

European medicines agencies network strategy to 2028

Stakeholder webinar

13 February 2025



Introduction

EMANS 2028 and stakeholder feedback received

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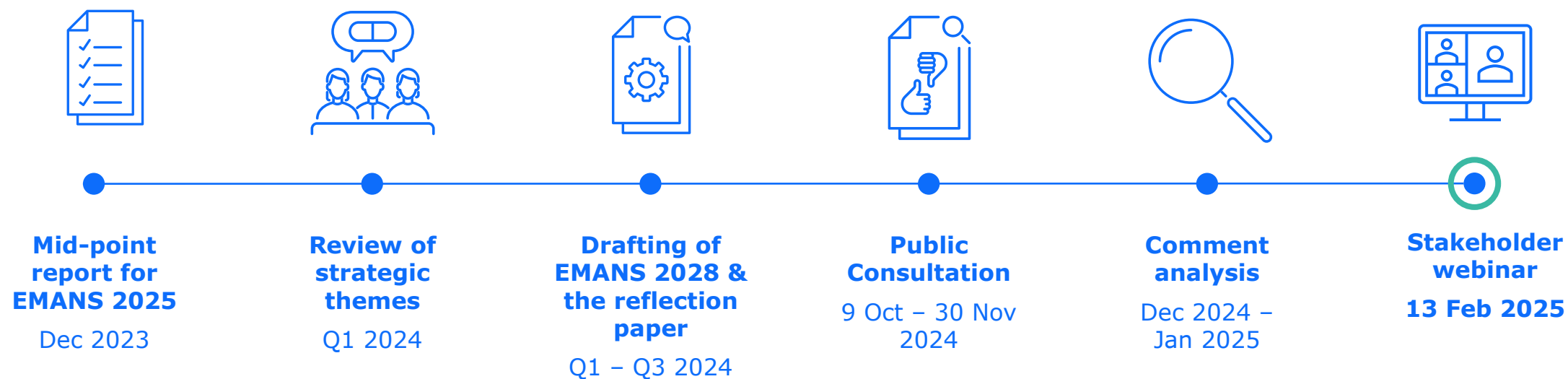
Michael Lenihan (EMA)



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

Road to the current draft of EMANS to 2028



Strategic focus areas (themes)



1. Accessibility



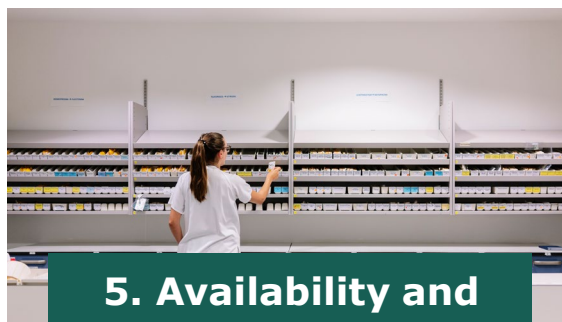
2. Leveraging data, digitalisation and artificial intelligence



