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Outcome of the public consultation on the EU Medicines Agencies Network Strategy to 2020

Summary of the comments received during the public consultation and the Network's response

1. Background

For the first time the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) of the Member States have developed a joint European Union (EU) Medicines Agencies Network Strategy to 2020. The Network Strategy outlines joint key priorities for the Network for the next five years and focuses on areas where collaboration within the Network can make a real difference to human and animal health in the EU.

The Network Strategy was launched for public consultation following agreement at the February 2015 HMA meeting and the March 2015 EMA Management Board meeting. Once finalised, the Network Strategy will be supplemented by multi-annual work programmes/implementation plans for EMA, HMA and the Coordination Groups for Mutual Recognition and Decentralised Procedures, Human and Veterinary (CMD(h) and CMD(v)).

2. Outline of the public consultation process

The Network Strategy was published on both EMA and HMA websites on 31 March 2015. Comments were invited until 30 June 2015.

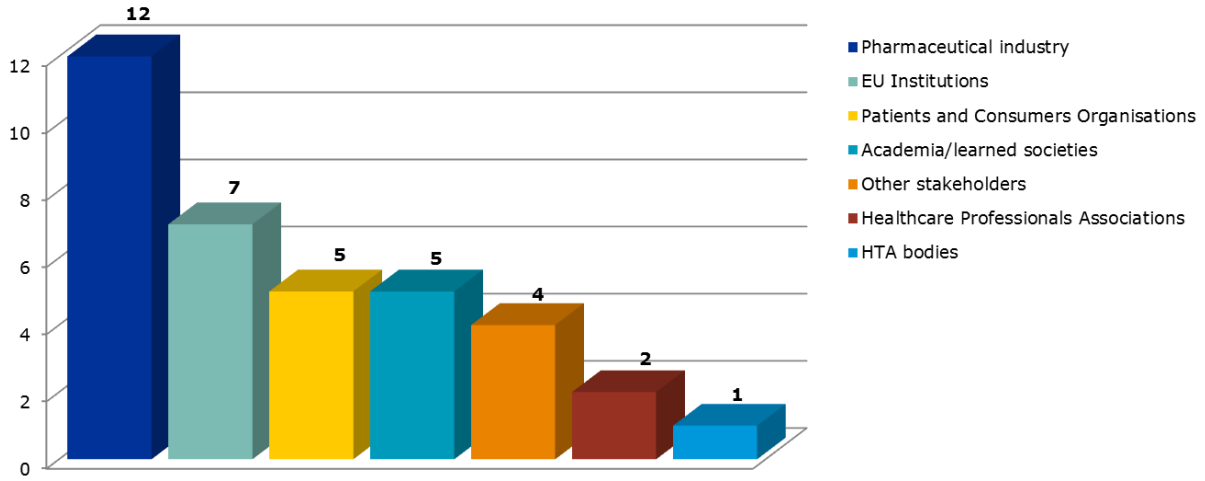
In addition, two face-to-face meetings have been held:

- On 4 June 2015 a meeting was held at EMA premises, with HMA participation, with representatives from patients' organisations, healthcare professionals' organisations and academia (see Annex 1).
- On 23 June 2015 a meeting was held at EMA premises with HMA participation, with representatives from the European Industry Associations in the field of medicinal products for human use (see Annex 2).

Furthermore, EMA held discussions on the Network Strategy at the level of all its scientific committees, in parallel to the public consultation.

3. Contributors

In total, 36 contributions were received in writing from a wide range of stakeholders, submitting 380 comments (59 general and 321 specific comments). The distribution of respondents was as follows:



The outcome of the two face-to-face meetings with stakeholders is provided as annexes 1 and 2.

4. Summary of the main points raised during the public consultation

All comments received in writing during the public consultation, or made during the two face-to-face meetings, have been analysed by the Network. Overall, the feedback received was very positive, both in terms of

- the development of a joint Network Strategy, and
- the strategic objectives outlined in the Network Strategy.

Due to the amount and diversity of the comments made, this summary report will focus on the main issues raised/recommendations and suggestions made. Likewise, section 5 of this document will provide the Network's response to these main points expressed.

The main comments made relate to the following areas:

4.1. Approach to the Network Strategy

- How will clarity of purpose be maintained amongst the Network and how will resource focus be ensured over the next five years taking into account competing priorities?
- Accountability for delivery of the Strategy should be addressed.
- Objectives should be prioritised following stakeholder consultation.
- There is a lack of differentiation between human and veterinary medicines. In addition, some areas, focusing on human medicines, could also be beneficial to veterinary medicines.
- Annual status reports should be published to inform on progress made.

