EMA EUROPEAN MEDICINES AGENCY

HMA Heads of Medicines Agencies

European medicines agencies network strategy to 2028

update

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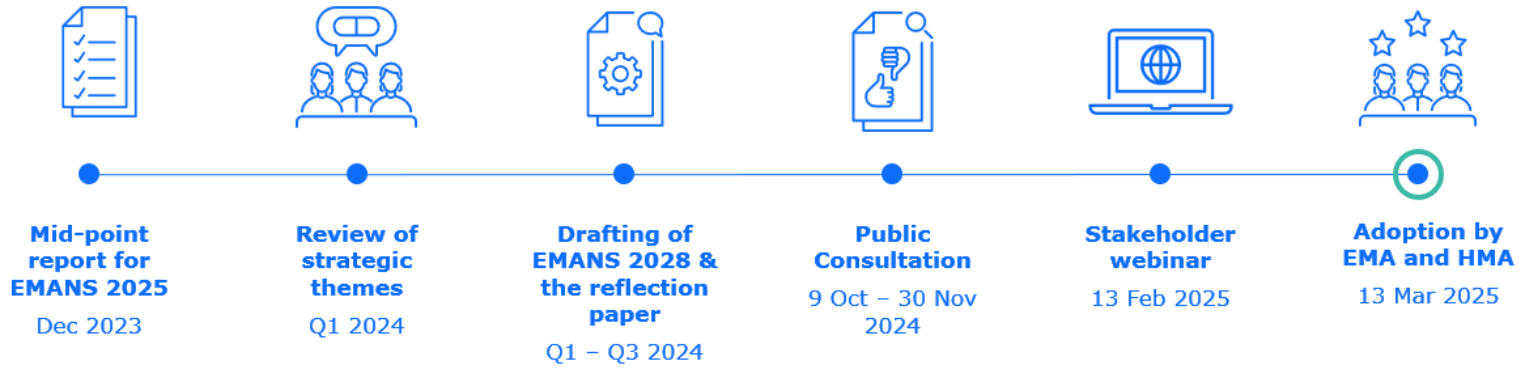
EMANS to 2028 – Introduction

- **Joint activity** between National Competent Authorities and EMA
- A **comprehensive update** to the original EMAN Strategy to 2025 – high-level strategy developed with input from experts from across the network and complemented with detailed Reflection Paper
- **Replaces EMANS to 2025** and includes strategic aspects of EMA's regulatory science strategy
- **A forward-looking, streamlined strategy** to guide the EU medicines regulatory network as it seizes opportunities and meets the future challenges
- Aligns with the EU's ongoing extensive revision of its pharmaceutical legislation and **lays the groundwork** for its implementation



EMANS to 2028 Strategic Focus Areas (themes)

