European Medicines Agencies Network Strategy to 2025

- Strategy for Digital transformation

Joint HMA/EMA Workshop on Artificial Intelligence in Medicines Regulation

2021 April 19th – 20th

Present by
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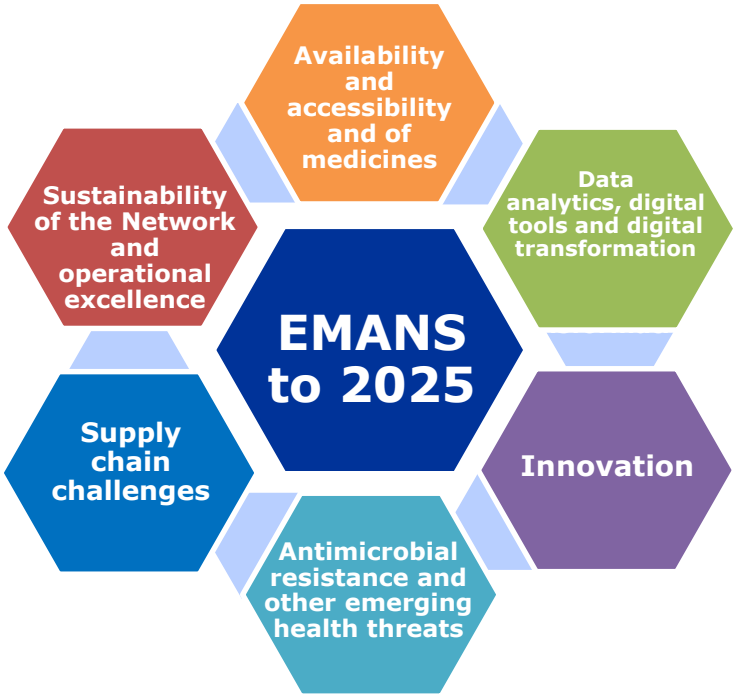
Outline of the presentation

1. Development and finalisation of the strategy
2. High level summary of the results of the public consultation
3. Final strategy document
4. Implementation plans

1. Development and finalisation of the strategy

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



Development and finalisation of the strategy

- A final document was agreed by EMA/HMA Drafting Group in mid-October
- EMA MB and HMA written procedure was launched on 30 October 2020 for review and adoption of the final version of the joint strategy document together with summary report of the public consultation with a deadline of 13 November 2020.
- The final strategy document was considered adopted following review of the comments received which was agreed by EMA/HMA Drafting Group.

2. High level summary of the results of the public consultation

Stakeholder consultation on the strategy

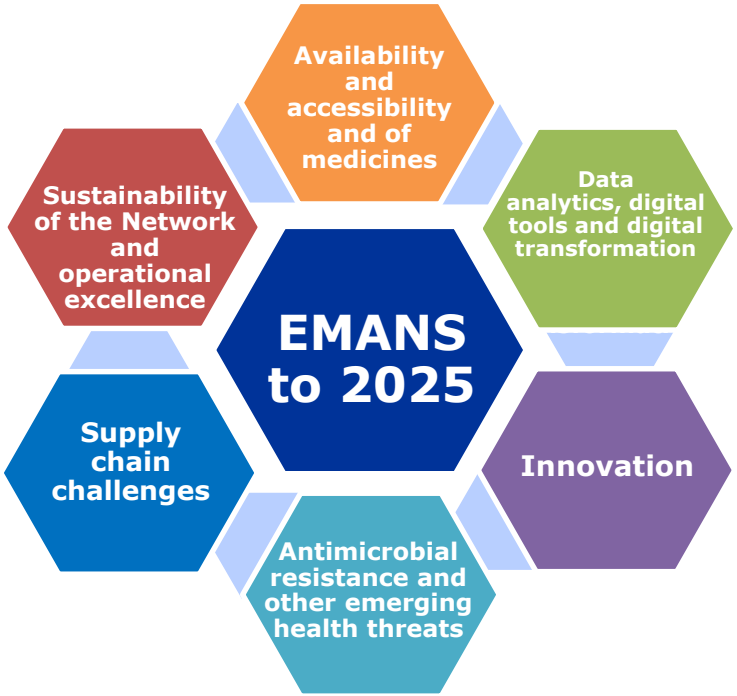
- Early stakeholder consultation in March and 2-month public consultation over summer:
  - input from a total of 177 different stakeholder groups
  - received a broad range feedback on all themes
  - overall impression from stakeholders was good
  - emphasised need for all stakeholders to collaborate to make it a success
- Final adoption by EMA Management Board and HMA in November 2020
- Published in Dec 2020 with the summary of public consultation analysis

