EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press release

Regulatory Science to 2025 – launch of six-month public consultation

EMA has published its draft 'Regulatory Science to 2025' strategy for a six-month public consultation. This is a proposed plan for advancing the Agency's engagement with regulatory science over the next five to ten years, covering both human and veterinary medicines.

Stakeholders are invited to send their comments via an online questionnaire by 30 June 2019.

"The Regulatory Science strategy to 2025 aims to build a more adaptive regulatory system that will encourage innovation in human and veterinary medicine," said Guido Rasi, EMA's Executive Director. "The strategy includes developments and challenges in medicines development that we together with the Commission and NCAs experts have identified in a thorough process of mapping and selection. Now we want to hear from our stakeholders whether they consider this strategy is ambitious enough."

Regulatory science is defined as 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.

The strategy will help shape the vision for the next EU Medicines Agencies Network Strategy (2020–2025). It seeks to offer informed guidance on modern medicines development, facilitate the optimisation of regulatory science and critically assess the benefits and risks of innovative therapies and diagnostics based on new technologies.

The five key goals of the strategy include:

- catalysing the integration of science and technology in medicine development;
- driving collaborative evidence generation - improving the scientific quality of evaluations;
- advancing patient-centred access to medicines in partnership with healthcare systems (for human medicines only);
- addressing emerging health threats;
- enabling and leveraging research and innovation in regulatory science.

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The strategy incorporates feedback gathered during two workshops organised by the Agency, focusing, respectively, on human medicines and on veterinary medicines. These events brought together representatives of our regulatory partners and stakeholders, including national competent authorities, patients', healthcare professionals' and veterinarians' organisations, health technology assessment bodies, payer organisations and pharmaceutical industry to discuss key areas of interest in human and veterinary medicines. Participants at both workshops reflected on the scientific and technological advances in the pharmaceutical arena, and on the challenges that EMA's scientific committees and working parties will face in the future due to these developments. Supporting materials from the human and veterinary workshops are available.

Stakeholders are encouraged to join the discussion on Twitter using the following hashtag: #RegScience2025.

Notes

1. In case of technical difficulties while completing the survey, please contact us via RegulatoryScience2025@ema.europa.eu.
2. Watch our new video on the 'Regulatory Science to 2025' strategy featuring Anthony Humphreys, Head of EMA's Scientific Committees Regulatory Science Strategy Division.
3. This press release, together with all related documents, is available on the Agency's website.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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