EUROPEAN MEDICINES AGENCY
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Advancing regulatory science in the EU – mid-point report published

News 22/03/2023

EMA has published a report summarising the mid-term achievements of its Regulatory Science Strategy (RSS) to 2025. The report provides an overview of the main deliverables achieved between March 2020 and December 2022 across the human and veterinary areas.

"The achievements highlighted in this report demonstrate that we have made considerable progress in advancing regulatory science to build a more adaptive regulatory system that encourages innovation in human and veterinary medicines," said Emer Cooke, EMA's Executive Director.

The mid-term report highlights achievements for the top five human and top three veterinary recommendations thought to deliver the most significant change over the course of the five-year strategy, according to an extensive stakeholder consultation process that took place with EMA's scientific committees, stakeholders and EU regulatory partners.

In the **human** domain, progress was made in several areas, including:

- fostering innovation in clinical trials;
- promoting use of high-quality, real-world data in decision making;
- reinforcing patient relevance in evidence generation;
- contributing to health technology assessment bodies' (HTA) preparedness and downstream decision making for innovative medicines;
- supporting developments in precision medicine, biomarkers and 'omics.

In the **veterinary** domain, progress was made in several areas, including:

- transforming the regulatory framework for innovative veterinary medicines;
- developing new approaches to improve the benefit-risk assessment of veterinary medicinal products;
- collaborating with stakeholders to modernise veterinary pharmacoepidemiology and pharmacovigilance.

The report also highlights achievements for the **human** and **veterinary medicines strategies**. Links are included in the report to detailed information on goals, core recommendations and underlying actions in these areas.

Work will continue at pace through 2023-2025 to deliver the strategic goals to their fullest potential.

"We will seek opportunities to further progress delivery of the Regulatory Science Strategy to 2025, and the broader European medicines agencies network strategy to 2025, as we emerge from a long period of business continuity. This work will be crucial to evolve the network's capability to engage with and enable innovative science and technology within the current pharmaceutical framework and pave the way for the legislative review," added Ms Cooke.

A final report on the regulatory science strategy will be published in 2026, once the strategy has been completed.

Background on the Regulatory Science Strategy to 2025

EMA published its Regulatory Science Strategy to 2025 in March 2020. The strategy was developed in 2018 and 2019 in consultation with a wide range of stakeholders and provides a plan for advancing regulatory science over a five-year period.

The motivation behind the strategy was the recognition that the pace of innovation had accelerated dramatically in recent years. As part of their mission to promote and protect human and animal health, regulators needed to be ready to support the development and assessment of ever more complex medicines that increasingly deliver healthcare solutions by converging different technologies.

Furthermore, the advent ofBig data opened up new sources of information on the use of medicines in healthcare settings. Regulators needed to take action to address the challenges arising from collecting and processing these data from patients.

The COVID-19 pandemic also underlined the need for rapid and close engagement of all stakeholders and partners involved in the development and supervision of medicines in the European Union and globally, which is one of the fundamental principles of this strategy.

Note

Regulatory science refers to the range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine. It encompasses basic and applied biomedical and social sciences and contributes to the development of regulatory standards and tools.

Related documents

EMA's Regulatory Science Strategy to 2025 - Mid-point achievements to end 2022 (PDF/1.21 MB) (new)

First published: 22/03/2023
EMA/211551/2022

EMA Regulatory Science to 2025 - Strategic reflection (PDF/4.8 MB)

Adopted

First published: 31/03/2020

Analysis and summaries of public consultation results: EMA Regulatory Science to 2025 - Strategic reflection (PDF/1005.11 KB)

First published: 31/03/2020
Last updated: 02/04/2020

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