3. Regulatory science, innovation and competitiveness



4. Antimicrobial resistance and other health threats

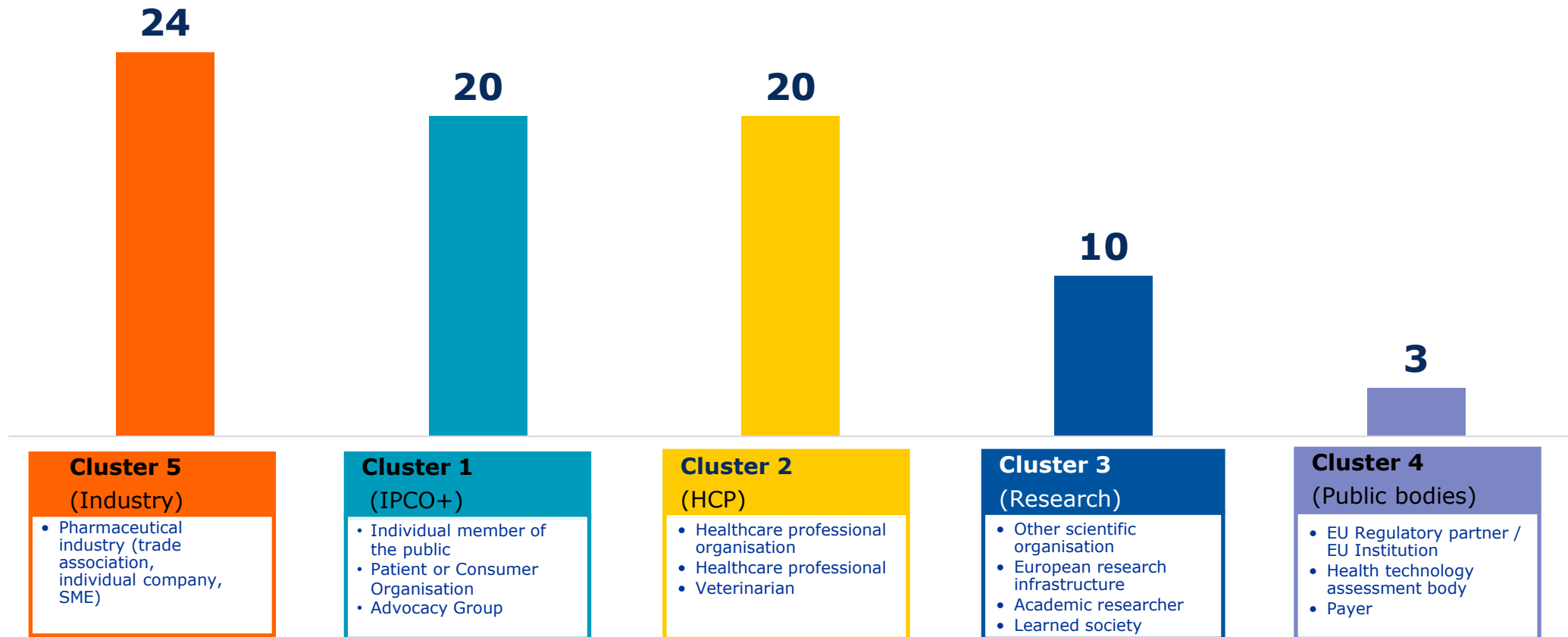


5. Availability and supply



6. Sustainability of the network

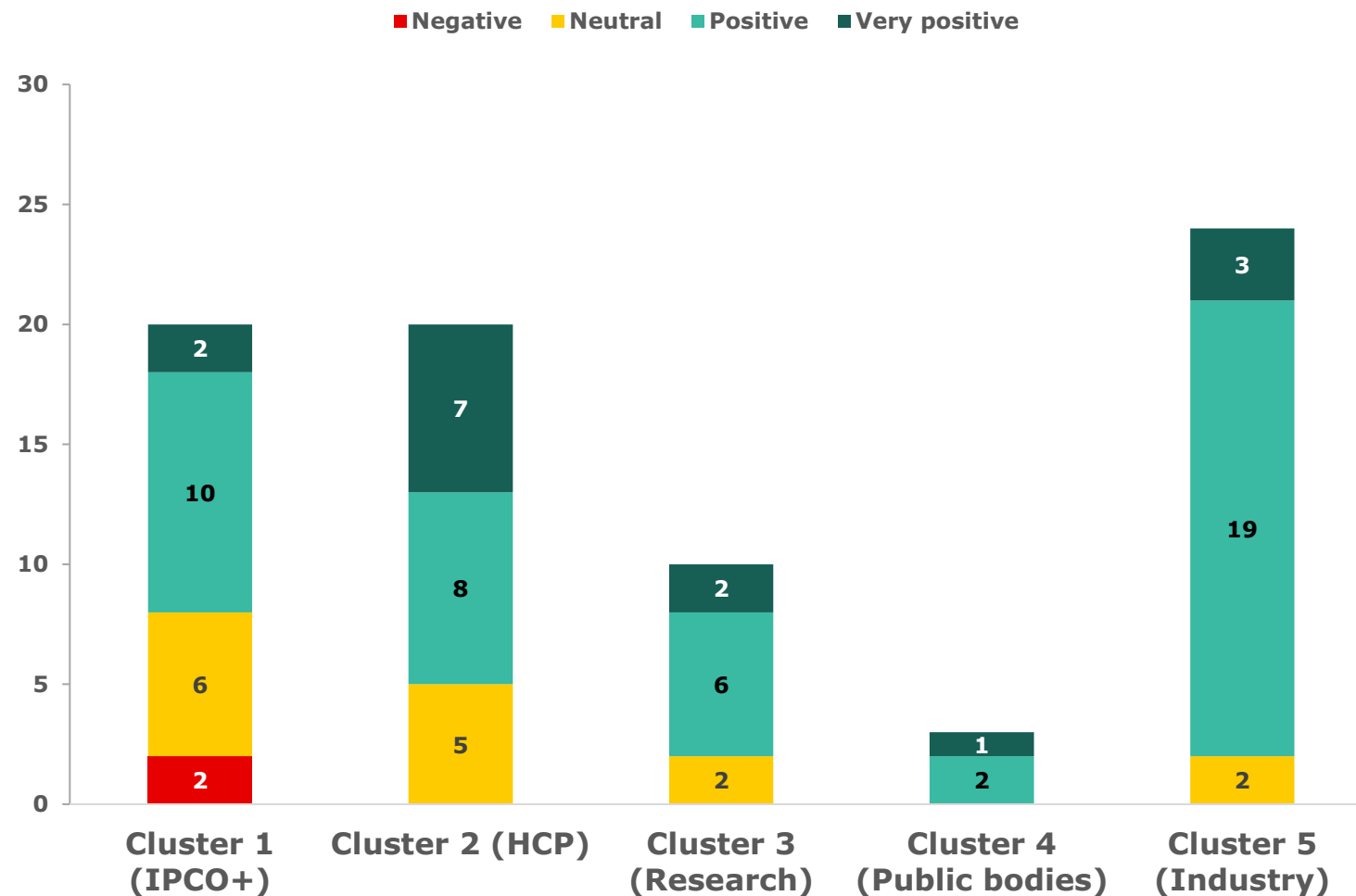
Response received to public consultation by stakeholder cluster groups (total 77)



