EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EC's Pharmaceutical Strategy

EMA's perspective on enabling sustainable innovation

ORGANIZAÇÃO

OLÉGIO de ESPECIALIDADE ASSUNTOS REGULAMENTARES

ORDEM DOS FARMACÊUTICOS 1835

Presented by Tony Humphreys on 13 May 2021
Head of Regulatory Science and Innovation Task Force, EMA

"It is a patient-centred strategy that aims to ensure the quality and safety of medicines, while boosting the sector's global competitiveness. It is a key pillar of the Commission's vision to build a stronger European Health Union."

Strategic Goals

Delivering for patients, fulfilling unmet medical needs and ensuring accessibility and affordability of medicines

Supporting a competitive an innovative European pharmaceutical industry

Enhancing Resilience ; Diversified and secure supply chains ; environmentally sustainable pharmaceuticals; crisis preparedness and response mechanisms

Ensuring a strong EU voice globally

Working together for success: a cooperative and layered approach to implementing Europe's strategic ambitions

EMA Regulatory Science Strategy to 2025

European Medicines Agencies Strategies to 2025

1. Availability and accessibility of medicines

2. Data analytics, digital tools and digital transformation

3. Innovation

4. Antimicrobial resistance and other emerging health threats

5. Supply chain challenges

6. Sustainability of the Network and operational excellence

EC Pharma Strategy

1. Learning from Covid-19- towards a crisis resistant system

2. Ensuring accessibility and affordability of medicines

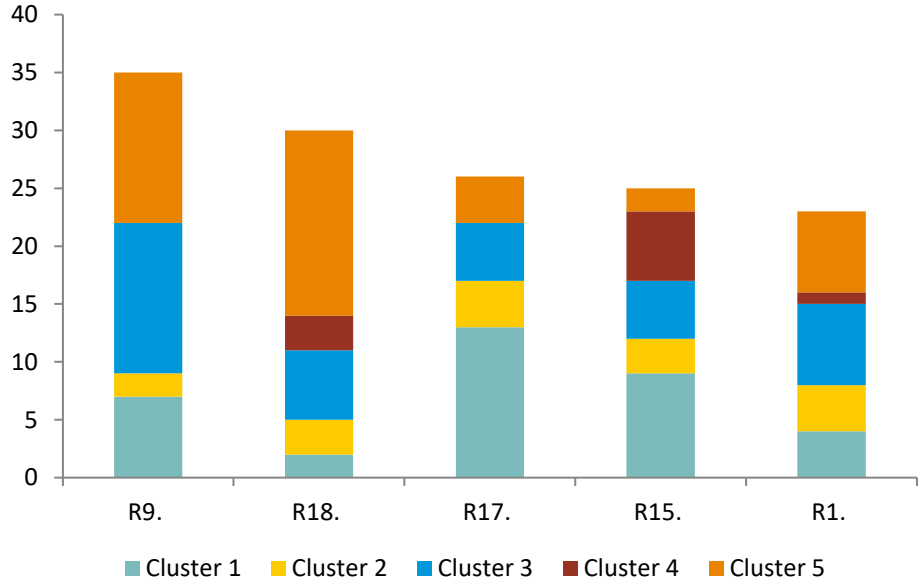
3. Supporting sustainable innovation, emerging science and digitalisation

4. Reducing medicines shortages and securing strategic autonomy

Listening to our stakeholders

Cluster 1 (IPCO+)	Cluster 2 (HCP)	Cluster 3 (Research)	Cluster 4 (Public body)	Cluster 5 (Industry)
• Individual member of the public • Patient or Consumer Organisation • Advocacy Group	• Healthcare professional organisation • Healthcare professional	• Other scientific organisation • European research infrastructure • Academic researcher • Learned society	• EU Regulatory partner / EU Institution • Health technology assessment body • Payer	• Pharmaceutical industry(trade association, individual company, SME)