3. Final strategy document

European Medicines Agencies Network (EMAN) Strategy to 2025

Strategic focus areas:

- Availability and accessibility of medicines
- Data analytics, digital tools and digital transformation
- Innovation
- Antimicrobial resistance and other emerging health threats
- Supply chain challenges
- Sustainability of the Network and operational excellence



Strategy outline

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

Theme 2 : Data analytics, digital tools and digital transformation - Goals

Goal 1: Enable access to and analysis of routine healthcare data, analysis of individual patient data from clinical trials, and promote standardisation of targeted data

Goal 2: Build sustainable capability and capacity within the Network including statistics, epidemiology, real world data and advanced analytics

Goal 3: Promote dynamic regulation and policy learning within the current regulatory framework

Goal 4: Ensure that data security and ethical considerations are embedded in the governance of data within the Network

Theme 2 : Data analytics, digital tools and digital transformation – Objectives (1/2)

Goal 1 - Objective 1: Deliver a sustainable platform to access and analyse healthcare data from across the EU (DARWIN EU)

Goal 1 - Objective 2: Pilot the analysis of individual patient data from clinical trials in initial marketing authorisation assessments with a view to a targeted roll out of such analysis.

Goal 1 - Objective 3: Establish collaborations with external stakeholders (including patients, academia, NGOs and industry) and with international regulatory authorities on Big Data initiatives

Goal 1 - Objective 4: Establish EU framework for data quality, discoverability and representativeness, through agreement on meta-data for regulatory purposes, a standardisation roadmap and registers of real-world data sources and of observational studies

Theme 2 : Data analytics, digital tools and digital transformation – Objectives (2/2)

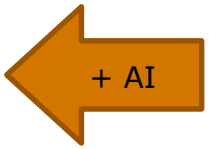
Goal 2: Objective 1: Build EU Network capability to analyse Big Data

Goal 2: Objective 2: Digital transformation of the EU Network's scientific and regulatory processes to enable use of digital tool and analytics and creation of a supporting digital infrastructure – e.g. to support uptake and review of big data (from eHR, registries, devices, etc.)

Goal 3: Objective 1: Modernise the delivery of scientific advice at central and national level by developing Network skills and processes

Goal 4: Objective 1: Ensure data are managed and analysed within a secure and ethical governance framework

Theme 3 : Innovation Goals



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.

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.

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

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

Theme 3 : Innovation Objectives (1/2)

Goal 1 – Objective 1: 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

Goal 1 – Objective 2: Transform the regulatory framework for veterinary medicines to support innovation and successful implementation of the veterinary medicines regulation

Goal 1 – Objective 3: 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

Goal 1 – Objective 4: Facilitate the implementation of novel manufacturing technologies

Goal 2 – Objective 1: Foster innovation in clinical trials and develop the regulatory framework for emerging clinical data generation

Goal 2 – Objective 2: Leverage non-clinical models and 3Rs principles and optimise capabilities in modelling, simulation and extrapolation and invest in special population initiatives

Goal 2 – Objective 3: Develop further the collaboration of various groups involved with scientific advice and/or regulatory guidance

+ AI

Theme 3 : Innovation Objectives (2/2)

Goal 3– Objective 1: Develop network-led partnerships with academia to undertake fundamental research in strategic areas of regulatory science

Goal 4 – Objective 1: 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

+ AI

Goal 4 – Objective 2: 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

4. Implementation plans

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