4.2. Areas not (enough) covered in the Network Strategy

- More emphasis should be put in the Network Strategy on generic/biosimilar and well-established medicines, taking into account their importance in the healthcare system. Likewise, the particularities of non-prescription medicines should be better recognised.
- The need to explore flexibility within the existing regulatory system is recognised, but this should be supplemented by new approaches, such as proportionate risk-based approaches to medicines regulation, that would facilitate timely access.
- The complexity of the current regulatory system results in a decrease of the EU attractiveness for research and development; therefore, activities should be undertaken to tackle this phenomenon.
- In the veterinary sector, more emphasis should be put on reducing regulatory burden for veterinary medicines ahead of the finalisation and implementation of the new veterinary legislation. In addition, reliance on animals should be further reduced through increased support to the 3R principles.

4.3. Interaction with stakeholders

- Demands for EDQM/PhEur to be recognised as a key player in various activities of the Network, and for the role of scientific societies to be strengthened.
- The links to public health authorities should be emphasised, in particular in situations where strengthened collaboration would be useful.
- Interaction between EMA and other EU Agencies on areas of common interest should be further strengthened.
- Requests were made to include stakeholder participation in activities aiming at improving operational excellence.
- An optimal platform for a strategic approach to integrating patient involvement in regulatory processes, especially at national level and making best use of EMA experience, should be established.
- Research activities performed through collaborative projects involving both pharmaceutical industry and non-pharmaceutical industry partners such as the Innovative Medicines Initiative (IMI) should be reinforced.

4.4. Other issues

- Clarification should be provided on the terminology used: "innovative" versus "new" versus "novel" medicines.
- Requests were made to better define the concept of unmet medical need.
- The independence of regulatory authorities should be emphasised in the Network Strategy.
- Early access programmes should not become the general rule and should not be at the expense of the safety of medicines.

5. EU Medicines Agencies Network response to the main points raised

As already mentioned, this section elaborates on the Network's response to the main point raised. Since the Network Strategy is a high-level document, several comments made have not been addressed in the Strategy as such, but will be taken into account in the drafting of the respective multi-annual work programmes/implementation plans.

5.1. Approach to the Network Strategy

- Priorities will be addressed in the multi-annual work programmes/implementation plans taking into account available human and financial resources. Likewise, performance indicators, where feasible, will be introduced to enhance accountability. Status reports on progress made will be published at regular intervals.
- A better differentiation has been made in the Network Strategy between aspects affecting human and veterinary medicines. Where relevant, areas of joint interest will be highlighted.

5.2. Areas not (enough) covered in the Network Strategy

- References have been included in the Network Strategy to emphasise that generic/biosimilar and well-established medicines are important medicines for the healthcare system. Activities to address the particularities of non-prescription medicines will be addressed in the respective multi-annual work programmes/implementation plans.
- The notion of a proportionate risk-based approach when balancing the need for more information on quality, safety and efficacy of medicines versus the need for timely access has been introduced in the Network Strategy.
- To tackle the complexity of the current regulatory systems, efforts will be directed on how to reduce administrative burdens and associated costs, taking into account best practices at the level of regulatory authorities.
- The importance of continued efforts to support the 3R principle has been stressed in the Network Strategy by emphasising the need to ensure compliance of new and existing guidelines with this principle.
- The multi-annual work programmes/implementation plans will elaborate on how to increase the efficiency of the regulatory procedures in the veterinary field within the current legislative framework.

5.3. Interaction with stakeholders

- Additional partners and stakeholders have been included in the Network Strategy, in particular as regards EDQM and EU Agencies. Where needed, their role has been elaborated upon.
- The need to provide further information on collaboration with other public health authorities has been recognised.
- The Network Strategy has been amended to include stakeholder participation in the review of scientific and operational procedures.

- The multi-annual work programmes/implementation plans will explore how to best ensure patient involvement in regulatory processes at national level.
- The multi-annual work-programmes/implementation plans will elaborate, where relevant, on a collaborative approach in the field of research activities.

5.4. Other comments

- A consistent description has now been provided as regards "novel" products.
- To respond to the need for clarification on areas of unmet medical need, a reference has been included in the Network Strategy to the WHO list of essential medicines.
- Further clarification on the independence of regulatory authorities has been introduced in the Network Strategy.
- Emphasis has been put in the Network Strategy on the fact that whilst earlier access programmes are needed, the importance of gathering robust information on the benefit-risk balance of medicines throughout the medicines' lifespan is equally important, for instance through the proactive gathering of real world data.

6. Annexes

Annex 1: Extract from the published minutes of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting

Annex 2: EU Medicines Agencies Network Strategy to 2020 - Summary report of the meeting with Industry Stakeholders Associations for human medicines, 23 June 2015