Overall aggregate ranking of core recommendations – Top 5



9. Foster innovation in clinical trials

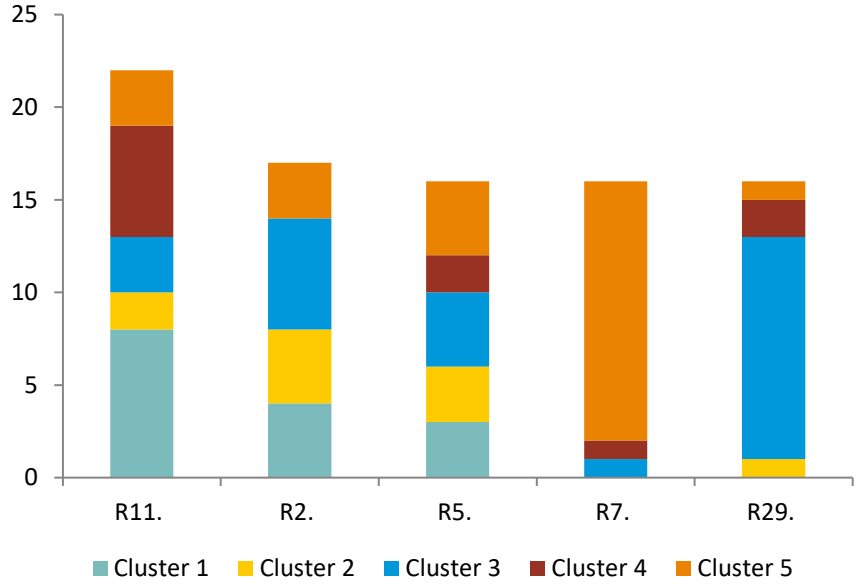
18. Promote use of high-quality real-world data (RWD) in decision making

17. Reinforce patient relevance in evidence generation

15. Contribute to HTA's preparedness and downstream decision making for innovative medicines

1. Support developments in precision medicine, biomarkers and 'omics

Overall aggregate ranking of core recommendations – Top 6-10



11. Expand benefit-risk assessment and communication

2. Support translation of advanced therapy medicinal products (ATMPs) into patient treatments

5. Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products

7. Diversify and integrate the provision of regulatory advice along the development continuum

29. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions

How do the core recommendations within the RSS to 2025 align with and support the delivery of the Pharmaceutical Strategy?

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AMR

Flagship initiative 1 – 2021 –	Flagship initiative 2 – 2021–	Flagship initiative 3 – 2022–	Other action 1 – 2021 –
Provide pull incentives for new antimicrobials	Promote RnD, Mfg deployment and use as part of HERA preparations	Legislative measures to restrict and optimise use incentives	Prudent use

24. Continue to support development of new antibacterial agents and their alternatives

Access to Medicines

Flagship initiative 1 – 2022 –	Flagship initiative 2 – 2022–	Other action1 – 2021–	Other action 2 – 2021 –
Revise system of incentives and obligations legislation	Improve access to generics and biosimilars (IC & Bolar)	EMA /MS pilot on root causes of deferred launches	"Big Buyers" initiative

12. Invest in special populations initiatives

21. Promote the availability and support uptake of biosimilars in healthcare systems

Unmet Medical Need (UMN)

Flagship initiative 1 – 2022 –	Flagship initiative 2 – 2021–	Other action1 – 2022 –	Other action 2 – 2021 –
Revise legislation children and rare diseases; Address UMN* & tailor incentives	Facilitate collaboration UMN & evidence generation between regulators HTA & payers	Incorporate PRIME into legislative framework	Enable parallel advice regulators & HTA vis HTA regulation
17. Reinforce patient relevance in evidence generation	**15.** Contribute to HTA's preparedness and downstream decision making for innovative medicines	**3.** Promote and invest in the PRIME scheme	**7.** Diversify and integrate the provision of regulatory advice along the development continuum
12. Invest in special populations initiatives	**16.** Bridge from evaluation to access through collaboration with payers		

Ensure affordability of medicines

Flagship initiative 1 – 2022 –	Flagship initiative 2 – 2021-2024 –	Other action1 – 2021-2024 –	Other action 2 – open –
Revise legislation to address aspects that impede market entry	Cooperative group of pricing payment procurement competent authorities	Transparency costing	"NHS" sustainability assessment

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Competitiveness

Flagship initiative 1 – 2022 –	Flagship initiative 2 – 2022 –	Flagship initiative 3 – 2021-2025 –	Flagship initiative 4 – 2021 –	Other action 1 – 2022 –
Optimise Supplementary Patent Certificate	Legislation European Heath Data Space	Establish I/O data access IS for EHDS – test via EMA pilot 2021	Support IHI especially SME's	Prioritise skills investment through NextGenerationEU
	18. Promote use of high-quality real-world data (RWD) in decision making	**19.** Develop network competence and specialist collaborations to engage with big data	**29.** Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions	**30.** Identify and enable access to the best expertise across Europe and internationally
				31. Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders

Innovation

Flagship initiative 1 – 2022 –	Flagship initiative 2 – 2021 –	Flagship initiative 3 – 2021-2022 –
Revise legislation to adapt to science/tech and tailor incentives	Enhance evidence generation dialogue between medicine and medical device regulators	Support collaborative projects High performance computing /AI and EU health data
2. Support translation of advanced therapy medicinal products (ATMPs) into patient treatments	**5.** Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products	**18.** Promote use of high-quality real-world data (RWD) in decision making
10. Develop the regulatory framework for emerging clinical data generation	**13.** Optimise capabilities in modelling, simulation and extrapolation	**14.** Exploit digital technology and artificial intelligence in decision making
4. Facilitate the implementation of novel manufacturing technologies		
8. Leverage non-clinical models and 3Rs principles		

Innovation

Flagship initiative 4 – 2025 –	Other actions 1-5 – 2021-2022 –
Establish federated access to 10 million genomes	Full CTR implementation, pilot repurposing, vaccine monitoring platform, training Academia, regulatory "sandbox" pilots

1. Support developments in precision medicine, biomarkers and 'omics

9. Foster innovation in clinical trials

29. Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions

27. Support the development and implementation of a repurposing framework

6. Develop understanding of, and regulatory response to, nanotechnology and new materials in pharmaceuticals

Regulatory efficiency

Flagship initiative 1 – 2022 –	Flagship initiative 2 – 2021-2023 –	Other actions 1-7 – 2021-2022; 2024 –
Revise legislation to simplify and streamline approval processes and timely adaptation to tech developments including device interplay	Revise variation framework to increase efficiency and adapt to digitalisation	Revise fee regulation, single ASMF assessment, GMO adaptation, Community register dashboard, ePI implementation, direct label changes; revised penalties
5. Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products	**4.** Facilitate the implementation of novel manufacturing technologies	**11.** Expand benefit-risk assessment and communication
		20. Deliver improved product information in electronic format (ePI)

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Open Strategic Autonomy

Flagship initiative 1 – 2022 –	Flagship initiative 2 – 2021 –	Flagship initiative 3 – 2021 –	Other actions 1-2 – 2021-2022 –
Revise legislation to enhance security and supply and address shortages	Formulate policy options to strengthen security of supply	Increase transparency on supply chains	MS cooperation on structural shortages; WTO resilience supply chains

25. Promote global cooperation to anticipate and address supply problems

Quality & Environmental sustainability

Flagship initiative 1 – 2022 –	Flagship initiative 2 – 2022 –	Flagship initiative 3 – 2021 –	Other actions 1-6 – ongoing-2022 –
Revise mfg & supply in legislation (supply/environment sustainability/new tech)	Revise legislation ERA & Conditions of Use medicines	Increase transparency on supply chains	GMP review; International inspection/audit; Quality of APIs ; linked EU databases sites and inspection status; continue PIE; de-carbonising value chains

4. Facilitate the implementation of novel manufacturing technologies

Europe's Health crisis response mechanisms

Flagship initiative 1
– 2021 –

Proposal for an EU Health Emergency Response Authority

22. Further develop external engagement and communications to promote trust and confidence in the EU regulatory system

23. Implement EMA's health threats plan, ring-fence resources and refine preparedness approaches

24. Continue to support development of new antibacterial agents and their alternatives

25. Promote global cooperation to anticipate and address supply problems

26. Support innovative approaches to the development, approval and post-authorisation monitoring of vaccines

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International Cooperation

Flagship initiative 1	Other actions
Promote regulatory convergence to ensure access to safe effective, high-quality and affordable medicines	Advance international harmonisation by proposing topics latest scientific developments, promote uptake of international stds and ensure level playing field for operators

Working together: international regulatory science cooperation

- EMA will therefore pursue a continued deepening of international cooperation with a focus on horizon scanning and science-based innovation.
- Nearly all the topics considered are relevant to other regulators, who share these challenges, and exchanging views on how to tackle them and to adapt is mutually beneficial.
- This should be pursued through all of the channels currently opened between regulators ranging from high level fora such as ICH, ICMRA, ICDRA as well as more specialist focus channels such as the range of cluster meetings with which the Agency is involved.

A new pharmaceutical strategy for Europe

"To ensure that this strategy succeeds we need a comprehensive, integrated approach that addresses the challenges and breaks down silos, working together across disciplines and regulatory competences throughout the lifecycle of medicines and medical technologies to find the right policy approaches."

A once in a generation opportunity to engage in shaping the future

Any questions?

Further information

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