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European Medicines Agency
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Analysis and summaries of public consultation results

European Medicines Agencies Network Strategy to 2028

Contents

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1. Introduction

In October 2024, the European medicines agencies network – comprising national competent authorities (NCAs) and the European Medicines Agency (EMA) – released its draft network strategy for a two-month public consultation.

The strategy – the European medicines agencies network strategy to 2028 (EMANS 2028) – aims to prepare the network for important changes in the technological and regulatory landscape. It also supports the network's core work of evaluating and promoting the development of medicines and ensuring they reach those who need them.

The public consultation was a key step in the preparation of the strategy. Stakeholders provided responses to five questions via an EUSurvey questionnaire (Table 1), using Likert scales to rate the goals, objectives and overall strategy. Respondents could also provide qualitative insights in free-text boxes.

At the end of the public consultation, the network in partnership with the EU Polish presidency, held a webinar with stakeholders to discuss the feedback received. This report summarises the outcome of the public consultation and how the network ultimately considered the feedback from stakeholders in preparing the final strategy.

EMANS 2028 was a collaboration between NCAs, under the auspices of the Heads of Medicines Agencies (HMA), and EMA.

Table 1. Questions in EUSurvey questionnaire

Question 1: What stakeholder, partner or group do you represent?
Question 2: Please indicate which area is relevant to your area of interest?
Question 3: Opinion on importance of each goal across the strategic themes.
Question 4: How would you rate each objective in terms of priority? Please provide any specific comments.
Question 5: Having read the proposed strategy, what is your overall impression? Any other comments?

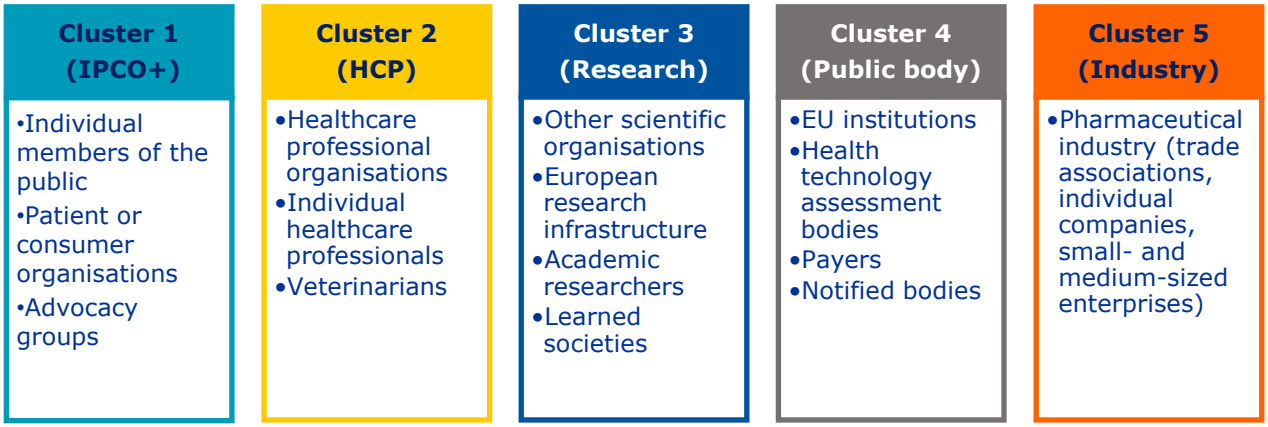
2. Methodology of analysis

Both quantitative and qualitative analyses were conducted for various survey questions. Quantitative analysis was performed using Microsoft Excel. For the survey's open-text questions, a framework method similar to that used for the network's previous strategy (EMANS 2025) was applied (see Section 2.3. below). To ensure there was no potential sample-size bias among different stakeholder groups, survey responses were weighted neutrally, regardless of stakeholder size or the combination of responses from multiple stakeholders.

2.1. Characterisation of survey respondents

Questions 1 and 2 collected information about the respondents and who they represented. The respondents were grouped into the same five stakeholder clusters used for the EMANS 2025 public consultation (Figure 1). Submissions received from within the European medicines agencies network were not included in this analysis but were considered separately.

Figure 1. Clusters of stakeholder types used in analysis of responses received during the public consultation



2.2. Quantitative data analysis

Responses to questions 1, 2, 3, 4 and 5 were analysed descriptively. A 5-point Likert scale was used for question 3, where responders provided feedback on the prioritisation of the goals per theme, rating them as not important, less important, moderately important, important or very important. A 3-point Likert scale was used for question 4 for each objective with the following options: low priority, medium priority or high priority. For question 5, stakeholders rated their overall views of the strategy as very negative, negative, neutral, positive or very positive.

2.3. Qualitative data analysis

Responses to the survey's open-ended parts of questions 4 and 5 were analysed thematically by six researchers. A framework method was chosen for thematic analysis as it enables multiple researchers to independently analyse one large dataset[1,2] following five iterative stages. Table 1 describes the application of the five iterative steps of the framework method as clarified by Lacey and Luff.[2]

Table 2. Iterative steps of the framework method for analysis of responses to questions 4 and 5

Familiarisation	Read input from stakeholders individually, highlighting answers that are unclear/confusing to discuss with your partner
Identifying a thematic framework	• Identify proposed actions / changes to EMANS • Link responses to theme and goal and, if possible, to "any other comments"
Coding	For each proposed action/change: • Identify overall feeling of objectives: "positive", "negative" neutral" • Categorise each action/change as "applicable" or "not applicable" or "unclear"
Summarising	Summarise at cluster level in two formats: • Overall summary – include more than one similar proposed action/change to EMANS • Points raised – includes each singular proposed action/change
Mapping and interpretation	Interpret by discussing and reviewing the summaries and making associations within and across stakeholder groups.

[1] Gale N, Heath G, Cameron E, Rashid S, Redwood S. Using the framework method for the analysis of qualitative data in multi-disciplinary health research. BMC medical research methodology. 2013;13(1):117.
[2] Lacey A, Luff D. Qualitative Research Analysis: The NIHR RDS for the East Midlands / Yorkshire & the Humber; 2007.

Identified suggestions for EMANS 2028 in the consultation responses were referred to topic leads nominated by the Heads of Medicines Agencies (HMA) and EMA for respective strategic themes, who analysed them and advised on potential updates to the strategy.

3. Results

3.1. Stakeholder participation levels and overall feedback on the strategy

A total of 77 responses to the survey were received, with a widespread from across the different cluster groups (Figure 2). Of these, 62 stakeholders indicated that their area of interest was human medicines, 8 veterinary medicines and 7 both areas. With regards to **final impressions of the EMANS 2028, three-quarters of stakeholders were either positive or very positive about the strategy, with only two negative and 15 neutral** (Figure 3).

As shown in Figure 2, a total of 20 responses were received for **cluster 1 comprising individual members of the public, patient or consumer organisations and advocacy groups (IPCO)**. There were seven animal welfare organisations, seven patient or consumer organisations, five individual members of the public and one multistakeholder organisation representing patients, healthcare professionals (HCPs) and industry. Six respondents were interested in the veterinary sector. Overall, most respondents, across all categories, had a positive or very positive impression of the strategy. Six respondents took a neutral stance, and two respondents expressed a negative view.

A few cluster 1 stakeholder groups provided input in the 'any other comments' question. Animal welfare organisations generally advocated for a stronger emphasis in the strategy on the 3Rs (replacement, reduction and refinement) and the use of non-animal methods and innovation to reduce animal testing. Patient and consumer organisations stressed the need for greater patient involvement in decision-making processes and the protection of patients through better enforcement of advertising rules, particularly in relation to social media, alongside improved labelling standards. Specific proposals were made regarding the availability of medicines. Two citizens provided overall comments: one called for more focus on reducing animal testing, while the other, expressing a negative view of the strategy, questioned the authority of NCAs and EMA to make decisions in these areas. Two respondents confirmed their willingness to engage with EMA. Some comments echoed those made on individual objectives.

For **cluster 2 (healthcare professionals)**, a total of 20 responses were submitted, from 10 healthcare professional organisations, 4 individual healthcare professionals (HCPs), five veterinarians and one other organisation representing patients, HCPs and industry. Four respondents were interested in the veterinary sector. Most respondents had a very positive or positive view of the strategy, while five respondents had a neutral stance.

Many respondents from cluster 2 offered comments in the 'any other comments' section. Many of the HCP organisations emphasised the need for key changes, particularly in addressing the healthcare needs of the paediatric population. They called for a comprehensive approach to children's healthcare, identifying gaps in drug development, access and safety. Recommendations included improving the accessibility of medicines, accelerating drug approvals for children and addressing drug shortages through better monitoring and multi-stakeholder collaboration. Additional proposals included requiring pharmaceutical companies to maintain adequate stocks of essential paediatric medicines, reducing off-label prescribing and increasing the percentage of medicines approved for paediatric use. A veterinarian respondent called for a more holistic 'One Health' approach, integrating veterinary medicines into the broader strategy rather than limiting them to theme 4. Another HCP organisation stressed the importance of enhancing international communication, robust data sharing and improved cybersecurity, emphasising the need to balance technological innovation with patient safety. They also

called for mandatory safety stocks, better shortage reporting mechanisms and more transparent decision-making. Another HCP organisation advocated for a shift away from a technology-driven, administrative approach towards prioritising public health, therapeutic value and patient outcomes, with a focus on improving medication safety and addressing risks related to digital tools and poly-medication.

Ten responses were provided from **cluster 3 (research stakeholder group)**, consisting of five academic researchers, one European research infrastructure representative, one learned society, one research organisation and two other scientific organisations linked to HCPs. One academic researcher was interested in the veterinary sector and the research organisation was interested in both human and veterinary sectors. All other contributors were focused on the human sector. A large majority of the respondents had either a very positive or positive impression of the EMANS 2028, with only two having a neutral view of the strategy.

Three academic researchers provided feedback in the 'any other comment' question. One respondent emphasised the importance of harmonising clinical trial approval across the EU to prevent clinical trials from moving outside the EU. Another supported the strategy's balanced approach, particularly its increased focus on data analytics, while recommending prioritisation of network sustainability to build capacity in this area and seeking global alignment across regulators. The third respondent urged the strategy to consider how repurposed medicines could reach patients more effectively.

A total of three responses were received for **cluster 4 (public bodies),** with one regulatory partner, one notified bodies organisation and one health technology assessment (HTA) body. They all had either a positive or very positive impression of the strategy. The HTA body respondent answered the 'any other comment' question and suggested that the strategy should acknowledge the varying levels of digitalisation across health systems and define minimum IT infrastructure requirements for network partners. They also emphasised the importance of protecting health IT infrastructure from third-country access. The notified bodies organisation offered to collaborate more closely with medicine regulators to support the strategy's goals.

In **cluster 5 (industry),** 24 responses were received from various stakeholders: 13 trade associations, 1 small- or medium-sized enterprise (SME), nine individual companies (non-SME) and one for-profit private company working with the pharmaceutical industry. Of the respondents, 19 rated the strategy positively, with two trade associations and the for-profit private company expressing a very positive view. Two other trade associations had a neutral stance.

The feedback in the 'any other comments' section emphasised reinforcing key priority areas such as availability, antimicrobial resistance (AMR), clinical trials and manufacturing to enhance competitiveness and innovation. Cluster 5 stakeholders suggested that the strategy should balance sustainability with ensuring uninterrupted patient access to medicines and support regulatory optimisation to reduce administrative burdens and resource constraints.

International collaboration and regulatory convergence were seen as essential for adapting to scientific and technological advances. Cluster 5 stakeholders also highlighted the need to monitor and address the impacts of cross-sectoral legislation within the network.

There was broad support for the strategic alignment of objectives across the European Medicines Agencies Network (EMAN) to achieve common goals in critical areas. Industry stakeholders suggested further emphasis on improving the EU's attractiveness and competitiveness, particularly in clinical trials, vaccines and future medicines. Cross-sectoral legislation was identified as potentially conflicting with medicinal product requirements.

On communication, industry respondents recommended focusing on risk communication for various health products to build trust in regulatory systems. Enhancing communication with industry was seen as crucial for delivering flexible guidance and improving the predictability of regulatory updates.

The accessibility of new pharmaceutical modalities and self-care products was seen as an important area for focus, along with support for mid-cap pharmaceutical companies in Europe. The accessibility of off-patent medicines was also noted as a significant factor for sustainability.

In terms of supply chain management, industry stakeholders called for enhanced transparency and the leveraging of market data reporting by marketing authorisation holders (MAHs) as part of shortage prevention plans. They proposed establishing EU-wide early warning systems, defining strategic stockpiles of essential medicines and adopting advanced digital tools to improve real-time monitoring, operational efficiency and quality control. Strengthening international partnerships was also a key proposal, particularly for areas dependent on external supplies of starting materials or finished products.

Concerns were raised about the regulatory network's capacity to implement the strategy, stressing the need for adequate resources, capabilities and infrastructure to foster a thriving clinical trial and regulatory ecosystem. AI and digital tools were broadly supported as tools to enhance regulatory services and improve the predictability and efficiency of advice.

In the area of AMR, stakeholders recommended the inclusion of vaccines and regulatory flexibilities to support the development of AMR-targeted vaccines. For public health emergencies (PHEs), industry stakeholders suggested reevaluating the production and management of medical countermeasures for high-impact, low-probability events, including their procurement and stockpiling by government agencies. They proposed defining a pre-PHE period to make these countermeasures accessible and to foster harmonisation, regulatory reliance or mutual recognition for costly products and materials.

