EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA Regulatory Science to 2025 Public Consultation Human Stakeholders Workshop

24 October 2018, 08:30 – 17:30

Meeting Rooms 3/A & 3/M (3rd Floor)

European Medicines Agency, London, United Kingdom

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Objectives of the meeting

The European Medicines Agency (EMA) is holding a multi-stakeholder workshop (invitation only) on 24 October 2018 aiming to gather initial insight on the areas to be covered in *EMA's Regulatory Science to 2025*. On this occasion, we will share the proposals for human medicines only. This would lead to:

- refinement of the proposals prior to public consultation
- focused attention of the relevant constituencies for ensuring further input during the public consultation leading to prioritization.

Programme overview

Sessions

Session 1: Responding to the needs of the 21st century Patient – Addressing challenges and opportunities across the European Regulatory Framework

Session 2: Enabling and leveraging research and innovation in regulatory science

Session 3: Catalysing the integration of science & technology in drug development

Session 4: Driving collaborative evidence generation – Improving the scientific quality of evaluations

Session 5: Advancing patient-centred access to medicines in partnership with healthcare systems

Session 6: Addressing emerging health threats and availability/therapeutic challenges

Organising Committee

Scientific Coordination Board (SciCoBo):

Martina Schussler-Lenz	CAT Chair, *Paul-Ehrlich-Institut (PEI), Germany*
Firstname Surname	CHMP Chair, *their Agency (Agency Acronym), Country*
Laura Oliveira Santamaria	CMDh Chair, *Agencia Española del Medicamento y Productos Sanitarios (AEMPS), Spain*
Bruno Sepodes	COMP Chair, *University of Lisbon, Portugal*
Marisa Delbò	HMPC Chair, *Agenzia Italiana del Farmaco (AIFA), Italy*
Dirk Mentzer	PDCO Chair, *Paul-Ehrlich-Institut (PEI), Germany*
Sabine Straus	PRAC Chair, *Medicines Evaluation Board (MEB), Netherlands*
Robert James Hemmings	SAWP Chair, *Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom*

European Medicines Agency (EMA):

Hans-Georg Eichler	Senior Medical Officer
Enrica Alteri	Human Medicines Research & Development Support Division
Zaïde Frias	Human Medicines Evaluation Division
Fergus Sweeney	Inspections, Human Medicines Pharmacovigilance & Committees Division
Alexis Nolte	Information Management Division
Melanie Carr	Stakeholders & Communication Division
Anthony Humphreys	Scientific Committees Regulatory Science Strategy Division
Marie-Helene Pinheiro	Industry Stakehholders Liaison - *Corporate Stakeholders*

Programme details

Wednesday 24th October 2018

08:30 – 08:40 Welcome and introductions

Guido Rasi, Executive Director, EMA

08:40 – 09:40 Session 1: Responding to the needs of the 21st century Patient Addressing challenges and opportunities across the European Regulatory Framework

Session Chair: **Hans Georg Eichler**, EMA

08.40-09.00 ***EMA's Regulatory Science Response***

Representative of EMA

09.00-09.10 ***View from the patient***

Representative of a Patient organisation

09.10-09.20 ***View from the European Parliament***

Representative of the European Parliament

09.20-09.30 ***View from the European Commission***

Representative of DG Santé

09.30-09.40 ***View from the innovator***

Representative of Industry Trade Association

09:40 – 10:40 Session 2: Enabling and leveraging research and innovation in regulatory science

Core recommendations in this section include:

- Develop and exploit a synergistic, network-led partnership with academic researchers to facilitate and apply innovation
- Leverage the establishment of regulatory science research hubs to accelerate innovative drug development
- Collaborate with the new research hubs to disseminate knowledge, expertise and innovation across the network and to its stakeholders
- Optimise the leverage of knowledge and expertise in the EU and globally

09.40-10.00 ***Enabling and leveraging research and innovation in regulatory science***

Peter Arlett, EMA

10.00-10.40 ***Questions and panel discussion***

Panellists:

Representative of DG RTD

Representative of Academia

10:40 - 11:00 Coffee break

11:00 – 12:30 Session 3: Catalysing the integration of science & technology in drug development

Core recommendations in this section include:

- Diversify and integrate the provision of regulatory advice along the development continuum
- Promote and invest in PRIME pathways
- Develop framework for integrated evaluation of Medical Devices, IVDs and borderline products
- Develop a collaborative framework to support developments in personalised medicine, biomarkers and 'omics'
- Support translation of cell, genes and tissue based products into patient treatments
- Facilitate the implementation of novel manufacturing technologies
- Develop understanding of and regulatory response to nanotechnology and new materials' utilisation in pharmaceuticals

11.00-11.20 ***Catalysing the integration of science & technology in drug development***
Ana Hidalgo-Simon, EMA

11.20-12.30 ***Questions and panel discussion***

Panellists:

Representative of Industry Trade Association – Innovation sector

Representative of Industry Trade Association – Biotech sector

Representative of Industry Trade Association – SME sector

Representative of Industry Trade Association – Medical Device sector

12:30 – 13:30 Lunch break

13:30 – 15:00 Session 4: Driving collaborative evidence generation – Improving the scientific quality of evaluations

Core recommendations in this section include:

- Leverage novel non-clinical models and 3Rs
- Optimise capabilities in modelling and simulation and extrapolation
- Foster innovation in clinical trials
- Develop the regulatory framework for emerging clinical data generation
- Expand risk-benefit assessment and communication
- Invest in special populations initiatives
- Develop adaptive pathways via scientific advice in conjunction with key stakeholders
- Exploit digital technology and artificial intelligence in decision-making

13.30-13.50 ***Driving collaborative evidence generation through use of: Modern trials and Data and digitalisation – Improving the scientific quality of evaluations***
Jordi Llinares Garcia, EMA

13.50-15.00 ***Questions and panel discussion***

Panellists:

Representative of Patient Association

Representative of HTA

Representative of IT Healthcare Provider

Representative of Industry Trade Association

15:00 – 16:00 Session 5: Advancing patient-centred access to medicines in partnership with healthcare systems

Core recommendations in this section include:

- Promote use of high quality real world evidence in decision-making
- Develop network competences and specialist collaborations to engage with big data
- Enable HTAs' preparedness and downstream decision-making for innovative medicines
- Share key therapeutic innovation impact assessment with Payers
- Reinforce patients involvement in medicines development
- Deliver real-time electronic product information (EPI)
- Promote the uptake of biosimilars in the healthcare system
- Implement the strategy for external communications to further promote trust and confidence in the work of the Agency

15.00-15.20 ***Advancing patient-centred access to medicines in partnership with healthcare systems***

Michael Berntgen, EMA

15.20-16.00 ***Questions and panel discussion***

Panellists:

Representative of Industry Trade Association

Representative of Healthcare Professionals

Representative of HTA

Representative of Payers

16:00 - 16:20 Coffee break

16:20 – 17:20 Session 6: Addressing emerging health threats and availability/therapeutic challenges

Core recommendations in this section include:

- Implement EMA's Health Threats Plan
- Promote global cooperation to anticipate and address availability/therapeutic challenges

16.20-16.40 ***Addressing emerging health threats and availability/therapeutic challenges***

Marco Cavaleri, EMA

16.40-17.20	***Questions and panel discussion***
	Panellists:
	Representative of WHO
	Representative of Industry Trade Association

17:20 – 17:30 Closing remarks

Tony Humphreys, EMA