EMA Regulatory Science to 2025

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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#RegScience2025

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EMA Regulatory Science to 2025

Five goals for human medicines regulation

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Goal 1

Catalysing the integration of science and technology in medicines development

- Support developments in precision medicine, biomarkers and ‘omics’
- Support translation of advanced therapy medicinal products (ATMPs) into patient treatments
- Promote and invest in the PRIority MEdicines scheme (PRIME)
- Facilitate the implementation of novel manufacturing technologies
- Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products
- Develop understanding of, and regulatory response to, nanotechnology and new materials in pharmaceuticals
- Diversify and integrate the provision of regulatory advice along the development continuum

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Goal 2

Driving collaborative evidence generation and improving the scientific quality of evaluations

- Leverage non-clinical models and 3Rs principles
- Foster innovation in clinical trials
- Develop the regulatory framework for emerging clinical data generation
- Expand benefit-risk assessment and communication
- Invest in special populations initiatives
- Optimise capabilities in modelling, simulation and extrapolation
- Exploit digital technology and artificial intelligence in decision making

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Goal 3

Advancing patient-centred access to medicines in partnership with healthcare systems

- Contribute to HTA's preparedness and downstream decision making for innovative medicines
- Bridge from evaluation to access through collaboration with payers
- Reinforce patient relevance in evidence generation
- Promote use of high-quality real-world data (RWD) in decision-making
- Develop network competence and specialist collaborations to engage with big data
- Deliver improved product information in electronic format (ePI)
- Promote the availability and support uptake of biosimilars in healthcare systems
- Further develop external engagement and communications to promote trust and confidence in the EU regulatory system

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Goal 4

- Implement EMA's health threats plan, ring-fence resources and refine preparedness approaches
- Continue to support development of new antibacterial agents and their alternatives
- Promote global cooperation to anticipate and address supply problems
- Support innovative approaches to the development, approval and post-authorisation monitoring of vaccines
- Support the development and implementation of a repurposing framework

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Goal 5

Enabling and leveraging research and innovation in regulatory science

- Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science
- Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions
- Identify and enable access to the best expertise across Europe and internationally
- Disseminate and exchange knowledge, expertise and innovation accross the network and to its stakeholders