Figure 2. Responses received by stakeholder type

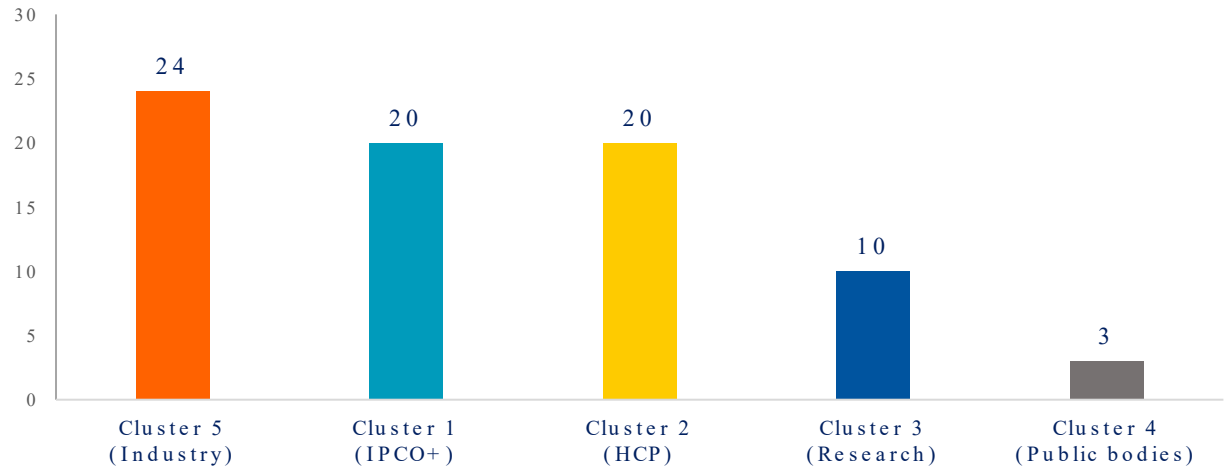
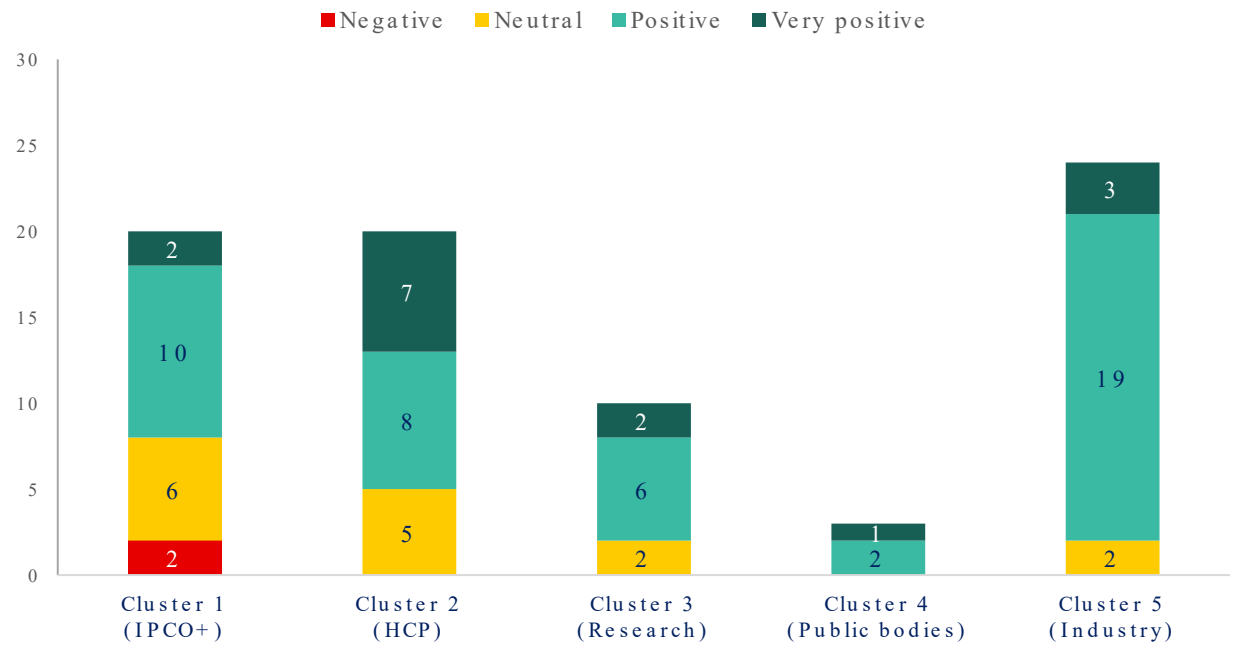


Figure 3. Overall impressions of the joint network strategy across cluster groups

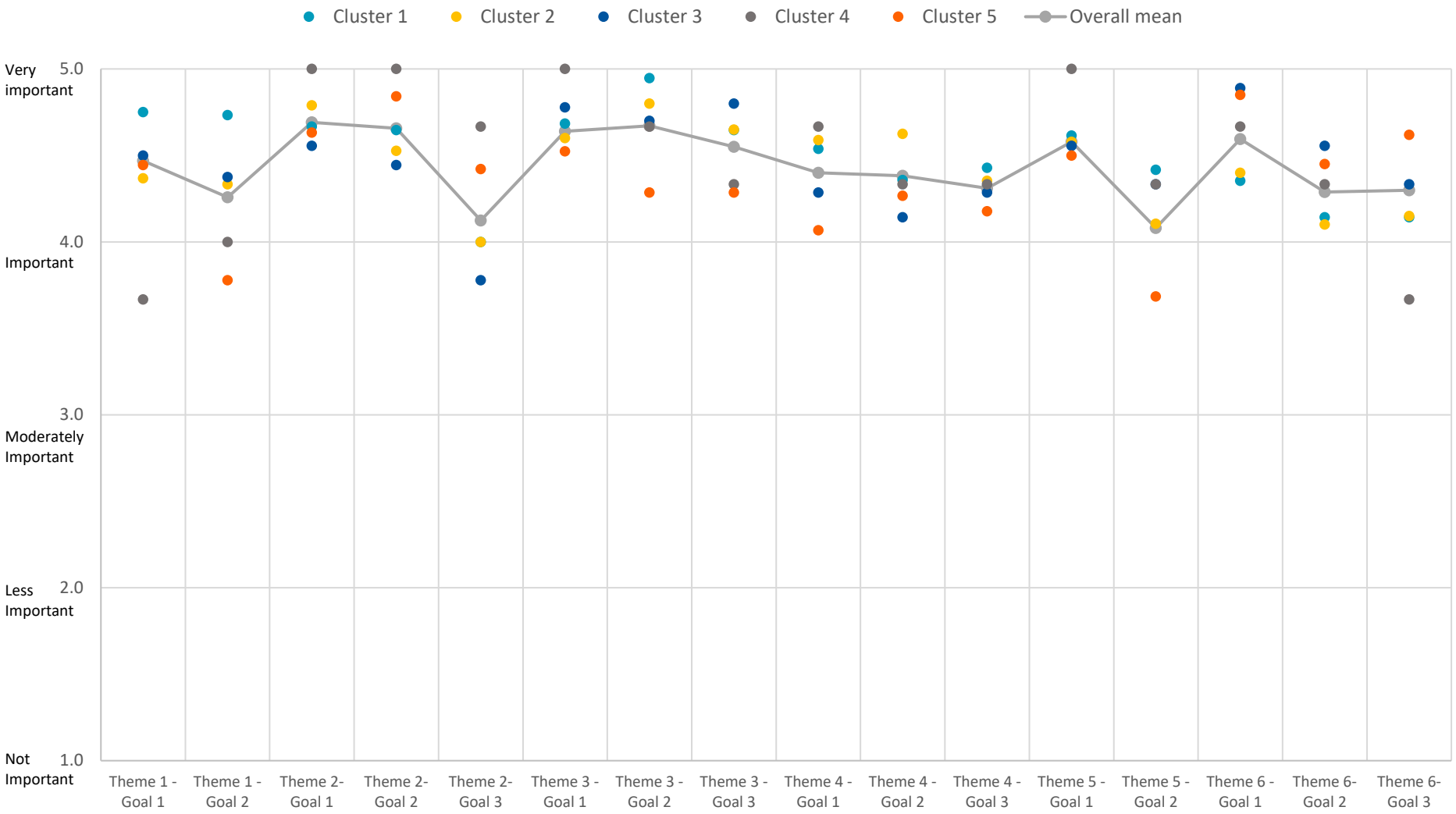


3.2. Feedback on the goals of the strategy

3.2.1. Quantitative analysis

Figure 4 presents a comparison of overall mean scores per goals of each theme, based on values of 1 for 'not important', 2 for 'less important', 3 for 'moderately important', 4 for 'important' and 5 for 'very important'. The overall mean for each goal is calculated as the mean of all responses. This analysis shows stakeholder opinions on the importance of the strategic goals. As seen from the chart, no stakeholder cluster scored any goal below 3 (moderately important) on the Likert scale and no overall mean score was below 4 (important). A subtle ranking difference can be observed in the overall mean.

Figure 4. Mean ratings of importance of all goals across each theme (question 3)



The sub-analysis per cluster illustrates the different views of each stakeholder cluster per theme goals.

Table 3. Table to illustrate ranking of goals across each theme by mean (question 3)

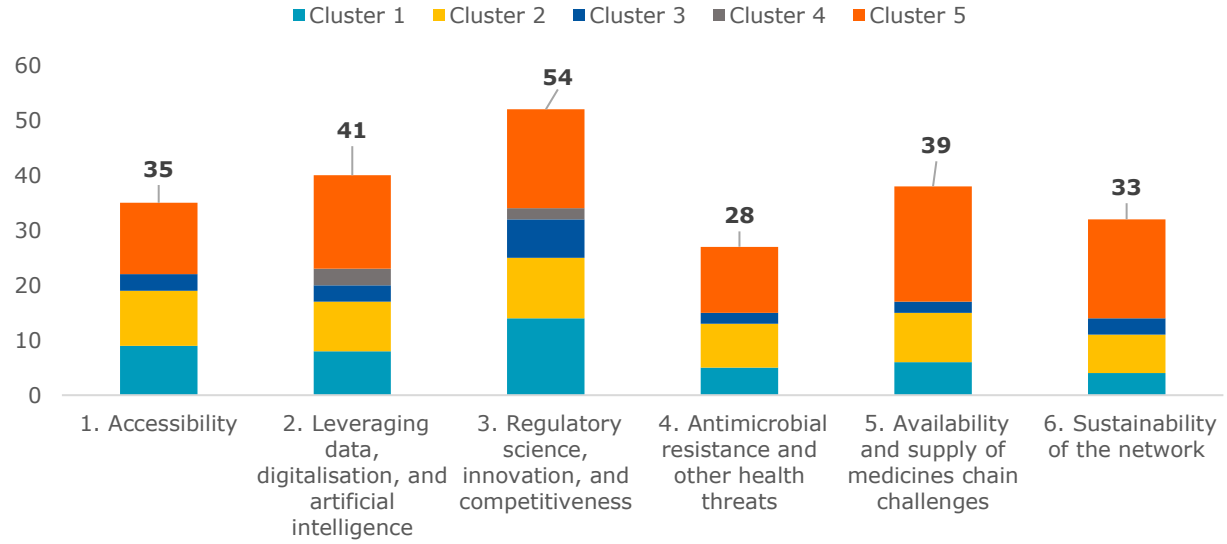
Theme & Goal	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5	Overall mean
Theme 1 - Goal 1	4.8	4.4	4.5	3.7	4.4	4.5
Theme 1 - Goal 2	4.7	4.3	4.4	4.0	3.8	4.3
Theme 2 - Goal 1	4.7	4.8	4.6	5.0	4.6	4.7
Theme 2 - Goal 2	4.6	4.5	4.4	5.0	4.8	4.7
Theme 2 - Goal 3	4.0	4.0	3.8	4.7	4.4	4.1
Theme 3 - Goal 1	4.7	4.6	4.8	5.0	4.5	4.6
Theme 3 - Goal 2	4.9	4.8	4.7	4.7	4.3	4.7
Theme 3 - Goal 3	4.6	4.7	4.8	4.3	4.3	4.5
Theme 4 - Goal 1	4.5	4.6	4.3	4.7	4.1	4.4
Theme 4 - Goal 2	4.4	4.6	4.1	4.3	4.3	4.4
Theme 4 - Goal 3	4.4	4.4	4.3	4.3	4.2	4.3
Theme 5 - Goal 1	4.6	4.6	4.6	5.0	4.5	4.6
Theme 5 - Goal 2	4.4	4.1	4.3	4.3	3.7	4.1
Theme 6 - Goal 1	4.4	4.4	4.9	4.7	4.9	4.6
Theme 6 - Goal 2	4.1	4.1	4.6	4.3	4.5	4.3
Theme 6 - Goal 3	4.1	4.2	4.3	3.7	4.6	4.3

Colour coding represents values with red for lowest possible value (1), yellow for mid-point (3) and green for highest possible value (5).

