and Response Authority (HERA), which was recently launched and is expected to be fully up and running in 2022. HERA will focus particularly on the development, availability and affordability of medicines and vaccines in health emergencies. (Also see "*Coronavirus Notebook: Valneva Vaccine To Begin EU Rolling Review, Synairgen Reports Progress With Inhaled IFN-Beta*" - Pink Sheet, 11 Nov, 2021.)

There has been some controversy over the new body's role, particularly whether there will be any overlap with the work of the EMA and the European Centre for Disease Prevention and Control, whose mandate is also being extended. Cooke said at a conference in October that the EMA and HERA would play "synergistic and complementary" roles. (Also see "*EU's New Health Crisis Response Body 'Won't Duplicate' Work Of EMA And ECDC*" - Pink Sheet, 8 Oct, 2021.)

> ***"I think the key here is to make sure we have effective coordination across the HERA and our own activities... I'm very confident that's going to be the case" – Emer Cooke, EMA executive director***

At the ENVI hearing she sought to reassure MEPs – who have been pressing for the parliament to have more of a say in HERA's operations – that all was under control. The EMA was planning to develop a memorandum of understanding that "makes it very clear what's under our responsibility and what's under HERA's responsibility," she said.

"I think the key here is to make sure we have effective coordination across the HERA and our own activities. And I would say I'm very confident that that's going to be the case."

ECDC's Extended Mandate Moves Ahead

As for the ECDC, the parliament and council reached a provisional agreement on the draft regulation expanding its mandate. The center will be responsible for coordinating the standardization of data collection, validation, analysis and dissemination at EU level, and will also develop risk assessments and maintain database for epidemiological surveillance.

It will also work closely with international organisations in the area of public health to avoid duplication of efforts. In particular, closer collaboration with the World Health Organization will include monitoring and reporting on trends in communicable diseases and exchanging information on unusual epidemic phenomena or new communicable diseases of unknown origin, including those in third countries.