Overall impression of the strategy

Relevant areas of interest indicated by Stakeholders:

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

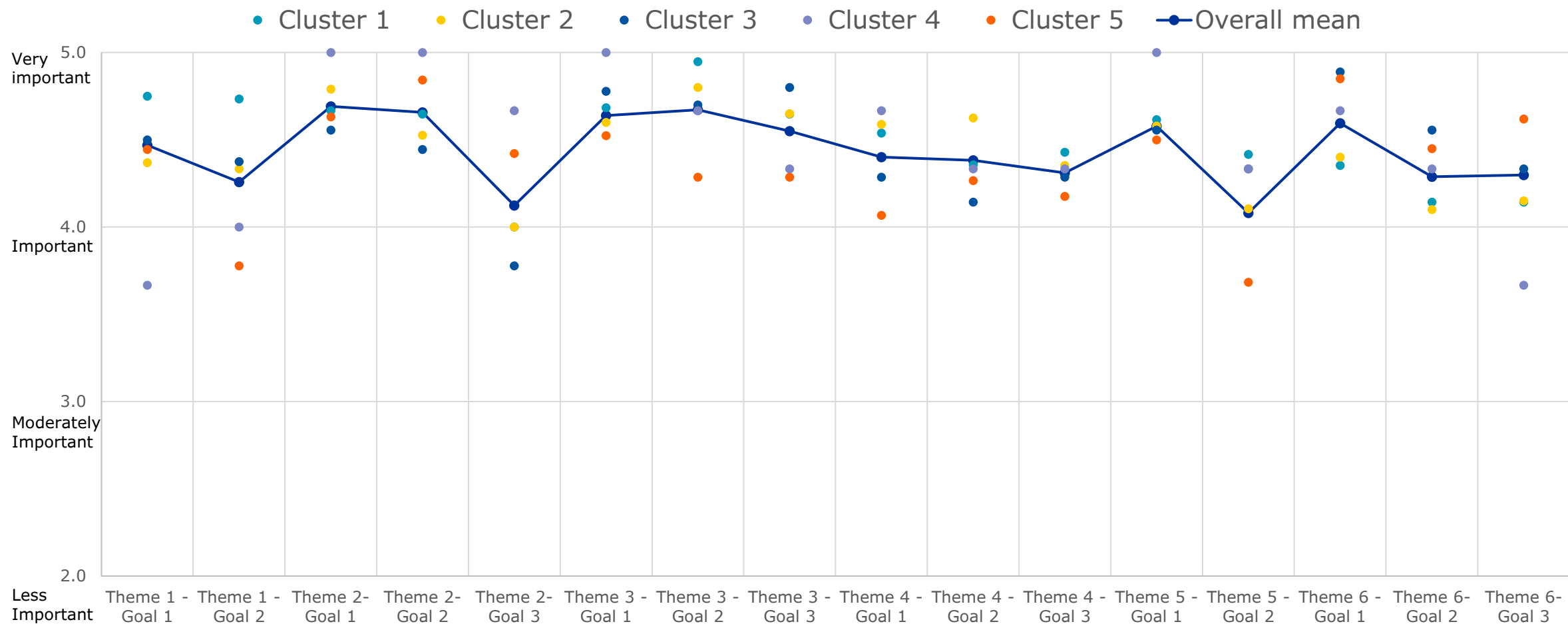


Overall comparison of all goals per cluster

Theme & Goal	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5	Overall mean
Theme 1 - Goal 1	4.8	4.4	4.5	3.8	4.4	4.5
Theme 1 - Goal 2	4.7	4.3	4.4	3.8	3.8	4.3
Theme 2 - Goal 1	4.7	4.8	4.6	4.8	4.6	4.7
Theme 2 - Goal 2	4.6	4.5	4.4	4.6	4.8	4.7
Theme 2 - Goal 3	4.0	4.0	3.8	4.4	4.4	4.1
Theme 3 - Goal 1	4.7	4.6	4.8	4.8	4.5	4.6
Theme 3 - Goal 2	4.9	4.8	4.7	4.0	4.3	4.7
Theme 3 - Goal 3	4.6	4.7	4.8	4.0	4.3	4.5
Theme 4 - Goal 1	4.5	4.6	4.3	4.4	4.1	4.4
Theme 4 - Goal 2	4.4	4.6	4.1	3.8	4.3	4.4
Theme 4 - Goal 3	4.4	4.4	4.3	4.4	4.2	4.3
Theme 5 - Goal 1	4.6	4.6	4.6	4.8	4.5	4.6
Theme 5 - Goal 2	4.4	4.1	4.3	4.4	3.7	4.1
Theme 6 - Goal 1	4.4	4.4	4.9	4.6	4.9	4.6
Theme 6 - Goal 2	4.1	4.1	4.6	4.2	4.5	4.3
Theme 6 - Goal 3	4.1	4.2	4.3	3.6	4.6	4.3