3.3. Feedback on the individual objectives of the strategy

As illustrated in Figure 5, which depicts the stakeholder contributions across strategic focus areas by cluster group, the consultation process revealed a complex range of perspectives from a diverse group of stakeholders. The figure visually demonstrates that theme 3 "Regulatory science, innovation and competitiveness" received the highest interest, with 54 different stakeholders providing feedback. Following closely was theme 2 "Leveraging data, digitalisation and artificial intelligence", which also attracted significant attention. Theme 5 "Availability and supply of medicines " received the third highest level of engagement. Themes 1 and 6 received similar numbers of responses, while theme 4 was the least selected strategic focus area, potentially indicating less stakeholder interest or perceived relevance. The visualisation in Figure 6 underscores the multi-perspective approach to developing the strategy (as illustrated by good representation of clusters across the various themes) and highlights stakeholders' particular enthusiasm for exploring areas like regulatory innovation, digitalisation, and availability of medicines.

Figure 5. Comparison of responses received from different clusters per theme.



3.3.1. Responses for theme 1: Accessibility

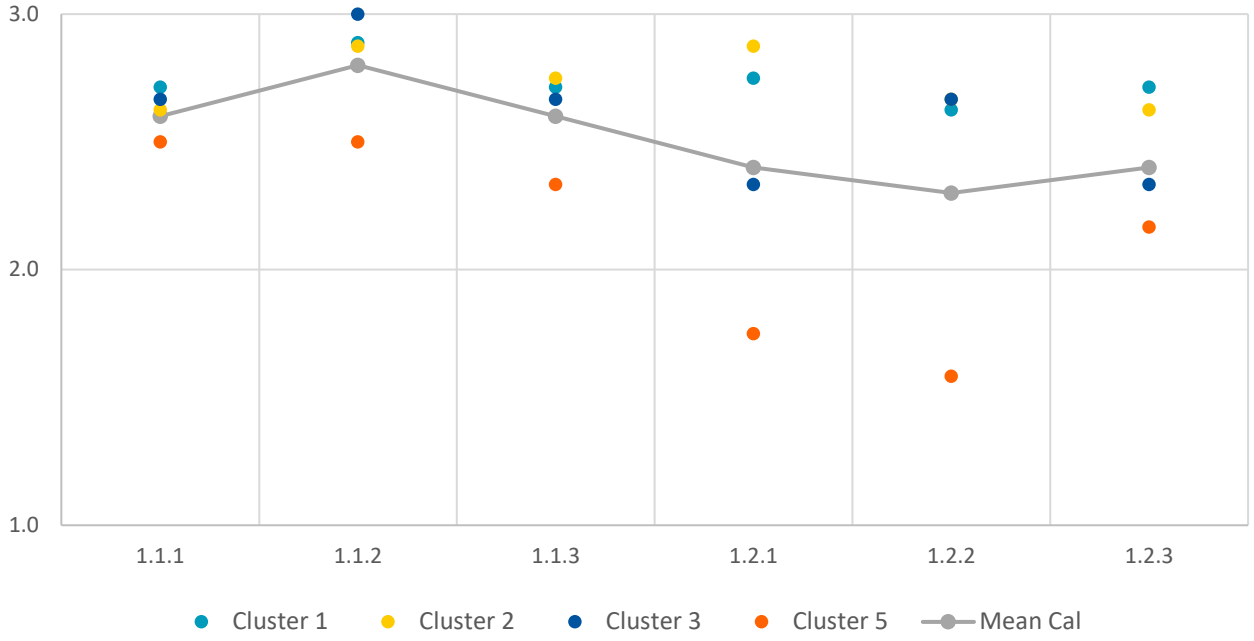
3.3.1.1. How would you rate each objective in terms of priority? – Quantitative

Table 4. Mean ratings of priority for Theme 1 objectives by different stakeholder clusters and overall

Objective	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5	Overall mean
1.1.1	2.7	2.6	2.7	n/a	2.5	2.6
1.1.2	2.9	2.9	3.0	n/a	2.5	2.8
1.1.3	2.7	2.8	2.7	n/a	2.3	2.6
1.2.1	2.8	2.9	2.3	n/a	1.8	2.4
1.2.2	2.6	2.7	2.7	n/a	1.6	2.3
1.2.3	2.7	2.6	2.3	n/a	2.2	2.4

Mean values of ratings, based on values of 1 for 'low priority', 2 for 'medium priority' and 3 for 'high priority'. Colour coding represents values with red for lowest possible value (1), yellow for mid-point (2) and green for highest possible value (3).

Figure 6. Visual representation of mean ratings of priority for objectives of Theme 1 by different stakeholder clusters and overall



3.3.1.2. How would you rate each objective in terms of priority? – Qualitative

Nearly half of **individual members of the public, patient or consumer organisations and advocacy groups (cluster 1, N=9)** considered all objectives critically important, with objective 1.1.2 receiving the highest scores. Recognising the need for increased coordination between regulatory and health technology assessment bodies, they advocated for a more integrated approach to medical research. Their recommendations placed particular emphasis on incorporating evidence from patient advocacy organisations into treatment development and marketing authorisation applications, specifically calling for randomised controlled trials that include the best proven interventions and clinical endpoints. The cluster stressed the importance of transparency in regulatory decisions, pushing for greater transparency in the decision-making process. They urged EMA to develop comprehensive guidance on obtaining robust and meaningful patient input, ensuring that patients are fully involved in defining critical concepts like "unmet medical needs" and highlighting the importance of recognising individual variations among patients with the same disease. The recommendations further underscored the necessity of patient-driven scientific and regulatory research, particularly in areas with significant unmet medical needs, and called for developing harmonised metrics for cross-country accessibility comparisons. Prioritising patient experience data emerged as a key focus, reflecting their commitment to putting patient perspectives at the heart of medical research and regulatory processes. The overall sentiment was overwhelmingly positive, with a clear vision of making patient perspectives central to drug development, medical research, and regulatory decision-making.

Half of **healthcare professionals, veterinarians and their organisations (cluster 2, N = 10)** considered most goals as very important, though one veterinary stakeholder interestingly ranked goals 1.1 and 1.2 as less important. Objectives 1.1.2 and 1.2.1 emerged as the highest priority objectives, supporting a comprehensive approach to improving medical regulation and patient care. Cluster 2 strongly advocated for the EMA to support the successful implementation of the new HTA Regulation through collaborative efforts with various stakeholders, emphasising the importance of inclusive decision-making. Communication emerged as another key focus, with recommendations to use state-of-the-art approaches when engaging with patients and healthcare professionals, particularly targeting

niche groups with the greatest medicine accessibility challenges, such as paediatric patients. They called for comparative trials versus standard therapies, requesting robust data from randomised controlled trials with adequate sample sizes and meaningful clinical endpoints. The cluster highlighted the need to consult internationally recognised specialists when considering regulatory changes, pushing for enhanced early communication with health technology assessment bodies and payer organisations. A significant recommendation was to establish a common definition of "innovative medicine" that genuinely addresses unmet medical needs, reflecting their commitment to meaningful therapeutic advancement. Despite an overall positive sentiment, the group showed a split with some having a negative view on objectives 1.2.2 and 1.2.3, particularly concerning lack of explicit paediatric considerations. They urged investigations into why timely marketing authorisation for children's medicines often fails, using novel biologic drugs for inflammatory bowel disease as an example, and called for developing new methodological frameworks to generate evidence for authorisation of paediatric medicines. The overall input reflected a desire for more rigorous, patient-centred, and comprehensive medical regulation that prioritizes genuine therapeutic innovation and accessibility.

Only a small number of stakeholders within **cluster 3 (research N=3)** rated the objectives of this strategic theme. They unanimously viewed the goals as important or very important and while all objectives were deemed of high or medium priority with, objective 1.1.2 emerged as the standout focus area. No specific comments were provided by cluster 3.

None of the **public bodies in cluster 4** that participated in the public consultation provided any comments on this specific theme.

Just over half of **trade associations, individual companies and SMEs (cluster 5, N= 14)** indicated strong support for goal 1.1, whereas goal 1.2 received mixed responses, with some rating it as only moderately important. Objectives 1.1.1 to 1.1.3 were generally seen as medium to high priority, while objectives 1.2.1 to 1.2.3 were considered lower to medium priority. There was an overall positive sentiment towards all proposed objectives, with one respondent raising concerns about accessibility issues even when medicines are approved.

The stakeholders from cluster 5 emphasised the importance of maintaining clear distinctions between the roles of regulators, HTA bodies, and payers, while fostering collaboration that supports both patient access and innovation. The group stressed the value of scientific advice from both regulators and HTA bodies but cautioned against excessive evidence demands that may hinder progress. Confidentiality concerns, particularly regarding EMA’s handling of information, needed to be addressed, and alignment of procedural calendars was crucial to ensure capacity and cooperation, including engagement with national immunisation technical advisory groups.

Respondents highlighted the need to preserve HTA system competitiveness and expedite regulatory pathways for product access, while balancing evidence generation without imposing restrictive requirements. They advocated for synergies between processes while maintaining their separation and supported the use of innovative approaches such as AI and advanced clinical trial designs to improve evidence generation. The respondents also emphasised that not all information should be shared between regulators and HTA bodies due to their distinct roles. Transparency was important, and applicants should be informed about shared data, with confidentiality maintained. EMA’s regulatory decisions should be explained clearly to HTA bodies to improve understanding of clinical contexts. Adequate resources and processes were essential to ensure timely, iterative advice for developers, and horizon scanning should also include off-patent medicines.

Feedback on ‘unmet medical needs’ deliberations stressed that these should focus on fostering innovation and access rather than introducing barriers. EMA’s approach to ‘Unmet Medical Needs’ should remain consistent, future-proof, and inclusive, while involving medical societies and patients in discussions. Transparency regarding patient insights was vital, and a narrow definition of ‘Unmet

Medical Needs' risked excluding valuable therapies. The EMANS 2028 strategy should prioritize infectious diseases and public health infrastructure.

Capacity-building for patient engagement was necessary, as well as efforts to streamline evidence requirements and reduce administrative burdens, particularly for small to mid-sized companies. A data-driven approach should focus on addressing the root causes of access delays and improving understanding of risk acceptance to expedite patient access.

Finally, the respondents advocated for a cooperative approach that supports scientific and regulatory reviews while leveraging innovative evidence-generation technologies. Scientific rigor and independence must be maintained, and there should be efforts to standardise methodologies to reduce inconsistencies. The collaboration should enhance evidence generation without hindering approvals or delaying access. Awareness of biomarkers, novel trial designs, and statistical methods should be raised, with particular attention to rare diseases and brain disorders, and consistency across HTA bodies in regulatory methodologies is crucial.

Overall, the feedback from respondents underscored the need for a balanced approach that supports innovation, regulatory efficiency, and patient access, with flexibility in evidence requirements. They called for greater collaboration, transparency, and methodological consistency, while always keeping patient-centric approaches at the forefront.

3.3.2. Responses for theme 2: Leveraging data, digitalisation, and artificial intelligence

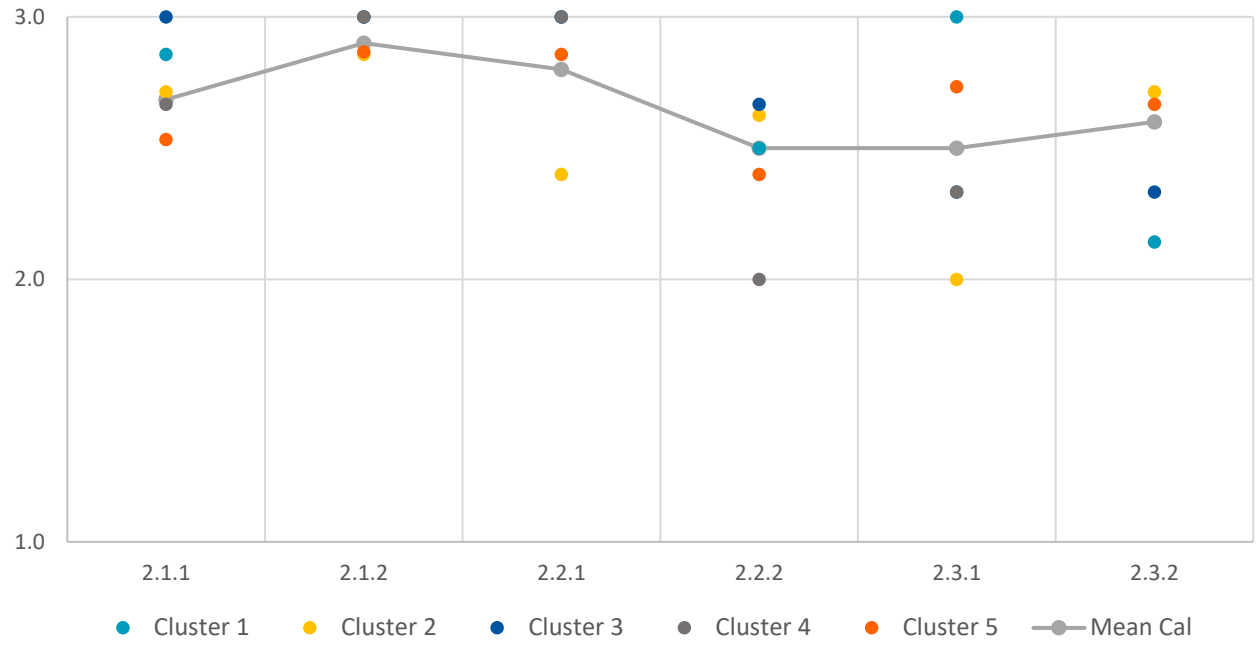
3.3.2.1. How would you rate each objective in terms of priority? – Quantitative

Table 5. Mean ratings of priority for Theme 2 objectives by different stakeholder clusters and overall

Objective	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5	Overall mean
2.1.1	2.9	2.7	3.0	2.7	2.5	2.7
2.1.2	3.0	2.9	3.0	3.0	2.9	2.9
2.2.1	3.0	2.4	3.0	3.0	2.9	2.8
2.2.2	2.5	2.6	2.7	2.0	2.4	2.5
2.3.1	3.0	2.0	2.3	2.3	2.7	2.5
2.3.2	2.1	2.7	2.3	3.7	2.7	2.6

Mean values of ratings, based on values of 1 for 'low priority', 2 for 'medium priority' and 3 for 'high priority'. Colour coding represents values with red for lowest possible value (1), yellow for mid-point (2) and green for highest possible value (3).