1. Accessibility

2. Leveraging data, digitalisation and AI

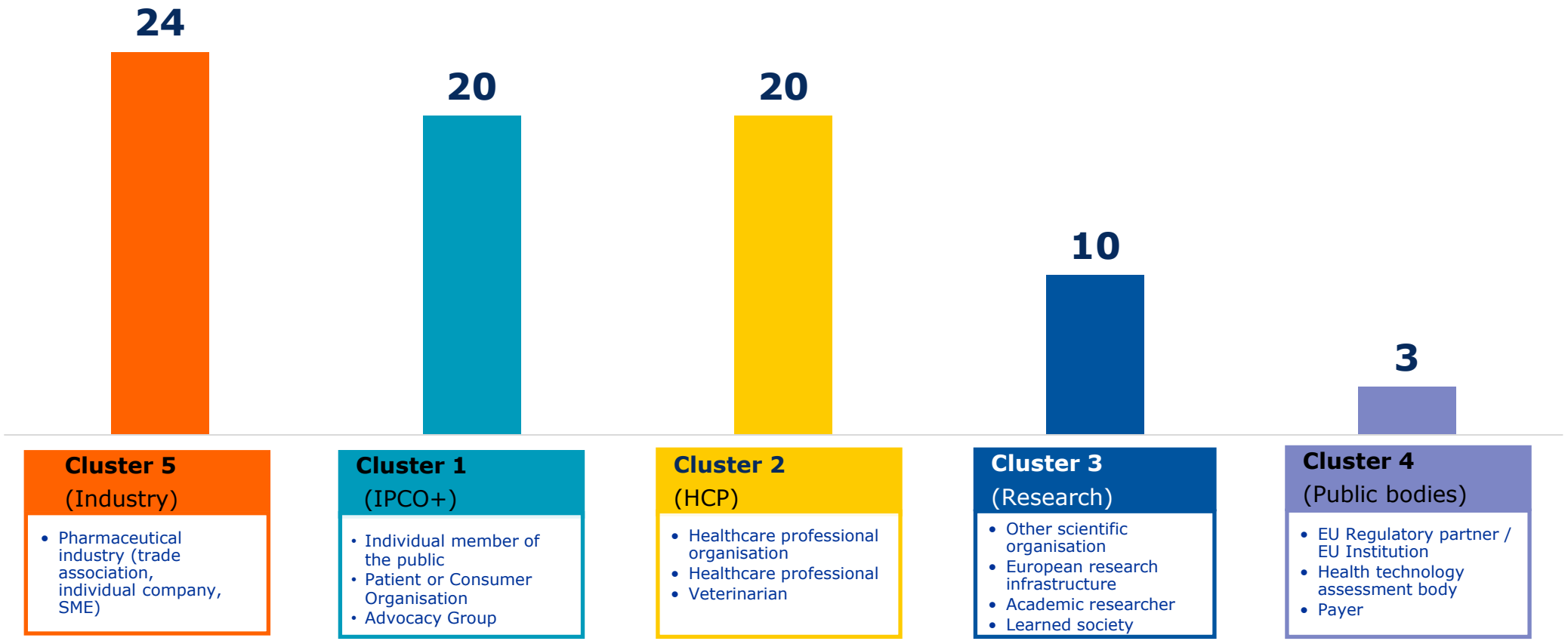
3. Regulatory science, innovation and competitiveness

