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EMA Chief Backs Restructuring Plan & 'Regulatory Sandbox' Proposal

by Ian Schofield

Emer Cooke told a European Parliament committee that she hoped the European Medicines Agency would be given sufficient resources to carry out its new tasks under the revision of the EU pharmaceutical legislation.

The head of the European Medicines Agency, Emer Cooke, has welcomed the European Commission's plans to simplify the agency's committee structures, saying the move will allow it to make better use of its resources and give it more flexibility in consulting experts on specific diseases or types of product.

She also backed the idea of establishing a "regulatory sandbox" for testing new ways of evaluating novel technologies, as well as the proposed EU "temporary emergency marketing authorization" for products to be used in health crisis situations.

Cooke was speaking this week at a meeting of the European Parliament's environment and public health committee (ENVI), which is the lead committee for discussions on the commission's legislative revision package.

A key part of the package – which consists of a draft directive and a draft regulation – is the proposal to streamline the way that the EMA works by reducing the number of its human medicines committees from six to two.

This would leave in place just the main drug evaluation committee (CHMP) and the pharmacovigilance committee (PRAC). The expertise on the other four committees – advanced therapies, pediatric medicines, orphan drugs and herbal medicinal products – would be distributed into working parties and a pool of advisory experts. (Also see "*EU Proposes To Chop EMA Committees, Drop Five-Year Renewals*" - Pink Sheet, 2 Mar, 2023.) The agency's veterinary medicines committee would be retained.

Asked by ENVI members what she thought of this proposal, Cooke said that while the committees did "excellent work," there had been "some overlaps" that made it "challenging in a resource poor environment to really make sure we have the right expertise for the particular job."

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Having just two human medicine committees "would allow us to focus the resources on these critical committees, but also allow us the flexibility to be agile and more expertise-focused when we need input on a particular disease or product type or where we need particular input to address rare diseases or pediatric considerations," she declared.

"We think this will help us to streamline the procedures without losing the expertise that we find very valuable in helping us with the assessments."

Will There Be Enough Resources?

Cooke was asked about the resources allocated to the EMA to meet its obligations under the revision package and whether the agency had been consulted on the financial aspects of the proposals.

"We were not consulted in advance on the actual proposal, but we were asked for input on some of the ideas," such as environmental risk assessments and actions to deal with medicine shortages," the EMA executive director explained. The agency was also asked to provide input as to the number of staff that it thought would be needed to address these issues.

"To the best of our ability, and based on the outline proposals that the commission provided us with, we put together some estimates and these have been included in the commission's proposal for the regulation."

Cooke said the EMA was "happy with what the commission has put forward for the resources based on what's in the text at the moment." However, she pointed out that "the proposal that the commission puts on the table does not always reflect the final proposal that comes out of the legislative process," and "we don't know… whether these resources will be sufficient."

She added that while the EMA was "very grateful" for the new resources that came with the agency's extended mandate (in managing drug shortages) and for some of the temporary COVID-19 work, "some of the proposals in the extended mandate, for example the shortages platform, never came with any finance, with any resource for the EMA. So we're sort of on the back foot as regards resources, and also because we've had a steady increase of almost 50% in nine or 10 years in our general day-to-day work and the number of procedures."

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Regulatory Sandbox Proposal

Cooke was also asked for her view on the proposed "regulatory sandbox," a mechanism that could be used where it was not possible to develop a product in line with existing requirements because of scientific or regulatory challenges related to the characteristics of the product.

Already used in other industries such as financial services, the sandbox would be a "controlled environment" within which new kinds of regulatory approaches could be used to test and assess novel drugs, according to the draft regulation.

But there has been disagreement in the parliament over the commission's proposal, with the rapporteur for the regulation, Tiemo Wölken, saying it was "vague in nature" and that he had "not been satisfied with explanations or examples of which types of products could be eligible" for the sandbox. (Also see "*EU Rapporteur Slams Commission's 'Regulatory Sandbox' & Antimicrobial 'Voucher' Proposals*" - Pink Sheet, 6 Oct, 2023.)

Cooke, though, likes the idea. She said that sometimes when the EMA is faced with a novel product or technology, "we don't know how to regulate it. And we try to fit it into the current regulation. And often it doesn't really fit."

The regulatory sandbox "gives us the possibility to experiment and say, OK, can we fit it into the existing framework? Or maybe are there some tweaks that we could [make] that would really help to ensure that we don't add unnecessary challenges" in the evaluation of such products.

While it was difficult to give precise examples of where the sandbox might be used, she said that "if I look back on our experience with advanced therapy medicinal products, we built a very tight oversight into the legislation that sometimes means we don't really realize the benefit of these new types of therapy."

If the agency had been able to discuss such products "in a closed environment... I think we might have been able to anticipate some of the challenges."

But she was keen to stress that the sandbox idea did not amount to a relaxation of regulatory standards.

"Just to be very clear," she told the committee, "we would have very strict regulatory oversight on this. This isn't about just letting anything loose onto the market. It's really about trying to understand how something new that maybe we've never thought of before would fit into the current environment or what might need to be changed to optimize the regulatory oversight of that product."

The TEMA For Crises

Another proposal that has prompted some debate is the "temporary emergency marketing authorization," or TEMA, which the commission describes as an "agile, fast and streamlined" process for approving crisis-related products where the benefits of rapid availability outweigh the lack of comprehensive data at the time of approval. (Also see "*EU's Proposed Emergency Approval Route For Crisis-Related Products – Would It Work?*" - Pink Sheet, 5 May, 2023.)

If this idea was to be implemented, Wölken said in his draft report on the regulation, "robust transparency measures and standards" for the EMA's activities would be needed, such as "the timely publication of all relevant information on approved medicinal products and medical devices and of clinical data, including clinical trial protocols." (Also see "*EU Rapporteur Slams Commission's 'Regulatory Sandbox' & Antimicrobial 'Voucher' Proposals*" - Pink Sheet, 6 Oct, 2023.)

Cooke noted that while other jurisdictions had the possibility of the "emergency use authorization" during the height of the pandemic, the EU did not. This meant that every product had to have a full regulatory package before it could be approved and placed on the market.

In a crisis, when there might be some promising products that needed "additional data generated or maybe some additional inspections to be performed," having a temporary emergency marketing authorization "could add a new approach to the toolbox and could be useful in certain restricted situations," she told the committee.