Figure 7. Visual representation of mean ratings of priority for objectives of Theme 2 by different stakeholder clusters and overall



3.3.2.2. How would you rate each objective in terms of priority? – Qualitative

Some **individual members of the public, patient or consumer organisations and advocacy groups (N=8)** considered goals 2.1 and 2.2 to be very important, while goal 2.3 was rated either important or very important. With regards to objectives, objective 2.2.2 was viewed as either a medium or high priority, while almost all other objectives were rated as high priority.

Three respondents from animal welfare organisations supported expanding the availability and use of various types of data and new technologies, including AI, as a means to reduce reliance on animal testing in non-clinical studies. Three respondents from patient or consumer organisations emphasised the importance of removing barriers to data access, advocating for a structured, stepwise approach aligned with clear guidance, standards, and concrete implementation plans. They also stressed the necessity of strong privacy and security mechanisms, including patient opt-outs and a comprehensive strategy for the use of synthetic data. A multi-stakeholder organisation highlighted the value of leveraging diverse data sources in diabetes care, stressing the need for representation across all populations and the prevention of bias.

Key recommendations included working with the European Commission and Council to ensure consistency in patient opt-out mechanisms across Member States (in the context of the EHDS implementation), developing a robust framework for synthetic data use, and safeguarding regulatory standards through binding guidance on the use of new data types while prioritizing patient safety. Additionally, respondents called for the integration of toxicogenomics and human data to assess individual differences and adverse effects, the standardization of data across regulatory frameworks, and the elimination of data bias in AI models. They also emphasised the potential of AI and machine learning in driving innovation without reliance on animal testing, advocating for independent expert oversight and transparency in AI governance throughout the lifecycle of medicines.

The majority of the respondents for **cluster 2 (healthcare professionals, N=9)** expressed views on objectives of theme 2 considered goals 2.1 and 2.2 as very important, while goal 2.3 was deemed

important. When scoring objectives, objectives 2.1.2, 2.3.1, and 2.3.2 were most often rated as medium priority, while the remaining objectives were generally considered high priority.

All responders were either healthcare professionals' organisations or entities involved in providing healthcare. They supported maximising the generation of data suitable for regulatory decision-making, particularly for niche patient groups such as children. Key concerns included ensuring data quality, strengthening cybersecurity, aligning with the European Health Data Space (EHDS), and generating trust through ethical data collection and use. The veterinary organisation noted the potential of AI in analysing pharmacovigilance (PhV) data.

Concrete suggestions for the objectives included comparing with EHDS standards, maximising data generation for regulatory purposes with a focus on vulnerable patient groups, addressing new cybersecurity risks associated with AI, and considering data quality challenges from various data sources. Responders also highlighted the importance of interoperability and standardisation, especially to ensure young patients' participation in clinical trials of the same molecules. They emphasised the need for appropriate network data management to build trust and set an example for the EHDS, as well as the establishment of ethically based codes of conduct for ICT professionals in the network to ensure compliance.

Only a few of the stakeholders representing **academic researchers, learned societies, European research infrastructures and other scientific organisations (cluster 3, N=3)** provided feedback on the objectives of theme 2. They viewed goal 2.1 as very important, with most considering goal 2.2 also very important and goal 2.3 as important. When scoring the objectives, most respondents rated all of them as high priority.

One respondent, a university, emphasised the importance of enforcing strict data privacy regulations and called for avoiding unnecessary increases in workload and energy consumption, as well as ensuring human oversight in the use of AI. Specific suggestions were made, including the use of EU healthcare data with strict adherence to data privacy rules (such as GDPR), reinforcing digital infrastructure and leveraging AI while avoiding unnecessary workload and energy consumption, and promoting the responsible use of AI with appropriate human oversight.

All responders in **cluster 4 (public bodies including HTA bodies and payers, N=3)** who shared their views on the objectives of theme 2 regarded goals 2.1 and 2.2 as very important, with the majority also considering goal 2.3 to hold significant importance. In terms of prioritisation, objective 2.2.2 was rated as medium priority, while the remaining objectives were deemed high priority by at least two of the responders.

Only one respondent provided comments and offered their support in collaborating to develop a regulatory framework specifically tailored for AI-enabled medical devices throughout the lifecycle of medicines.

The **majority of the pharmaceutical industry cluster responders (cluster 5, N=17),** which included both individual non-SME companies (N=7) and industry associations (N=10), considered goals 2.1 and 2.2 as very important, while nearly an equal number regarded goal 2.3 as either important or very important. When it came to prioritising objectives, objectives 2.1.2, 2.2.1, 2.3.1, and 2.3.2 were most frequently rated as high priority, with objectives 2.1.1 and 2.2.2 also receiving strong support but slightly less frequently designated as high priority.

The stakeholders of cluster 5 emphasised the need for a digital transformation in regulatory processes and the use of novel technologies such as AI, while also stressing that AI should be viewed as a tool to achieve the network's goals rather than as an end in itself. They highlighted that the AI-driven transformation must directly benefit sponsors and be implemented within a well-structured, predictable framework.

Concrete suggestions from cluster 5 stakeholders focused on improving data collection, accessibility, and standardisation across regulatory processes. One key proposal was to foster the inclusion of over-the-counter (OTC) medicines in electronic health records (EHRs), ensuring that patient experience data is captured and used effectively. Additionally, stakeholders recommended compiling EHR data into a centralised system that would allow for cross-country evaluations of specific diseases or medicines, facilitating more efficient and accurate decision-making. They also called for consistent data access rules under the European Health Data Space (EHDS) Regulation that would not compromise intellectual property protection but would still allow for the use of diverse data types from various populations.

Furthermore, stakeholders highlighted the importance of better contextualising data diversity, particularly in the context of EU versus US data, to ensure that regulatory decisions are based on relevant and representative data for the EU. They suggested considering multinational centres of excellence to accelerate the adoption of novel data types and promote knowledge-sharing among rapporteurs. Another key recommendation was the development of overarching cross-domain regulatory guidance on healthcare data use, ensuring that it remains flexible enough to allow for innovation while still providing clear direction. They also called for clear and predictable acceptability criteria for novel data types, which would help companies incorporate these new approaches into their regulatory submissions.

Other suggestions included addressing the accessibility of novel data types to prevent any disadvantages for follow-on products and reflecting that applicants remain responsible for generating the necessary data to support regulatory decision-making. Stakeholders also emphasised the need for patient input, particularly regarding treatment tolerability and trade-offs, as well as the importance of using the EHDS to promote data access for public health while respecting commercial confidentiality. Lastly, the cluster highlighted the importance of incorporating Product Management Service (PMS) and the implementation of a unified system for data standardisation, interoperability, and quality assurance throughout the lifecycle of medicines.

3.3.3. Responses for theme 3: Regulatory science, innovation, and competitiveness

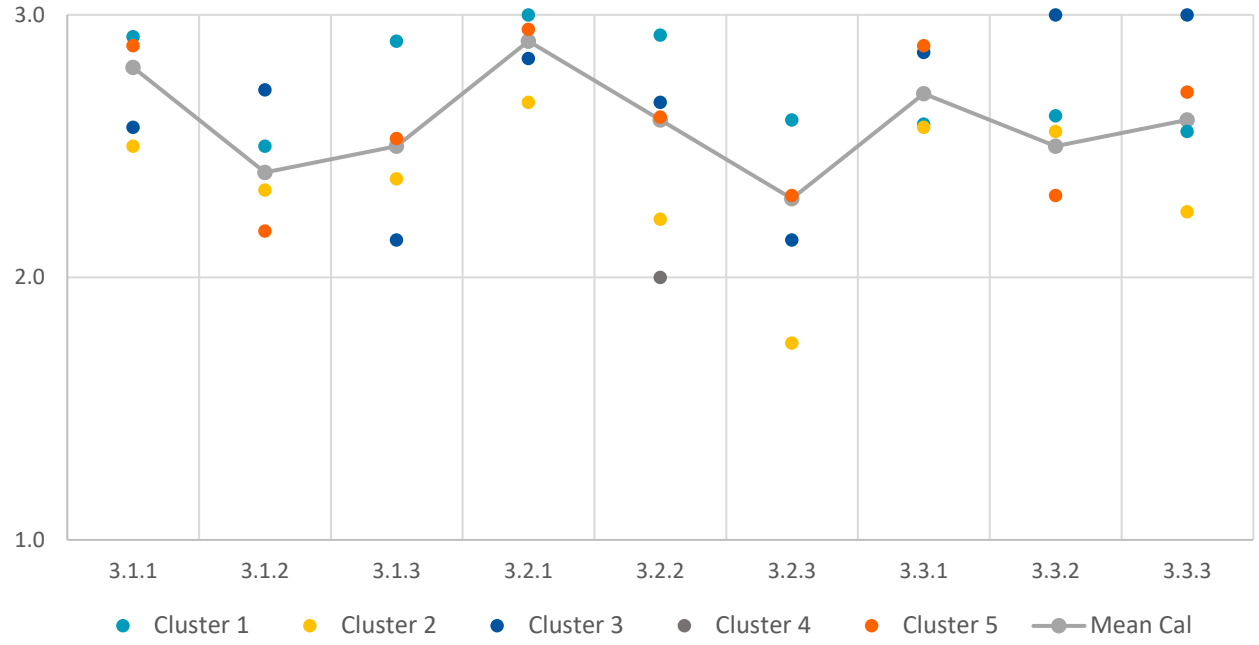
3.3.3.1. How would you rate each objective in terms of priority? – Quantitative

Table 6. Mean ratings of priority for Theme 3 objectives by different stakeholder clusters and overall

Objective	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5	Overall mean
3.1.1	2.9	2.5	2.6	n/a	2.9	2.8
3.1.2	2.5	2.3	2.7	n/a	2.2	2.4
3.1.3	2.9	2.4	2.1	n/a	2.5	2.5
3.2.1	3.0	2.7	2.8	n/a	2.9	2.9
3.2.2	2.9	2.2	2.7	2.0	2.6	2.6
3.2.3	2.6	1.8	2.1	n/a	2.3	2.3
3.3.1	2.6	2.6	2.9	n/a	2.9	2.7
3.3.2	2.6	2.6	3.0	n/a	2.3	2.5
3.3.3	2.6	2.3	3.0	n/a	2.7	2.6

Mean values of ratings, based on values of 1 for 'low priority', 2 for 'medium priority' and 3 for 'high priority'. Colour coding represents values with red for lowest possible value (1), yellow for mid-point (2) and green for highest possible value (3).

Figure 8. Visual representation of mean ratings of priority for objectives of Theme 3 by different stakeholder clusters and overall



3.3.3.2. How would you rate each objective in terms of priority? – Qualitative

A majority of **Cluster 1 (individual members of the public/patients, N= 14)** who provided feedback on the objectives of theme 3 considered goals 3.1 and 3.2 to be very important, while goal 3.3 was viewed as 'important' or 'very important'. Most respondents rated the objectives as high priority, with objectives 3.2.1 and 3.2.2 receiving the most significant attention. Among these stakeholders, five represented animal welfare organisations, and one was a member of the public. They called for a stronger focus on replacing animal testing in drug development, urging regulators to transition toward non-animal alternatives. Additionally, two respondents from patient and consumer organisations emphasised the need for greater transparency in scientific advice to improve accountability and foster better knowledge-sharing within the research and development (R&D) community. They also highlighted the importance of a broad regulatory approach driven by public health needs, stressing the role of communication and behavioural sciences in countering misinformation, understanding vaccination drivers, and improving adherence to medicines.

Several concrete proposals were made under the EMANS Strategic theme Area 3. Cluster 1 stakeholders suggested ensuring the timely update of regulatory guidance to incorporate innovations that reflect new technologies while eliminating outdated or unsafe methods. They also proposed establishing mechanisms to keep regulators informed about changes and avoid both ethical and financial waste. Additionally, respondents highlighted the importance of leveraging diverse research data and reducing reliance on animal testing. They called for addressing the regulatory implications of integrating real-world clinical and market data into clinical trial designs and providing guidance on this practice. The promotion of real-world evidence (RWE) and patient-reported outcomes (PRO) was another key suggestion, with stakeholders advocating for clearer guidance on how these should be reported and used to support product applications.

Respondents also called for greater confidence in the use of non-animal models by validating new approach methodologies (NAMs) for quality control and safety testing. This would ensure that regulatory bodies remain equipped to manage emerging drug modalities. They recommended extending EMA's regulatory support tools to patient advocacy groups funding early-stage research,

enabling these groups to seek scientific and regulatory advice. Additionally, they suggested accelerating the development and approval of human medicines by utilising human-specific methods. Fostering patient involvement in clinical research was also emphasised, with proposals to improve access to clinical trials, enhance diversity and inclusion, and simplify informed consent processes.