4. Antimicrobial resistance and other health threats

5. Availability and supply

6. Sustainability of the network

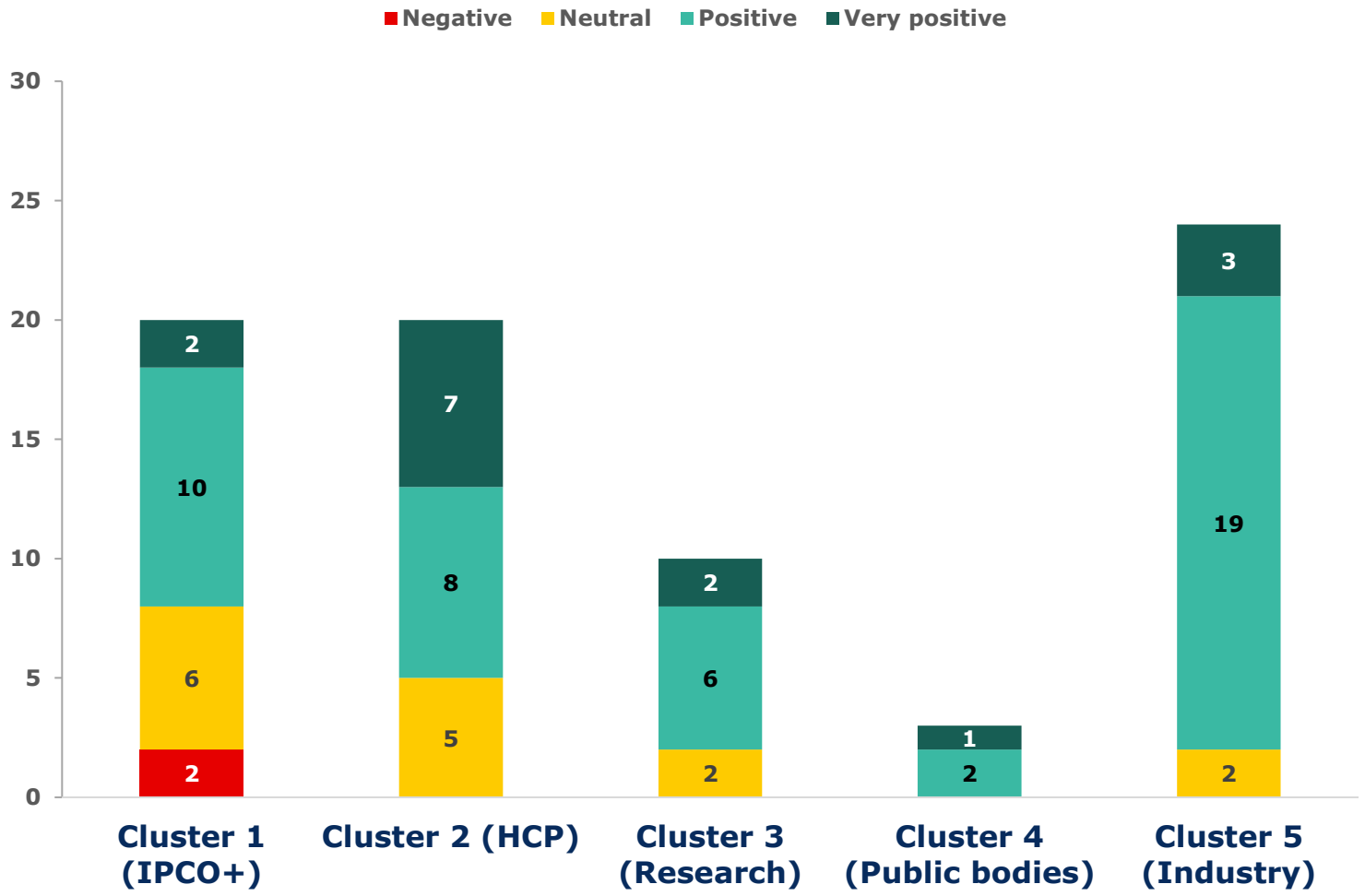
Response received to public consultation by stakeholder cluster groups (total 77)