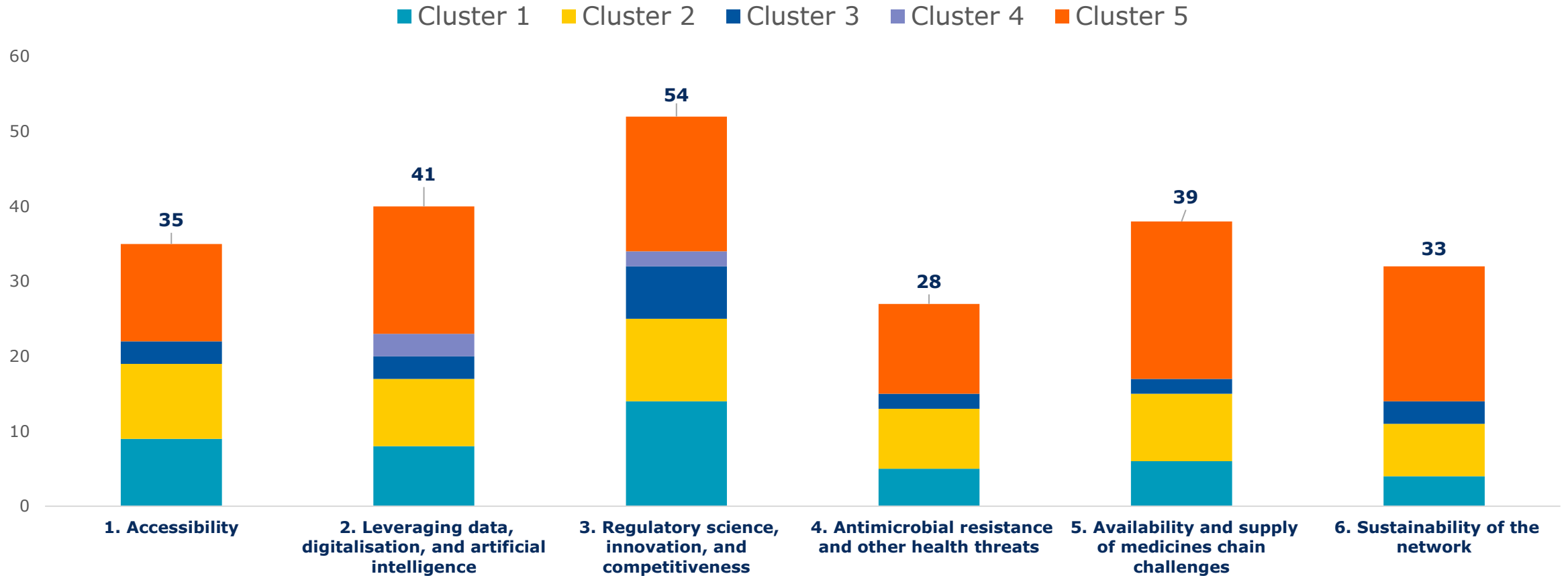
Mean values of ratings, based on values of 1 for 'not important', 2 for 'less important', 3 for 'moderately important', 4 for 'important' and 5 for 'very important'

Overall comparison of all goals per cluster



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Input received per objectives for strategic theme area – cluster breakdown



General comments not linked to individual themes

Potential changes to the overall narrative of the strategy

- Position 'One Health' as a general topic across all topic areas
- Emphasis on both human and veterinary medicines
- Considerations on cross-sectoral legislation and other initiatives, e.g. concerning environment or single assessment of substances

Other general / recurring comments

- Extensive engagement with stakeholders (already reflected in EMANS)
- Paediatric population (is included)
- Support for a further update after revision of Pharmaceutical legislation