Further proposals included making relevant data more accessible to researchers to prevent duplication of efforts and facilitate scientific progress. This cluster of stakeholders also called for additional guidance on device validation, data capture in contract research organisations (CROs), and the collection of patient-reported data to support regulatory decision-making. They stressed the need for alignment between research and regulatory requirements from the outset, ensuring clarity on what data is necessary for regulatory decisions. Another recommendation was the introduction of a third independent scientific control entity to ensure transparency and accountability in partnerships involving external collaborators, particularly from industry. Respondents also suggested involving patient advocacy groups in keeping regulators informed of patient priorities for diseases and the latest research.

Finally, the need for pre-competitive research collaborations to focus on human-centric approaches was underscored, along with the promotion of regulatory approval for more innovative medicines. Stakeholders advocated for simplifying regulatory procedures for complex combined devices such as advanced therapy medicinal products (ATMPs) and disease-modifying therapies and supporting the use of phased reviews and regulatory sandboxes. They also called for establishing a forum where stakeholders could regularly convene with trade and patient organisations to break down barriers between various regulations such as GPL, substances of human origin, and Medical Devices. The inclusion of animal-free methods was seen as crucial in this context. Respondents further emphasized the need for better alignment among Member States regarding the classification of 'borderline products' and urged regulators to remain vigilant about products attempting to gain authorisation through less stringent pathways.

Respondents from **cluster 2 (Healthcare professionals, N=11)** generally regarded goals 3.1 and 3.2 as important, with goal 3.2 receiving the highest priority among the group. Goal 3.3 was considered important but did not have the same level of emphasis. Objective 3.3.2, in particular, was highlighted as the highest priority by stakeholders from cluster 2. However, there was some variation in the prioritisation of the other objectives.

Only a few stakeholders from cluster 2 provided concrete feedback on the objectives. They called for marketing authorisation applications to be supported by robust and meaningful data, especially when considering the use of RWE in paediatric populations. There was a strong emphasis on generating appropriate regulatory advice and frameworks to ensure RWE is used effectively for paediatric patients.

An important concern raised by these few respondents from cluster 2 was the need to maintain the independence of the regulatory process, ensuring that public health objectives are not overshadowed by private interests. They stressed the importance of a rigorous policy on conflicts of interest, both for individual experts and in the establishment of partnerships. Additionally, there was support for innovation in clinical trial design, provided these new methods adhere to the same safety, quality, and ethical standards as traditional trials. Furthermore, cluster 2 stakeholders advocated for regulatory assessments to be based on human data, rather than relying on in silico models. They also highlighted the importance of leveraging existing networks like conect4children and EPTRI to improve clinical trial access and coordination.

On the veterinary medicine front, there were calls for initiatives aimed at enhancing regulatory competence within academic institutions, particularly veterinary universities. This would help boost innovation and encourage stronger research collaborations in the field. Cluster 2 contributors recommended incorporating pro-public safeguards in public-private partnerships. This includes

ensuring transparency in public contributions and promoting clauses around accessibility and affordability in projects that receive public funding, particularly in the early stages of biomedical research.

For **cluster 3 (researchers, N= 7),** most contributors largely viewed the goals as very important, with goal 3.3 receiving the highest rating. Objectives 3.3.2 and 3.3.3 were broadly recognized as top priorities by stakeholders from cluster 3, with wide agreement on their significance. Objective 3.1.3, however, was ranked more moderately, and the remaining objectives had mixed views, with some respondents from cluster 3 considering them of medium priority and others elevating them to high priority.

Among the respondents from cluster 3 who expanded on the proposed objectives, a few critical actions were highlighted. One key suggestion was to focus on refining existing approaches, enhancing them with stronger clinical evidence and a more balanced risk/benefit analysis. Another recommendation was to strengthen collaboration with medical ethics committees to leverage their expertise in risk assessment and mitigation. This would help improve the scientific rigor of clinical trials, particularly in assessing the proportionality and feasibility of trial designs. Additionally, cluster 3 stakeholders called for a global approach to regulatory solutions, with increased cooperation between regulators and industry partners on technical issues and data standardisation. This would facilitate more consistent and aligned regulatory practices across borders.

There was no feedback received from **cluster 4** (public bodies/HTA and payers) who took part in the public consultation on this particular theme.

The majority of respondents for the **industry cluster (cluster 5, N=18)** considered the goals outlined in the strategy to be important or very important. Goal 3.1 was rated as very important by most respondents, while goal 3.2 was viewed as moderately important by some. Overall, the proposed objectives were largely seen as high priority, with objectives 3.1.1, 3.2.1 and 3.3.1 receiving the highest levels of priority from respondents. These objectives were deemed essential for driving regulatory progress and innovation within the pharmaceutical and healthcare sectors. Among the 18 respondents in this cluster, 11 elaborated on the proposed objectives, suggesting actions aimed at improving the regulatory landscape to foster innovation, enhance manufacturing capabilities, and address current challenges in clinical trials and drug development.

One primary focus was the facilitation of scientific and technological advancements in medicine development and manufacturing. Respondents emphasised the need for regulatory guidance and flexible pathways to help small and mid-sized companies integrate innovative technologies. There was a strong call for clear and adaptive support systems, particularly for spin-offs and startups, which often share similar challenges with small and mid-sized companies. Proposals included accelerating the implementation and competence building of new methodologies, as well as establishing novel evidentiary frameworks for innovative technologies. In line with this, stakeholders advocated for greater encouragement and support for advanced manufacturing technologies, such as biomanufacturing and device-product combinations, which could be integrated more effectively into regulatory processes.

Respondents also recommended that the EU's regulatory framework evolve to keep pace with other regions, advocating for a comparison of EU evidentiary standards and review times to better attract new treatments and ensure competitiveness in global markets. There was an emphasis on integrating advanced diagnostics within the regulatory framework, as this could significantly improve patient outcomes and accelerate the development of combination therapies. Furthermore, respondents highlighted the importance of a more European approach to clinical trials, with a specific focus on aligning the requirements for Clinical Trial Applications (CTAs) and addressing the decline in clinical research within the EU. They suggested that multi-country clinical trials could be facilitated by

streamlining regulatory processes and creating a more unified approach to the oversight of clinical trials, including pragmatic guidance for RWE.

Another key area of concern was reducing regulatory complexity and fostering novel solutions. Many cluster 5 stakeholders stressed the need for a coherent legislative framework to prevent fragmentation, particularly among new EU agencies, and called for the removal of national requirements in favour of a unified process for CTAs and Marketing Authorisation Applications (MAAs). The regulatory assessment process was seen as needing reform, with suggestions to simplify and remove redundant requirements to improve resource availability and operational efficiency. A significant concern among industry stakeholders was the timeliness of regulatory interactions, with many expressing a need for more frequent and effective dialogue with regulators to optimize development plans.

As part of the effort to enhance the EU's competitiveness, stakeholders suggested that the regulatory network should invest in education and training, particularly for the next generation of regulatory professionals. This investment in upskilling was seen as crucial for maintaining Europe's position at the forefront of drug research and development. Moreover, collaboration with academia, hospitals, startups, and other non-commercial researchers was highlighted as essential for advancing regulatory science and improving the tools available for drug development. Multistakeholder collaborations were seen as key to driving progress, particularly in areas like patient-focused drug development, where involving patient communities in the regulatory process could help ensure that new treatments align with patient needs and preferences.

In addition to these broader regulatory concerns, cluster 5 respondents also focused on specific challenges related to vaccines, highlighting the need for tailored regulatory pathways for mRNA medicines and ATMPs. They emphasised the importance of reducing approval timelines, addressing the challenges of multi-country trials, and harmonising vaccine registries across Europe. Furthermore, the respondents stressed the need for an international approach to reduce the reliance on animal models in research, proposing the use of innovative technologies such as digital twins, AI, and biomarker research to minimise animal testing.

Overall, stakeholders in cluster 5 underscored the importance of timely and effective regulatory processes to support innovation, improve the EU’s attractiveness for clinical research, and ensure that new technologies and treatments can be brought to market efficiently. The key themes included a desire for clearer guidance, more robust support for small and mid-sized companies, and the need for greater alignment across the EU to foster a more cohesive regulatory environment.

3.3.4. Responses for theme 4: Antimicrobial resistance and other health threats

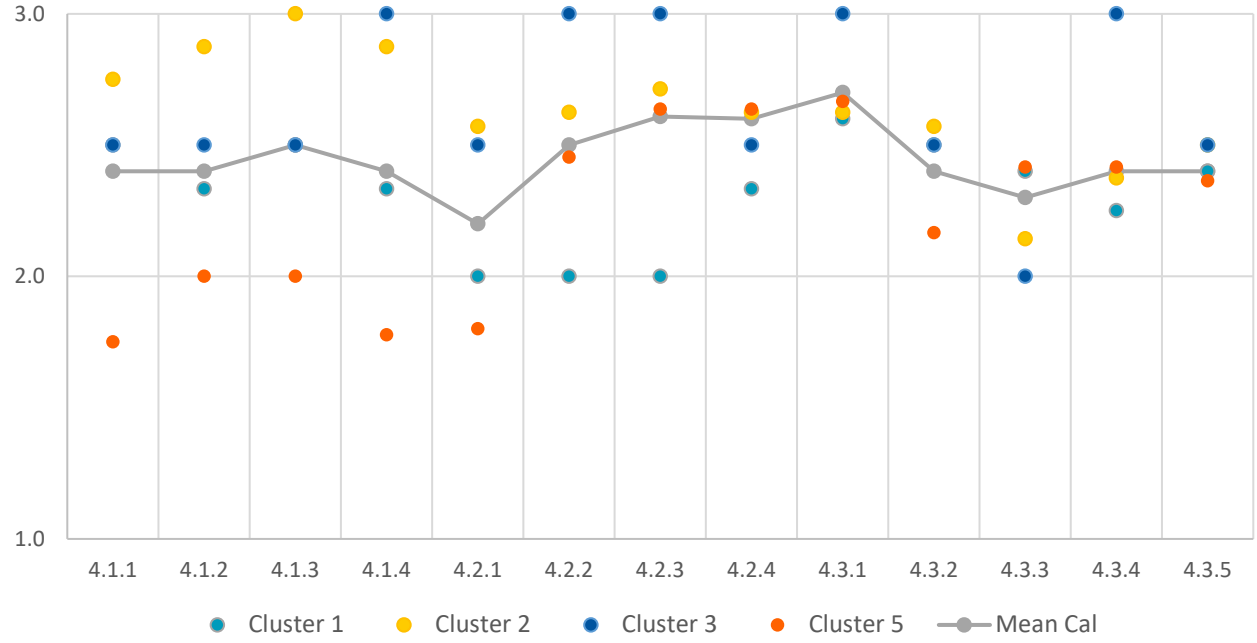
3.3.4.1. How would you rate each objective in terms of priority? – Quantitative

Table 7. Mean ratings of priority for Theme 4 objectives by different stakeholder clusters and overall

Objective	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5	Overall mean
4.1.1	2.5	2.8	2.5	n/a	1.8	2.4
4.1.2	2.3	2.9	2.5	n/a	2.0	2.4
4.1.3	2.5	3.0	2.5	n/a	2.0	2.5
4.1.4	2.3	2.9	3.0	n/a	1.8	2.4
4.2.1	2.0	2.6	2.5	n/a	1.8	2.2
4.2.2	2.0	2.6	3.0	n/a	2.5	2.5
4.2.3	2.0	2.7	3.0	n/a	2.6	2.6
4.2.4	2.3	2.6	2.5	n/a	2.6	2.6
4.3.1	2.6	2.6	3.0	n/a	2.7	2.7
4.3.2	2.5	2.6	2.5	n/a	2.2	2.4
4.3.3	2.4	2.1	2.0	n/a	2.4	2.3
4.3.4	2.3	2.4	3.0	n/a	2.4	2.4
4.3.5	2.4	2.5	2.5	n/a	2.4	2.4

Mean values of ratings, based on values of 1 for 'low priority', 2 for 'medium priority' and 3 for 'high priority'. Colour coding represents values with red for lowest possible value (1), yellow for mid-point (2) and green for highest possible value (3).

Figure 9. Visual representation of mean ratings of priority for objectives of Theme 4 by different stakeholder clusters and overall



3.3.4.2. How would you rate each objective in terms of priority? – Qualitative

Cluster 1 (n=5), **including representatives from patient organizations, an animal welfare NGO, and an individual member of the public**, ranked the goals outlined in the strategy as very important. Most of the proposed objectives were viewed as high priority. However, some objectives received mixed evaluations, with some respondents considering them of high priority, while others

rated them as medium or low priority. One individual member of the public rated all the actions as low priority.

With regards to specific comments on the objectives, respondents emphasised the importance of including AMR awareness initiatives in medicine packaging, ensuring that information is accessible in both paper and electronic formats. They also stressed the need for involving stakeholders and patient organizations in the development of guidance to ensure that it addresses patients' needs, while also supporting better dissemination and uptake. Improved training for healthcare professionals in prescribing and dispensing antimicrobials was another key recommendation.

