HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Agencies Network Strategy to 2025 Regulatory

Conference on Accessibility, Availability & Affordability of Medicines and Medical Devices for a Stronger and Resilient EU
29-30 April 2021

Presented by
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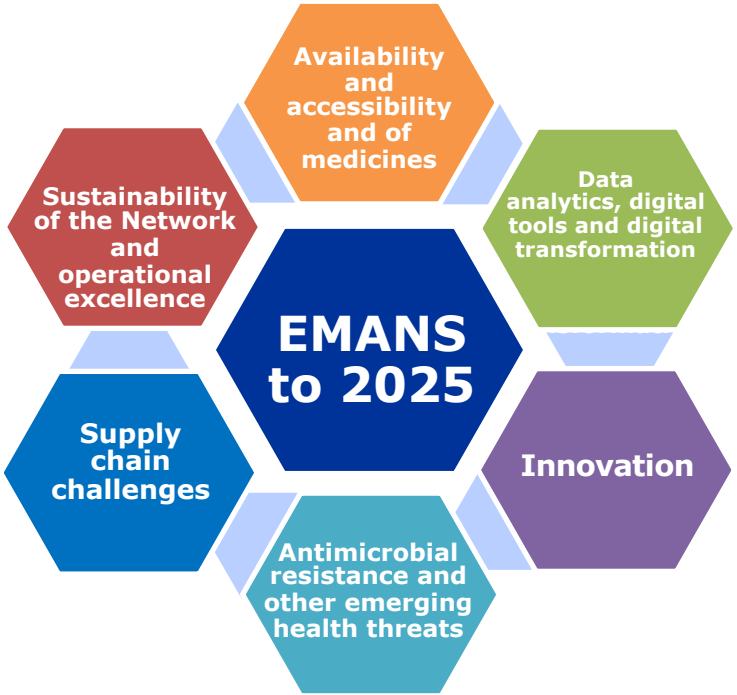
Outline of the presentation

1. Development and finalisation of the strategy
2. High level summary of the results of the public consultation
3. Focus on theme 1 on Accessibility and Availability of medicines
4. Focus on theme 3 on Innovation
5. Implementation plans

European Medicines Agencies Network (EMAN) Strategy to 2025

- EMA/HMA agreed 6 strategic focus areas for next 5 years
- Joint drafting group defined goals and objectives, challenges
- Alignment with EC pharma strategy, RSS and interdependencies with other initiatives
- Consultation with EMA committees/working parties and HMA working groups
- Discussed recommendations for action for implementation through multi-annual work plans
- Extensive stakeholder consultation
- Publication December 2020



Strategy outline

3 July 2020
EMA/321483/2020

European medicines agencies network strategy to 2025
Protecting public health at a time of rapid change

https://www.ema.europa.eu/en/documents/other/european-medicines-agencies-network-strategy-2025-protecting-public-health-time-rapid-change_en.pdf

Theme 1 : Availability and accessibility of medicines Goals

Goal 1: Strengthen availability of medicines to protect the health of EU citizens and animals, via:

- efficient and targeted regulatory measures, made possible through an in-depth understanding the root causes of unavailability of patented and off-patent products (e.g. low volume products such as paediatrics);
- identification of possible challenges in implementing legislation, removal of national barriers, increased coordination of the EMRN, sharing and implementation of best practices including by the stakeholders and increased transparency are the essential steps towards this goal.

Goal 2: Optimise the path from development, evaluation through to access for beneficial medicines (innovative and follow-on) through collaboration between medicines regulators and other decision makers in the areas of:

- evidence planning, including post-licensing evidence;
- engagement in review of evidence and methodologies, respecting remits of the various players;
- collaboration on horizon scanning.

- **As a result of this work, medicines that address unmet medical needs should have broader and earlier access coverage.**

Theme 1 : Availability and accessibility of medicines Objectives (1/2)

Goal 1 - Objective 1: Identify the specific root causes of shortages for medicines for human and veterinary use and develop strategies to improve prevention and management of shortages (a better understanding of the specific causes for shortages of generics/off-patent products versus products still under patent protection is essential). Based on the outcome of this study, help to identify and suggest areas where changes to EU or national legislation could improve supply.

