



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Update on HCP POG drafting groups

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HCPWP Plenary

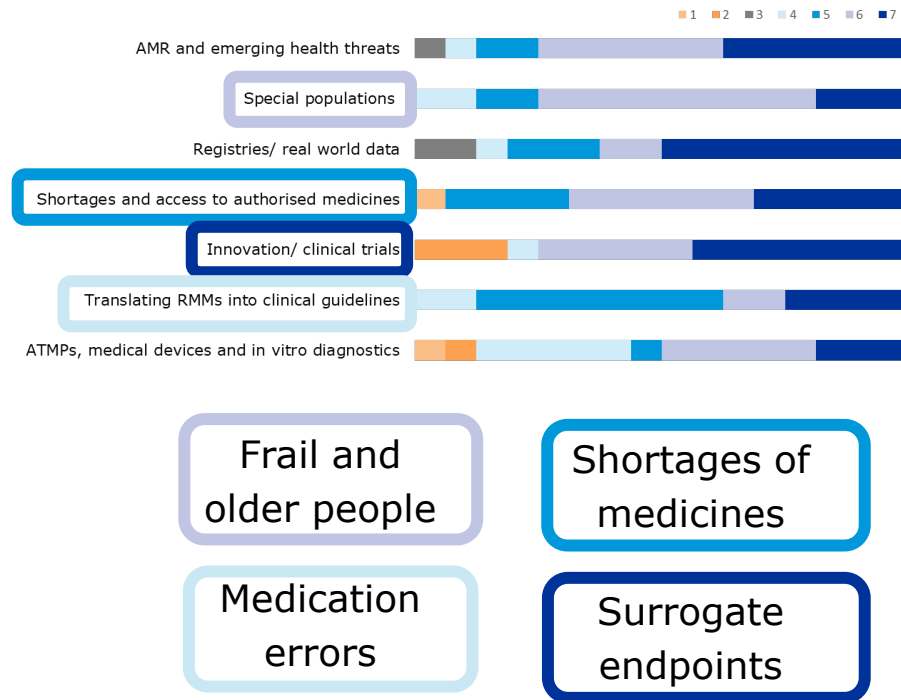
Presented by Ivana Silva on 3 July 2024  
Healthcare Professionals and Learned Societies Liaison, Public and Stakeholders Engagement Department

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# Prioritising areas of work

- Survey to all eligible HCP organisations in 2021
- HCP POG meetings were not enough to collect input from organisations
- Establishment of 4 HCP POG 'drafting groups'
  - Deliver concrete outputs on selected topic
  - For some topics, work required clinical experts in addition to policy officers





## Drafting groups – progress update

- **Frailty and older people considerations** in medicine development and evaluation
  - *Inclusion of functional measures and frailty in the development and evaluation of medicine for older adults*: published in Lancet Health and Aging in November 2023
- Use of **surrogate endpoints** for regulatory approval
  - A comprehensive document addressing classification of surrogate endpoints and ethical considerations has been prepared; work is ongoing to split the document into different topics which can then lead to separate publications.



## Drafting groups – progress update

- Pharmacovigilance with focus on **medication errors**
  - A comprehensive draft has been prepared:
    - Explores the EU pharmacovigilance system, from the perspective of healthcare professionals
    - Looks at the legislative framework, identifying areas where more support for HCPs could be envisaged, with specific attention to the identification and prevention of medication errors
  - Analysis from EMA perspective is ongoing



# Drafting groups – progress update

- **Shortages of medicines**

- Aim: bridging a gap in terms of having a comprehensive overview of HCP organisations' views on policy developments and practice implications regarding medicines shortages, clarifying aspects pertaining to current policy and instruments stemming from EMA extended mandate.
  - Part A addressing EMA extended mandate; mechanisms differing at times of crisis; recent developments.
  - Part B addressing guidance for HCPs in terms of proposed preventive and reactive shortage mitigation measures, common themes and relevance thereof; examples from different specialities as mini case studies.
  - Part C – Discussion and proposal for next steps, incl. input from patient and consumer groups.
- Indicative timeline: draft for HCPWP consultation in Aug/Sep

## Conclusion

- Valued group to strengthen engagement of eligible HCPOs in EMA activities
  - Supporting the link between EMA and HCPWP strategic priorities/workplan and the policy work developed by HCPOs.
- HCP POG to be maintained with following scope:
  - Tool for 'stakeholder listening' and enhanced early engagement with **all eligible HCP organisations** through policy officers;
  - A forum for EMA to provide updates on ongoing work and strategic priorities;
  - A forum for all eligible organisations to provide input and raise issues or concerns with EMA at an earlier stage;
  - Ad-hoc drafting groups may be established on a temporary basis to deliver specific outputs, upon agreement of the HCPWP. Membership of drafting groups may include non-HCP POG members.



# Any questions?

## Further information

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