For future guidance, cluster 1 stakeholders called for decisions to be based on public health needs and transparency. They also highlighted the necessity of regulatory guidance and scientific advice to overcome potential barriers in the approval of promising products. Efforts should also be directed towards areas of unmet needs, with patient organisations playing a key role in defining these areas based on evidence. Enhancing transparency and making scientific advice more accessible for priority antimicrobials, SMEs, and non-profits was a recurring theme. Additionally, developing new models and regulatory guidance to encourage the development of new antimicrobials was seen as crucial, along with ensuring equitable access to both older and newer antimicrobial products through coordinated incentives.

Respondents within cluster 1 called for a shift toward non-animal approaches in regulatory processes and advocated for building lessons learned from rolling regulatory reviews to streamline approval timelines. Strengthening multinational clinical trial networks was also seen as vital to facilitating innovation and the timely approval of new medications. Collaboration with public health bodies like the ECDC was recommended to better utilise epidemiological data for preparedness plans and prevent medicine shortages. A focus on the link between environmental health and adopting sustainable, patient-centred approaches throughout the lifecycle of medicines was seen as a key priority.

The harmonisation of regulatory requirements across countries to enable global marketing and prevent unnecessary testing was also a major recommendation. Incorporating advanced technological models, such as organoid and organ-on-chip technologies, into regulatory submissions was encouraged, alongside ensuring that high evidentiary standards are maintained globally. Stakeholders also suggested applying regulatory flexibilities, as seen during the COVID-19 vaccine rollout, to address future health threats. This included using rolling reviews and prior platform testing data to accelerate approval while ensuring that flexibility does not compromise medicine safety and efficacy.

Finally, the importance of maintaining high levels of transparency regarding the work and decisions of medicines agencies was emphasised. This transparency is critical to maintaining public trust and ensuring effective responses to health crises.

Regarding **cluster 2 (healthcare professionals, N=8)**, including representatives from veterinary interests, most respondents considered the goals to be very important, with some rating them as important. While most objectives were assigned high priority, some received more mixed evaluations. Objective 4.3.3 was predominantly rated as medium priority, while objectives 4.3.4 and 4.3.5 were evenly split between high, medium, or low priority. Objectives 4.1.4, 4.2.1, 4.3.2 and 4.3.3 received no written feedback.

A key recommendation from this cluster was to enhance data collection and reporting on antibiotic use in animals, ensuring responsible use and preventing antimicrobial resistance. Respondents called for stricter regulations to prevent the routine preventive use of antibiotics in healthy animal groups, restrict critically important antimicrobials in agriculture, and ban over-the-counter sales, including online, across all Member States. Compliance with current legislation should be reinforced through national and European-level controls.

Regarding the human medicines sector, the importance of maintaining paper-based information alongside electronic product information was emphasised. Strengthening infection prevention and control measures across all sectors and Member States was also seen as critical, alongside ensuring that healthcare professionals have access to rapid, efficient diagnostic tools to support prudent antibiotic prescribing. The prescribing of antibiotics without laboratory or point-of-care diagnostics should remain an exception.

Standardising evidence requirements for new antimicrobial drugs was seen as essential to ensure responsible use of public funds and evidence-based patient care. Respondents also advocated for an end-to-end approach in antibiotic development and proposed an innovative incentive model to decouple revenue from sales volume. Various financial incentives were suggested, including market entry rewards, minimum turnover guarantees, and milestone payments.

To maintain the integrity of scientific advice, respondents called for robust conflict-of-interest policies to ensure independence in regulatory processes. Practical measures were also suggested, such as packaging antimicrobials in appropriate quantities for treatment cycles and using unit-dose blister packs to ensure safe and appropriate dispensing.

Alternative business models for antibiotic R&D were highlighted, including delinking research and development costs from pricing. Respondents supported the development of needs-driven financing models to stimulate antibiotic innovation while ensuring responsible use and equitable access. Some suggested shifting focus away from market-based mechanisms and instead investing in non-legislative tools, such as funding incentives and tested payment models.

The importance of establishing strong networks capable of conducting meaningful multinational clinical trials was emphasised. Respondents noted that challenges remain in ensuring adequate sample sizes and clinical endpoints for such trials. Concerns were raised regarding regulatory flexibilities, particularly in maintaining strong evidence requirements. Respondents stressed that robust data on treatment efficacy and risks are crucial to maintaining trust and avoiding uncertainty, as demonstrated by the COVID-19 experience.

Adopting a One Health approach was a key recommendation, ensuring that both human and animal health are considered in addressing health threats. This approach should support the development of veterinary medicines, tackle zoonotic diseases, and address broader issues such as food security. Transparency, accountability, and access to data were highlighted as fundamental principles for decision-making, along with ensuring a strong evidence base for the efficacy and risks of medicines.

Only a few stakeholders representing cluster 3 **(research, N=2),** from academia and another from a scientific organisation, provided feedback to this theme. Goals 4.1 and 4.2 were both considered very important, while goal 4.3 was rated as very important by one respondent and important by the other. Most objectives were assigned high priority, with the exception of objective 4.3.3, which both respondents rated as medium priority. No detailed comments or specific recommendations were provided regarding the objectives in this theme.

Cluster 4 (public bodies/HTA and payers) did not provide any input on this theme during the public consultation.

Half of respondents in cluster 5 (Industry, N=12) provided input for theme 4, including five individual non-SME companies and seven industry associations, with no representation from veterinary medicines companies or associations. The majority rated goal 4.2 as very important, while goals 4.1 and 4.3 were seen as either very important or important by nearly equal numbers of respondents. Among the objectives, the highest priority was given to those related to fostering innovation, regulatory flexibility, and antimicrobial R&D incentives. While some objectives received a mix of high

and medium priority ratings, others, particularly those concerning information accessibility and stewardship, were predominantly rated as medium priority.

Respondents highlighted the need for clear eligibility criteria and effective implementation of incentive mechanisms to stimulate antimicrobial research and development. They stressed the importance of integrating vaccines into the strategy, streamlining regulatory pathways, and ensuring regulatory flexibility during health emergencies. Calls were made for stronger public-private partnerships, particularly in facilitating early regulatory interactions and fostering innovation in antimicrobial products. The importance of a coordinated approach to antimicrobial incentives across the EU was emphasised, including mechanisms like transferable exclusivity vouchers and subscription-style models at the national level.

Industry stakeholders also underlined the significance of ensuring clear and accessible electronic patient information, improving health literacy, and aligning patient information modernisation with digital advancements. Strengthening clinical trial networks, enhancing regulatory support for emerging health threats, and harmonising international standards to accelerate access to innovative medicines were also recurrent themes. There was a strong push for environmental considerations to be incorporated into AMR-related initiatives, including addressing pharmaceutical pollution and the broader impact of climate change on health.

Calls were made for the EU to maintain its competitiveness in pharmaceutical innovation through regulatory streamlining, better coordination among regulatory agencies, and the adoption of new business models to support antimicrobial development. Industry representatives stressed the importance of maintaining public trust in regulatory decisions and ensuring accurate, transparent communication on AMR-related issues, particularly in times of crisis.

3.3.5. Responses for theme 5: Availability and supply of medicines

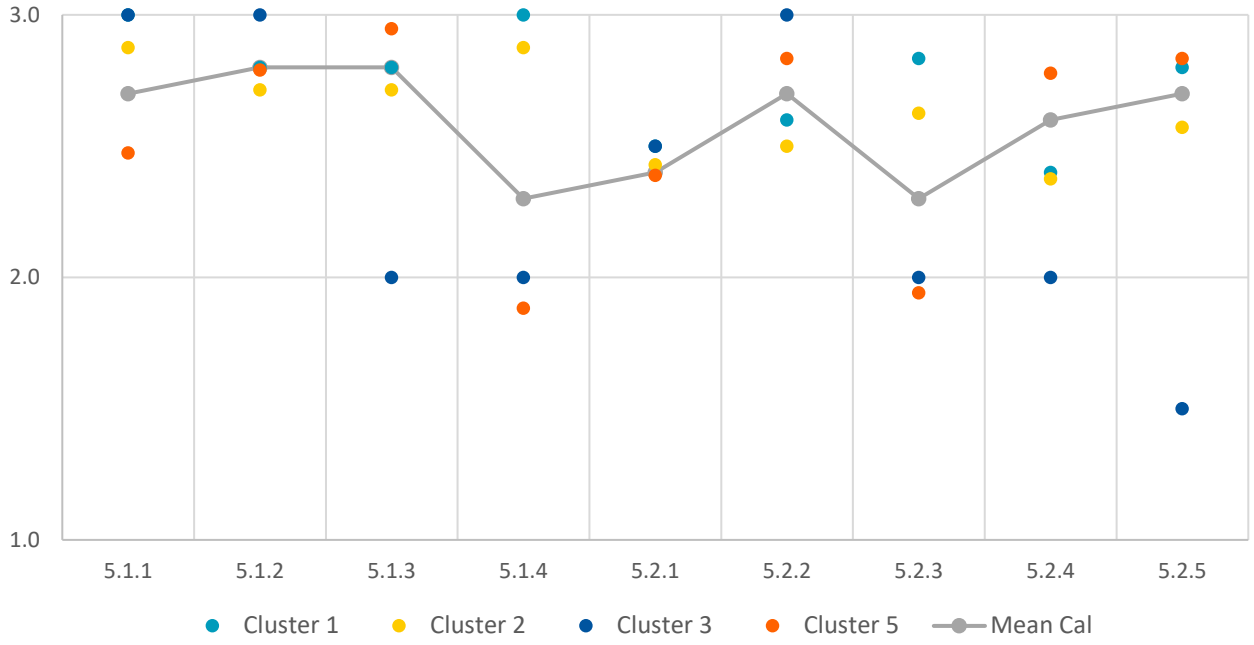
3.3.5.1. How would you rate each objective in terms of priority? – Quantitative

Table 8. Mean ratings of priority for Theme 5 objectives by different stakeholder clusters and overall

Objective	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5	Overall mean
5.1.1	3.0	2.9	3.0	n/a	2.5	2.7
5.1.2	2.8	2.7	3.0	n/a	2.8	2.8
5.1.3	2.8	2.7	2.0	n/a	2.9	2.8
5.1.4	3.0	2.9	2.0	n/a	1.9	2.3
5.2.1	2.5	2.4	2.5	n/a	2.4	2.4
5.2.2	2.6	2.5	3.0	n/a	2.8	2.7
5.2.3	2.8	2.6	2.0	n/a	1.9	2.3
5.2.4	2.4	2.4	2.0	n/a	2.8	2.6
5.2.5	2.8	2.6	1.5	n/a	2.8	2.7

Mean values of ratings, based on values of 1 for 'low priority', 2 for 'medium priority' and 3 for 'high priority'. Colour coding represents values with red for lowest possible value (1), yellow for mid-point (2) and green for highest possible value (3).

Figure 10. Visual representation of mean ratings of priority for objectives of Theme 5 by different stakeholder clusters and overall



3.3.5.2. How would you rate each objective in terms of priority? – Qualitative

Cluster 1 (n=6), comprising representatives from patient and consumer organisations as well as one individual member of the public, largely regarded the goals outlined under Theme 5 as either very important or important. Many objectives were considered high priority, with some objectives receiving exclusively high priority ratings, while others were rated predominantly high priority, with occasional medium priority assessments.

Stakeholders highlighted the importance of reducing the EU's reliance on plasma imports from the US and working towards self-sufficiency in plasma supply. They also emphasised that all the objectives stated should be undertaken in close collaboration with HERA and DG SANTE, with competent authorities gathering more comprehensive data from pharmaceutical companies to identify the root causes of shortages. Ensuring that public interest takes precedence over commercial confidentiality concerns was seen as a key priority. Strengthening patient communication and providing clearer guidance on treatment alternatives, alongside improving local reporting and monitoring of shortages, were also strongly recommended.

Cluster 2 respondents expressed concerns that certain measures could disrupt the institutional balance within EU bodies and national competencies. They advocated for requiring Marketing Authorisation Holders (MAHs) to maintain a minimum two-month stock of critical medicines in each Member State where a product is marketed. Additionally, they called for clear criteria to prevent national stockpiling measures from negatively impacting other Member States and supported continued facilitation of the 'Voluntary Solidarity Mechanism' to allow for stock redistribution in times of shortage.

Timely and transparent communication regarding medicine shortages was another key focus. Stakeholders urged for improved dissemination of information to patients, consumers, and healthcare professionals, as well as the development of accessible databases in all Member States. These databases should provide details on the cause and expected duration of shortages, as well as possible therapeutic alternatives.

Regulatory oversight and international collaboration were also highlighted as critical areas for improvement. These respondents advocated for establishing specific inspection agreements to facilitate regulatory oversight in third countries, ensuring that inspectors can carry out their duties effectively. Enhancing the EMA's global presence was seen as necessary to strengthen regulatory oversight of imported products. The importance of patient safety in EMA's engagement with international regulators and third countries was stressed, along with a call for increased transparency in supply chains. Lessons from incidents such as falsified Ozempic pens should inform future strategies to prevent similar occurrences.

To address medicine shortages effectively, Cluster 1 stakeholders emphasised the need for the European Shortages Monitoring Platform to be fully operational by the following year. Ensuring its interoperability with national IT systems was seen as vital for enhancing monitoring and response capabilities across Member States.

Respondents representing healthcare professionals (Cluster 2, n=9), consisting of healthcare professional organisations, healthcare professionals, and one veterinarian, broadly regarded the goals outlined under Theme 5 as either very important or important. The objectives were largely viewed as high priority, with most receiving strong support, though a few stakeholders rated certain objectives as medium priority.