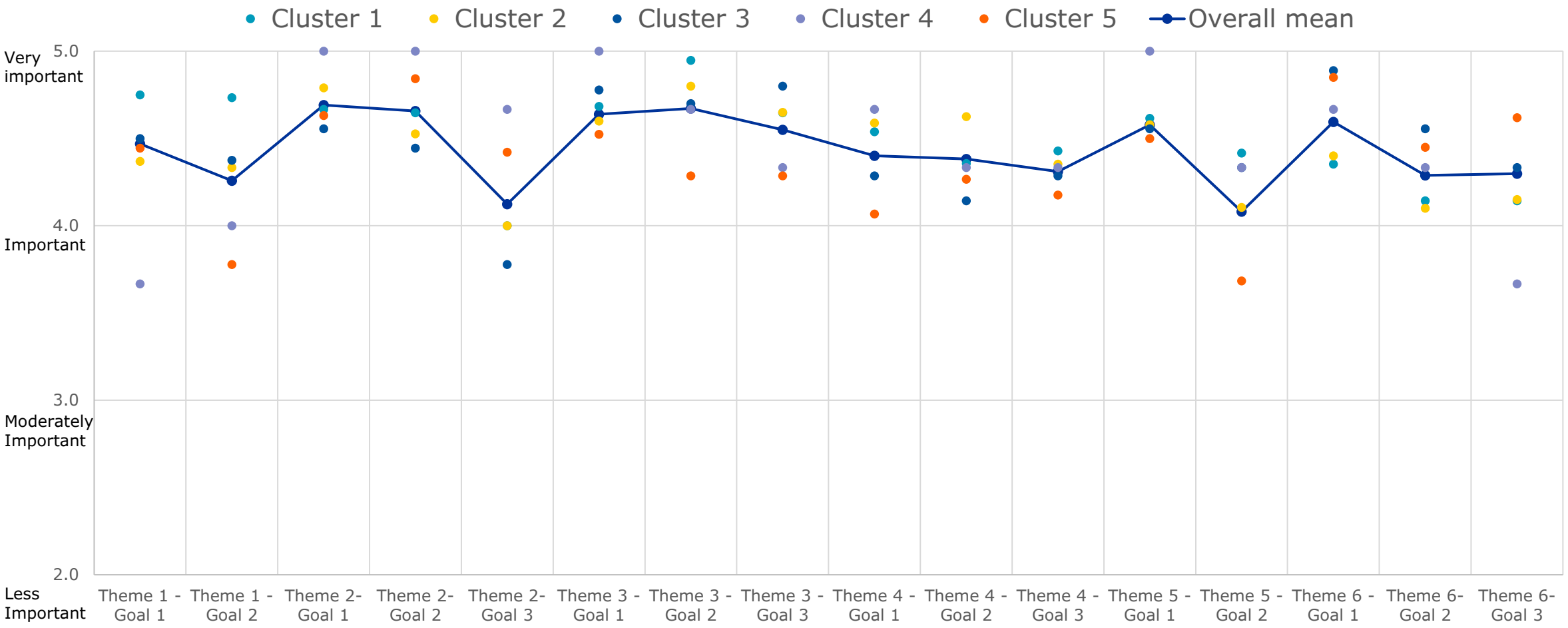
Overall impression of the strategy

Relevant areas of interest indicated by stakeholders:

- **62** Human only
- **7** Human and veterinary
- **8** Veterinary only



Overall comparison of all goals per cluster



Mean values of ratings, based on values of 1 for 'not important', 2 for 'less important', 3 for 'moderately important', 4 for 'important' and 5 for 'very important'

Key comments on EMANS Themes (1/2)

1. Accessibility

- Key role of off-patent medicines (generics, biosimilars) to enhance accessibility;
- Consider guidance and improved public awareness of (complex) generics and biosimilars;
- Consider early interactions also for off-patent medicines.

2. Leveraging data, digitalisation and artificial intelligence

- Reference to European Health Data Space;
- SPOR master data; reflect public engagement on digital tools such as the e-PI;
- Highlight compliance with data protection rules.

3. Regulatory science, innovation and competitiveness

- Foster biomanufacturing competitiveness;
- Highlight that innovation and competitive-ness apply also to off-patent medicines;
- Reinforce reference to non-animal models (Replacement, Reduction, Refinement);
- Provide regulatory guidance and flexible pathways to support small and mid-sized companies in integrating advancements.

Key comments on EMANS Themes (2/2)

4. Antimicrobial resistance and other health threats

- Highlight the role of vaccines in AMR;
- Align efforts with stewardship plans and the One Health approach.

5. Availability and supply

- Reference the Critical Medicines Act;
- Reference need for a balanced communication;
- Progress with ongoing activities including application of regulatory flexibilities.

6. Sustainability of the network:

- Resourcing improvements to also refer to veterinary medicines and off-patent medicines;
- Reference environmental sustainability;
- Highlight the role of AI and digitalisation.

EMANS TO 2028

Plans for Implementation

- Updated strategy will replace EMANS to 2025
- HMA/EMA theme leads are currently defining key activities which will be included in EMA and HMA multi-annual work plans
- Implementation will be monitored by HMA and EMA Theme Leads
- Mid-point report is foreseen in 2027

Thank you

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