Goal 1 - Objective 2: Foster the awareness of the public and healthcare professionals on the approval standards, safety, effectiveness and immunogenicity of similar biological products to facilitate the uptake of biosimilars in healthcare systems

Goal 1 - Objective 3: Improve coordination of information and actions, including implementation of best practices, both for EU regulatory authorities, stakeholders and international partners

Goal 1 - Objective 4: EMA should be empowered and provided with sufficient capacity to monitor and coordinate medicines' availability and supply. EMA should also coordinate the activities of the EMRN in order to ensure availability of critical medicines in the EU/EEA by supporting increase of production capacity to meet demand.

Goal 1 - Objective 5: Increase transparency on availability/launch to facilitate targeted regulatory actions and communication with patients, HC professionals and HTA bodies.

Theme 1 : Availability and accessibility of medicines Objectives (2/2)

Goal 2 - Objective 1: Develop better scientific evidence which serves different decision makers along the decision chain (regulators, HTA bodies, payers), including evidence to support post-licensing follow-up of medicinal products thereby stimulating a life-cycle approach to evidence generation and the possibility to adjust decisions based on new evidence.

Goal 2 - Objective 2: Clear and enhanced communication to patients, health care professionals, veterinarians and animal owners as well as down-stream decision makers about the regulatory assessment including information gap inherent for medicinal products approved on the basis of limited scientific data and secondary endpoints (e.g. Orphans, limited market veterinary medicinal products)

Goal 2 - Objective 3: New metrics for accessibility of medicines that better represents real patient access to newly authorised medicinal products in different markets.

Goal 2 - Objective 4: Foster alignment of national implementation of compassionate use programmes in order to promote equity in access for patients during late stage development and improved utilisation of data from such programmes to support later decision making

Theme 3 : Innovation – goals & objectives

Goal 1: Catalyse the integration of science and technology in medicines development and ensure that the Network has sufficient competences to support innovators in various phases of medicines development.

Objectives:

- Support the integration of scientific and technological progress in the development of medicines (e.g. precision medicine, biomarkers, 'omics and ATMPs) and ultimately into patient treatment
- Transform the regulatory framework for veterinary medicines to support innovation and successful implementation of the veterinary medicines regulation
- Implement an EU-level model for efficient, timely and coordinated horizon scanning and priority setting that fulfils the needs of both regulators, HTA-bodies and payers
- Facilitate the implementation of novel manufacturing technologies

Theme 3 : Innovation – goals & objectives

Goal 2: Foster collaborative evidence generation – improving the scientific quality of evaluations and ensuring generation of evidence useful to all actors in the lifecycle of medicines, including HTAs, and pricing and reimbursement authorities.

Objectives:

- Foster innovation in clinical trials and develop the regulatory framework for emerging clinical data generation
- Leverage non-clinical models and 3Rs principles and optimise capabilities in modelling, simulation and extrapolation and invest in special population initiatives
- Develop further the collaboration of various groups involved with scientific advice and/or regulatory guidance

Theme 3 : Innovation – goals & objectives

Goal 3: Enable and leverage research and innovation in regulatory science

Objective:

- Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science

Goal 4: Enhance collaboration with other stakeholders including medical device experts, notified bodies, SMEs and research/academic groups.

Objectives:

- Increase collaboration with Medical Device Authorities and Notified Bodies, exchange knowledge and facilitate collaboration and sharing of expertise to ensure effective and appropriate regulation of combination products
- Promote early interaction with academia, researchers and SMEs with a view to increasing awareness of regulatory requirements and facilitating the translation of research into authorised medicinal products and ultimately into clinical practice

Plans for implementation of the strategy

- Within EMA the multi-annual programming 2021-2024 has 3 main pillars: products related activities, strategies and public health activities, programmes and projects.
- In 2021 the COVID-19 pandemic continues to be prime focus, alongside other priorities for the veterinary legislation, communication and international activities, digital innovation and extension of the EMA mandate.
- EMA/HMA will continue to collaborate to identify and translate actions into the relevant work-programmes/implementation plans.
- Progress reports will be presented regularly to both EMA Management Board and HMA.
- An overall review of the strategy will be conducted every 18 months to ensure that all goals and objectives are still applicable.

Thank you for listening

Further information

See websites for contact details

Heads of Medicines Agencies www.hma.eu
European Medicines Agency www.ema.europa.eu

The European Medicines Agency is an agency of the European Union