Cluster 2 stakeholders highlighted the need to prioritise essential medicines for children under this theme, though specific actions for this objective were limited. Another key suggestion was to relocate medicine production to Europe and enforce stricter regulations on industries. Respondents suggested assessing which products would benefit most from relocation and supporting this through revised tendering procedures that incorporate supply chain resilience criteria, particularly concerning the location of production sites. The introduction of a 'medicine made in Europe' label as a requirement in tendering processes was encouraged, alongside diversifying external supply sources and enhancing data collection on supply chain risks to identify vulnerabilities and strengthen resilience.

For veterinary medicine, coordination between countries was emphasised, particularly in responding to emerging diseases and preventing stockpiling that could disrupt supply chains. Stakeholders proposed that national stockpiling should only be implemented when it does not negatively impact neighbouring countries, healthcare facilities, or regions with pressing medical needs. To mitigate shortages, respondents proposed that stockpiling of essential medicines should ensure at least a four-week supply in hospitals and a two- to three-month reserve within wholesalers' inventories.

Ensuring greater transparency in medicine availability throughout the prescription process was another key recommendation. Respondents called for improved communication with healthcare professionals in veterinary medicine and increased reporting from pharmaceutical companies and supply chain actors regarding stock levels and availability. Enhanced supply chain regulations were also proposed, including requiring pharmaceutical companies to develop contingency plans for risk identification and mitigation, alongside stricter obligations for supply reporting.

Relocating supply chains and production was considered essential, with respondents cautioning against selling off manufacturing capabilities to speculators. Strengthening international cooperation was seen as particularly crucial for veterinary medicines, given the heavy reliance on active pharmaceutical ingredient (API) manufacturers located in China and India. Stakeholders stressed the need for more inspectors to oversee these production sites to ensure quality and supply continuity.

Regarding the use of AI in regulatory and pharmaceutical processes, respondents cautioned against its acceptance without robust evidence of its benefits. They expressed concern that AI methodologies should not replace standard methods unless a high level of evidence demonstrates clear improvements in accuracy, reliability, and safety.

Two respondents contributed to Cluster 3, representing one research organisation and one other scientific institution. The goals outlined under Theme 2 were all regarded as very important. Among the objectives, respondents ranked objectives 5.1.1, 5.1.2, and 5.2.2 as high priority, while objectives 5.1.3 to 5.2.1 were generally rated as medium priority. Opinions on objectives 5.2.3 to 5.2.5 were more varied, with one stakeholder assigning high priority and the other rating them as low priority.

The only specific actions proposed related to objective 5.2.1. Stakeholders suggested reviewing the current inspection model to determine its effectiveness and exploring alternatives like self-certification or third-party inspections. They also recommended assessing whether existing standards adequately support risk and quality control or create barriers to innovation in these areas.

No input on this theme was received from **Cluster 4 (public bodies, HTA, and payers)** during the public consultation.

Many stakeholders for Cluster 5 (n=21) provided input, comprising seven individual non-SME companies, one SME, one for-profit private company, and twelve trade associations. Cluster 5 stakeholders largely considered Goal 1 as very important or important with only one respondent rating it lower. Goal 2 received more mixed feedback, with responses ranging from very important to less important, though many leaned toward a moderate importance. Several objectives, including 5.1.1, 5.1.2, 5.1.3, 5.2.2, 5.2.4, and 5.2.5, were largely assigned high priority, with only a small number of stakeholders viewing them as medium priority. However, objectives 5.1.4, 5.2.1, and 5.2.3 received mixed ratings across high, medium, and low priority levels. Although objectives were rated mostly positively, opinions differed on their feasibility and implementation. Some stakeholders highlighted the need for clearer prioritisation and measurable outcomes to ensure effective execution.

Respondents from Cluster 5 strongly emphasised the need for improved shortage reporting, coordinated prevention plans, and enhanced EU-wide collaboration. Many supported defining critical medicines at both national and EU levels, harmonising shortage definitions, and improving interoperability of regulatory systems. Concerns were raised about the impact of EU Green Deal regulations on supply chains, with calls for regulatory flexibility and streamlined processes to mitigate risks. A harmonised approach to addressing shortages and fostering collaboration between MAHs, supply stakeholders, and authorities was widely supported.

Mamy contributors highlighted the need for a unified list of critical medicines and a coordinated response to public health emergencies. Stakeholders urged reducing policy fragmentation across Member States to prevent supply chain disruptions and called for better visibility of national demand to improve supply planning. The importance of regulatory incentives and a European Shortages Monitoring Platform was also highlighted. While many respondents supported an EMA-led oversight role, concerns were raised about the potential for overregulation and bureaucratic delays. Some advocated for a balanced approach, ensuring national authorities retain flexibility while aligning with broader EU strategies.

EU coordination of national measures was deemed essential, with stakeholders advocating for an EMA-led oversight role. Concerns were raised about national stockpiling distorting supply chains, with calls for an EU-wide safety stock policy to ensure equitable distribution. Respondents stressed that stockpiling should be a last resort and supported a coordinated procurement strategy to optimise supply allocation.

Cluster 5 stakeholders also called for a balanced approach to shortage management, ensuring transparency while protecting commercially sensitive information. Some warned that publicising shortages could lead to panic hoarding, exacerbating supply issues. Maintaining a standard notification period and engaging in regular dialogue between regulators and industry were seen as key to effective management.

Finally, Cluster 5 proposed additional recommendations, including expanding Mutual Recognition Agreements on GMP inspections to cover biologics and advanced therapies, increasing EU inspector capacity, and enhancing reliance on trusted authority inspections. Stakeholders supported risk-based inspection planning, advocating for global regulatory alignment and the use of digital tools to improve efficiency. While the role of AI in regulatory compliance was acknowledged, concerns were raised about overregulation hindering innovation. Improving the interoperability of regulatory databases and integrating monitoring platforms with existing verification systems were also highlighted as key priorities for real-time data assessment and response.

3.3.6. Responses for theme 6: Sustainability of the Network

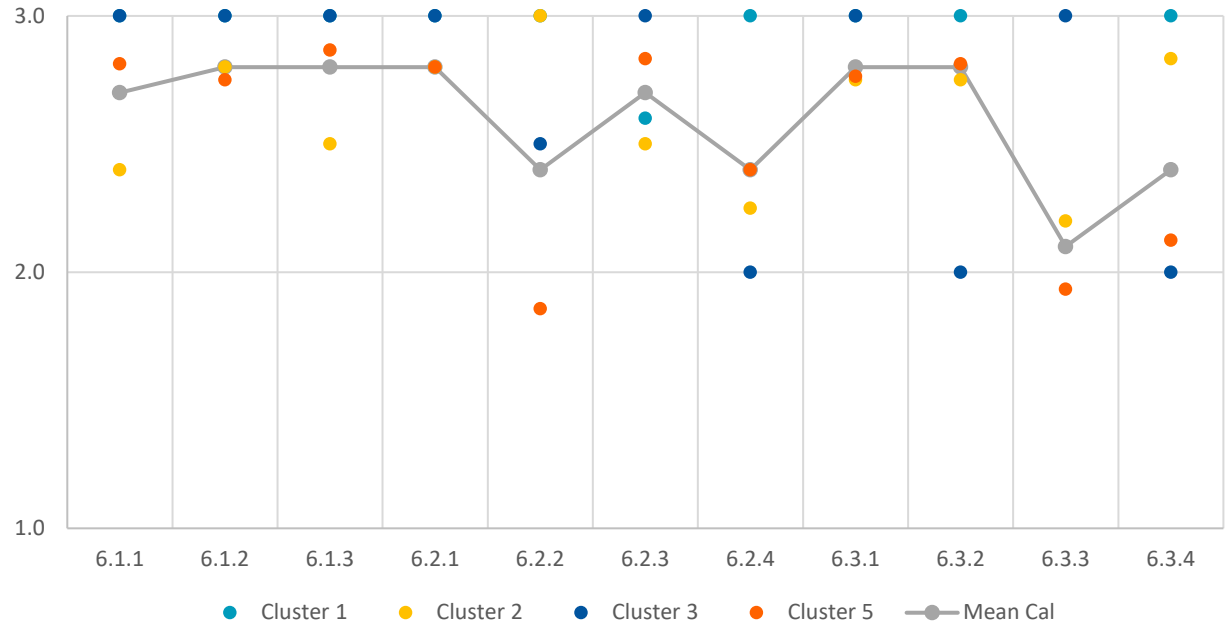
3.3.6.1. How would you rate each objective in terms of priority? – Quantitative

Table 9. Mean ratings of priority for Theme 6 objectives by different stakeholder clusters and overall

Objective	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5	Overall mean
6.1.1	3.0	2.4	3.0	n/a	2.8	2.7
6.1.2	3.0	2.8	3.0	n/a	2.8	2.8
6.1.3	3.0	2.5	3.0	n/a	2.9	2.8
6.2.1	3.0	2.8	3.0	n/a	2.8	2.8
6.2.2	3.0	3.0	2.5	n/a	1.9	2.4
6.2.3	2.6	2.5	3.0	n/a	2.8	2.7
6.2.4	3.0	2.3	2.0	n/a	2.4	2.4
6.3.1	3.0	2.8	3.0	n/a	2.8	2.8
6.3.2	3.0	2.8	2.0	n/a	2.8	2.8
6.3.3	n/a	2.2	3.0	n/a	1.9	2.1
6.3.4	3.0	2.8	2.0	n/a	2.1	2.4

Mean values of ratings, based on values of 1 for 'low priority', 2 for 'medium priority' and 3 for 'high priority'. Colour coding represents values with red for lowest possible value (1), yellow for mid-point (2) and green for highest possible value (3).

Figure 11. Visual representation of mean ratings of priority for objectives of Theme 6 by different stakeholder clusters and overall



3.3.6.2. How would you rate each objective in terms of priority? - Qualitative

With regards to **cluster 1 (patients or consumers and their organisations, N=4),** the respondents expressed that the goals of this theme were considered either very important or important. The objectives within this theme were given high priority, although not all were scored.

Two respondents from animal welfare organisations emphasised the importance of dedicating resources and expertise to implementing new methodologies aimed at reducing the use of animals in medicine development. They also highlighted the need for better communication and for ensuring the public's voice is included in these discussions. The remaining two respondents, representing patient and consumer organisations, focused on the importance of EMA's funding. One specifically stressed the need to uphold transparency and avoid conflicts of interest, suggesting that the EMA should seek public funding to ensure its independence.

Specific proposals included enhancing capacity for faster adoption of new technologies and methodologies aligned with the transition away from animal testing. The network was also urged to develop a framework promoting transparency around the use of animals in medicine development, ensuring that decisions are accessible and readily available to the public. Respondents also stressed that in implementing the new EMA fee regulation, rules on conflicts of interest and transparency should be maintained. Additionally, the EMA was encouraged to explore alternative funding sources, such as increased contributions from governments.

In **Cluster 2 (healthcare professionals),** seven respondents provided input, including one healthcare professional organisation representing veterinary interests. Most respondents considered the theme's goals to be either 'very important' or 'important'. Most objectives were rated as 'high priority', though objectives 6.2.3, 6.2.4, and 6.3.3 received lower priority scores from some respondents, and objective 6.1.1 was more frequently rated as 'medium priority' than 'high priority'.

Respondents emphasised the need to utilise existing expertise outside the NCAs to improve regulatory processes. They suggested networks such as Enpr-EMA could focus on paediatric issues, with the possibility of establishing specialised 'Centres of Excellence' for vulnerable groups, such as children. They also recommended adjusting objective 6.1.1 to better highlight the importance of patient protection, proposing a rewording to ensure the network can support patient safety when implementing new methods.

Several contributors highlighted the importance of enhancing the network's ability to drive digital transformation, particularly for veterinary medicines. Respondents suggested using advanced technologies to reduce administrative tasks, allowing human resources to focus on more critical work. However, they stressed that digital changes should only be implemented when clear benefits are demonstrated, and human oversight must remain part of the process. Some respondents proposed using predictive IT models to assess the impact of legislation.

In veterinary medicines, there was a call for more clinical research involving animals and for better use of health data, real-world data (RWD), and outcomes.

Data-driven governance was seen as key to improving the regulatory framework, with some suggesting that international harmonisation could make markets more attractive to businesses. Respondents also called for greater engagement with patient organisations in decision-making processes to increase transparency. They emphasised that EMA's medicine overviews should better reflect patient needs, providing more detailed information about treatment goals, potential benefits, uncertainties, and side effects. There was also a push for the publication of all clinical trial results, including negative ones. Finally, respondents recommended establishing a framework for

communication to address information needs and combat misinformation, with a focus on improving digital health literacy.

Among **researchers and academia (cluster 3, N= 3),** all contributors represented the human healthcare sector. The goals were generally considered either very important or important. However, only two respondents provided scores for the objectives. Among the objectives, numbers 6.2.4, 6.3.2, and 6.3.4 were rated as medium priority, while the remaining objectives were largely seen as 'high priority'. One key suggestion from respondents was to learn from international regulators who have experience in new capabilities to drive convergence.

No feedback regarding this specific theme was provided by **cluster 4 (public bodies/HTA and payers)**.

A large number of industry stakeholders **(cluster 5, N=18)** contributed to this strategic area, including 10 trade organisations (one representing SMEs) and eight individual companies, encompassing both innovative and generic/biosimilar industries. None of the respondents represented veterinary interests. Overall, the goals were generally considered very important or important, though goal 6.3 was marked as moderately important by one respondent. Most objectives were rated as high priority, although objectives 6.2.3, 6.3.3, and 6.3.4 received mostly medium priority scores, while objectives 6.1.1, 6.2.2, 6.2.4, 6.3.1, and 6.3.4 received at least one low priority score. Objective 6.2.2 received a majority of 'low priority' scores. Many respondents expressed support for the goals and provided specific proposals for improvement.

Industry stakeholders expressed positive views on the concept of Centres of Excellence but called for a thorough evaluation to assess their added value and potential impact on the broader regulatory network. To ensure adequate capacity for assessment, some respondents committed to improving submission predictability, while others emphasised the need to focus resources on assessment for the Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP). Respondents expressed strong support for implementing the new EMA Fee Regulation, expecting it to increase capacity within the NCAs.

Furthermore, stakeholders called for increased resources within the regulatory network, including funding, expertise, and IT capabilities, to improve the capacity of NCAs. This included hiring additional assessors and enhancing submission predictability. There was strong support for leveraging AI, data analytics, and digital tools to streamline regulatory processes, especially to benefit small and mid-sized companies with enhanced guidance and more efficient procedures.

Efficiency in resource allocation was a key concern, particularly in lifecycle management, with suggestions to redeploy resources to keep pace with scientific and technological advancements such as biomanufacturing. Several industry stakeholders proposed preparing to shorten review times for marketing authorisation procedures ahead of the scheduled implementation of the revised General Pharmaceutical Legislation.

Increased capacity for scientific advice was another key proposal, including more engagement opportunities and greater flexibility in seeking advice. To improve timely access to off-patent medicines, respondents called for additional resources to address delays in marketing authorisation procedures and ensure NCAs are sufficiently staffed to manage the majority of EU applications.

Stakeholders also recommended better integration of IT systems such as European Shortages Monitoring Platform (ESMP), European Medicines Verification System (EMVS), and Product Management Service (PMS) to improve data quality, transparency, and operational efficiency. There was support for collaboration among industry, academia, and health authorities to address regulatory resource constraints and enhance stakeholder training.

International cooperation was another key proposal, with stakeholders suggesting expanding the scope of the EU-US Mutual Recognition Agreement (MRA), sharing regulatory assessments through platforms, and leveraging the EU's regulatory experience to promote global convergence, particularly in post-approval activities.

The need for improved training and expertise in science, regulation, and digital technologies for regulators was highlighted, with suggestions to use fee increases for targeted education and modernising IT tools. Lastly, stakeholders proposed eliminating administrative tasks, such as those related to PMS and variations, to free up resources for more complex regulatory work, with a focus on advancing multinational assessment teams (MNATs).

4. Discussion

Feedback from the public consultation suggests that the revised and updated network strategy to 2028 has been generally well-received by the various cluster groups and this is true for the various strategic themes (see Figure 3). Stakeholders widely recognised that the strategy and its proposed goals and objectives are important and appropriate priorities for the network. The limited number of negative comments or low ratings of goals and objectives indicates that the strategy provides a well-structured and comprehensive roadmap for progress over the lifetime of the strategy.

The consultation process generated a wide range of comments, many of which have contributed to revisions in the final strategy document. This section outlines how stakeholder input has influenced the final content. The discussion is structured in two parts: the first highlights the feedback that has led to specific modifications to the final strategy, while the second highlights general reflections on comments that, while noteworthy, did not result in changes to the text of the strategy document.

4.1. Feedback leading to changes in the strategy document

A variety of potential changes were identified by numerous respondents, prompting revisions to the overall strategy. While specific amendments were incorporated within individual themes, several proposed changes were more overarching, aiming to enhance the strategy as a whole. The most significant of these concerned the One Health approach, which emphasises the interconnectedness of human, animal, and environmental health. Furthermore, extensive consultation and engagement were recognised as crucial elements, which were subsequently more clearly emphasised throughout the strategy. Several respondents also emphasised the need to consider cross-sectoral legislation and other EU policy initiatives that could impact the strategy in the coming years, including the ongoing revision of pharmaceutical legislation. These recommendations were integrated into the updated strategy.

Based on the feedback received, the strategy has been updated to incorporate the following changes:

Theme 1: Accessibility

For theme 1, key suggestions were made regarding the clarification of roles and responsibilities of regulators and health technology assessment (HTA) bodies. Respondents recommended that the strategy place greater emphasis on ensuring that both innovative and off-patent medicines benefit from enhanced communication efforts and additional activities aimed at improving accessibility. These changes aimed to clarify regulatory roles and improve the availability of medicines.

Theme 2: Leveraging data, digitalisation, and artificial intelligence

For theme 2, proposals included reinforcing the network's commitment to comply with data protection laws and cybersecurity requirements and including explicit links to the European Health Data Space

(EHDS). Stakeholders also suggested including explicit references to master data, including Product Management Service (PMS), as well as reflecting public engagement on digital tools such as electronic product information (ePI).

Theme 3: Regulatory science, innovation, and competitiveness

Proposals under theme 3 sought to future-proof the EU innovation ecosystem by enabling rapid adaptation to scientific and technological advancements. There was a call for the development of new regulatory tools and approaches, as well as identifying areas where additional expertise is needed. Stakeholders highlighted the importance of supporting the competitiveness of the biomanufacturing sector and fostering the generation of high-quality evidence in non-clinical areas, including non-animal methods. Furthermore, integrating real world data into the strategy and aligning approaches internationally were suggested to enhance the global relevance of the strategy. Finally, a strong emphasis was placed on fostering dialogue and communication among stakeholders to ensure a collaborative and adaptive approach.

Theme 4: Antimicrobial resistance and other health threats

For theme 4, stakeholders recommended the inclusion of explicit references to marketing authorisation terms, particularly in the context of developing options to guide prescribing practices. It was also suggested that the strategy document include examples, such as vaccines, as alternatives to the use of antimicrobials, further supporting sustainable healthcare practices and helping mitigate the risks of antimicrobial resistance.

Theme 5: Availability and supply of medicines

Under theme 5, stakeholders underscored the importance of a balanced approach to communication regarding medicine shortages. It was acknowledged that a transparent yet balanced approach to communication is needed in order to avoid undue public concern and ensure that information is conveyed responsibly.

Additionally, respondents suggested that the strategy adopt a more robust and holistic One Health approach, incorporating veterinary medicines more comprehensively and enhancing measures for emerging disease preparedness across the entirety of the strategy.

Theme 6: Sustainability of the network

Stakeholders emphasized the integration of environmental sustainability within the strategy as part of theme 6, recognizing its growing importance. Recommendations also included incorporating knowledge management as part of the digital transformation efforts and explicitly referencing artificial intelligence (AI) as a potential area for shared initiatives. Further changes proposed included providing support for regulatory systems in EU candidate countries, ensuring the strategy fosters inclusivity and cooperation beyond current EU member states. Finally, there was a call to reinforce stakeholder engagement, particularly in terms of aligning diverse interests and ensuring broad participation in the strategy's implementation.

4.2. Feedback that did not lead to changes in the strategy document

The feedback provided in the public consultation reflected diverse stakeholder perspectives on regulatory processes, evidence requirements, legislative updates, environmental concerns and pharmaceutical supply security. For example, contributors repeatedly suggested incorporating additional explicit references to engagement with stakeholders and to addressing the needs of the paediatric population. Respondents also repeatedly noted that a further update of the strategy will be needed following revision of EU Pharma legislation. However, many of the points raised have been

deemed as already covered. They were also often too detailed for the strategy document but were to be taken into consideration as part of activities to support implementation of the strategy. Others were dependent on ongoing legislative processes or outside the current scope of either the strategy document or the remit of medicines agencies.

Theme 1: Accessibility

Several stakeholders raised suggestions about various aspects of the HTA process, regulatory obligations and evidence requirements. Specifically, feedback highlighted the desire for greater involvement of stakeholders and partners in the HTA process, clarification of legal obligations regarding product launches, and engagement in pricing and reimbursement procedures. Comments also touched on operational steps of HTA under the relevant regulations and implementing acts, as well as concerns over the imposition of additional evidence requirements beyond regulatory needs. Additionally, there were calls for opt-out provisions for known substances. Concerns were also raised regarding restrictive evidence requirements, economic and pricing considerations, fostering competitiveness through HTA implementation, and addressing inequalities in access across different countries.

Theme 2: Leveraging data, digitalisation, and artificial intelligence

Stakeholders commented on the development and implementation of the EHDS, advocating for a broader scope beyond the elements within the remit of regulators. Suggestions also included focusing initially on EHDS implementation at the national level before expanding further. There were also comments linking certain measures to the conclusion of the EU pharmaceutical legislation review.

Other feedback included requests for more explicit detailed references to standards or systems such as for identification of medicinal products (IDMP), Fast Healthcare Interoperability Resources (FHIR), and IRIS (cloud-based software tool to manage scientific and non-scientific procedures at EMA), as well as offers of cooperation from stakeholders with supervisory roles in related areas. Additionally, concerns about safeguarding evidence standards, consideration of data limitations, protection of intellectual property, and maintaining the applicant's responsibility for data and evidence generation were raised.

Theme 3: Regulatory science, innovation, and competitiveness

Some stakeholders emphasised the need for timely updates to regulatory guidance to reflect technological advancements and phase out ineffective methods. Improved mechanisms were suggested to keep pace with regulatory changes to prevent ethical and financial inefficiencies. Calls were made for regulatory flexibility to support small and mid-sized companies in adopting advancements efficiently.

Additionally, some stakeholders highlighted the opportunities within the ongoing pharmaceutical legislation revision, expressing concerns that certain provisions were not ambitious enough. Suggestions were made to revisit the strategy once the legislation is finalised.

Other comments related to network capacity and capability, which are already addressed under Theme 6 and ongoing initiatives such as IncreaseNET, the EU Network Training Centre offer, and efforts to enhance overall system efficiency.

Theme 4: Antimicrobial resistance and other health threats

Concerns were raised regarding environmental impacts of pharmaceutical products, with calls for common solutions to mitigate pollution while considering climate change factors.

Additional comments addressed various topics already covered in the strategy document, including transferable vouchers, standardised regulatory requirements, and developer support. The role of ePI, new antibiotics for veterinary use, and the legal framework regulating antibiotic use in agriculture and food production were also noted.

Theme 5: Availability and supply of medicines

Many comments provided by stakeholders were related to the revision of the pharmaceutical package and other EU policy initiatives, offering various suggestions for improvement. But these ultimately concerned areas outside the remit of medicines agencies. Amongst others, key recommendations were made on shortage reporting requirements, the usage of harmonised electronic package information, and the strengthening of supply chain regulations to reduce reliance on third countries. There was also a call to address public health crisis response measures. Additionally, stakeholders advocated for the expansion of MRAs on GMP inspections to cover vaccines, plasma-derived products, and ATMPs.

Further feedback highlighted strong support for EMA's role in preventing and managing medicine shortages, with calls for more robust measures to enhance supply security, relocate supply chains, and reinforce EMA's global presence. Some stakeholders noted that concerns about illegal supply chains are already addressed under the Falsified Medicines Directive. Moreover, challenges were raised regarding the limited incentives for companies to adopt sustainable manufacturing processes under the EU Green Deal.

Theme 6: Sustainability of the network

Several comments focused on improving efficiency through the streamlining of regulatory frameworks and updating legislation to account for technical advances. Proposals included leveraging advanced IT models to predict legislative impacts and considering legislative changes to facilitate global development of off-patent medicines.

Additional feedback suggested expanding national-level initiatives at the EU level regarding data sharing, processes and technology. Other comments reiterated the importance of PMS, SPOR master data, international cooperation, transparency, and providing the right information to stakeholders. Many of these topics are already addressed within the strategy document. Calls were also made to allocate additional public funding for regulators and to include off-patent medicines in international cooperation efforts.

5. Conclusion

The public consultation gathered a wide variety of feedback from different stakeholders across all themes and was not dominated by a single group focusing on just a few thematic areas. The overall response from stakeholders was positive, with many viewing the strategy as promising, especially since it acknowledges current challenges and proposes solutions to address them. However, there was an expectation of more detailed information on specific actions within the strategy itself. Additionally, numerous comments were received relating to matters outside the remit of medicines agencies, many of which related to other legislative or EU policy initiatives, including the ongoing revision of the pharmaceutical legislation. Some stakeholders pointed out that, if the proposed goals and objectives can be implemented, it would represent significant progress in improving timely access to medicines for patients. Many emphasised that the success of the strategy hinges on the collaboration and support of all stakeholders.

As presented at the multistakeholder webinar on 13 February 2025, some feedback from the public consultation has been incorporated into the final draft of the EMANS document which was adopted by the EMA Management Board and HMA in March 2025.

It is important to note that the joint strategy is intended as a high-level, overarching framework to guide the work of both the EMA and HMA over the next 3 years. Specific actions, timelines, and measurable outcomes will be detailed in the EMA's multiannual work programme and the HMA's

multiannual work plan. Many of the suggestions raised during this consultation that were too detailed to be reflected in the strategy document will still inform the implementation of the strategy.

In conclusion, the feedback from stakeholders outlined in this document was vital for validating and refining the EMANS 2028. We anticipate that the insights collected will not only influence the network's priorities but also guide stakeholders' perspectives on the critical issues to be addressed over the coming years.