

European Medicines Regulatory Network Strategy to 2025

Introduction on the route to joint strategy, stakeholder consultation process, timelines

3 March 2020
PCWP/HCPWP meeting

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European Medicines Regulatory Network Strategy to 2025

Background information

- In December 2015, EMA and HMA published the first common strategy to 2020 for the European Medicines Regulatory Network (EMRN).
- At the 96th Heads of Medicines Agencies (HMA) meeting in June 2019 in Bucharest, it was agreed to have a new EMRN Strategy to 2025.
- A Joint EMA/HMA Drafting group was created to draft the new common strategy with an aim to have a final document adopted by both the HMA and EMA Management Board in September/October 2020.
- The strategy will cover human and veterinary medicines.

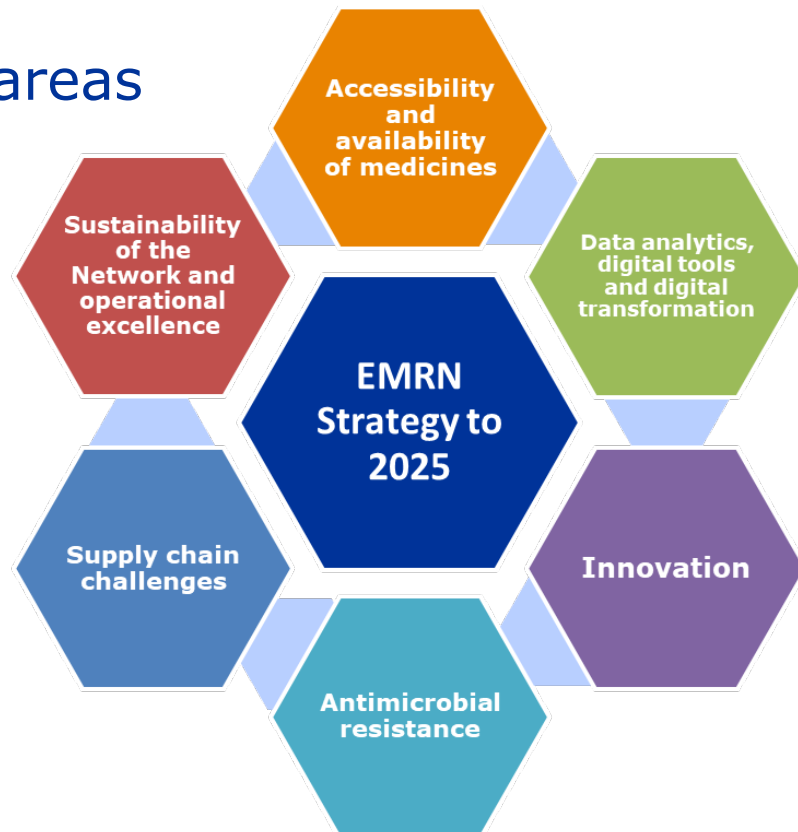
Route to joint strategy to 2025: topics focus and timelines

EMA Strategy Reflection to 2025

Main preliminary Strategic Theme areas

Main themes identified :

- ❖ Accessibility and availability of medicines
- ❖ Data analytics, digital tools and digital transformation
- ❖ Innovation
- ❖ Antimicrobial Resistance
- ❖ Supply chain challenges
- ❖ Sustainability of the Network and operational excellence



Network Strategy to 2025 - Strategy outline

- The common strategy will be a high-level document and will include the preliminary six strategic focus areas.
- A single overarching introduction and methodology of the process will start the document.
- Under each subsection of each Strategic focus area, the main challenges and opportunities of each area including an environmental assessment will be included.
- Strategic goals for each of the six strategic focus areas will be identified.
- The high-level document will be around 30-40 pages long.
- The strategy will be operationalized with HMA work plan; EMA work plan.



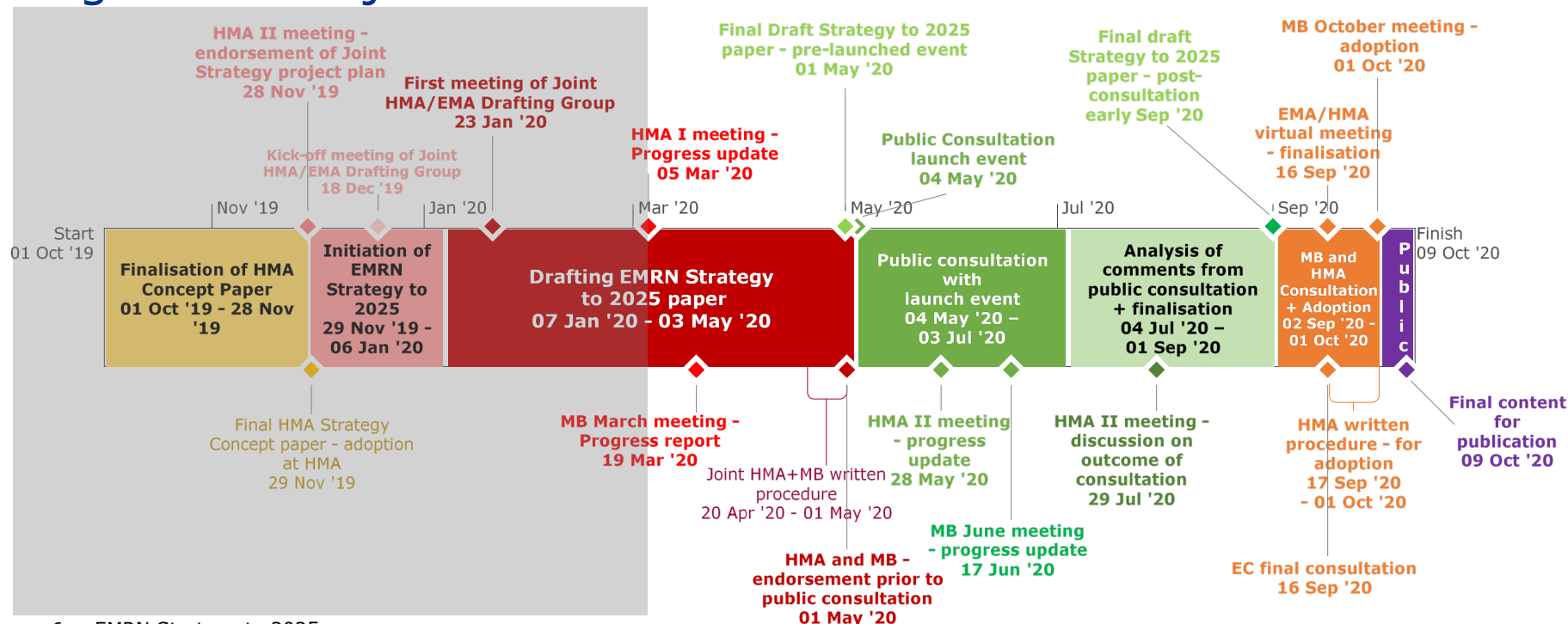
EMA/HMA Drafting Group

- A Joint EMA/HMA Drafting group has been created to draft the document.
- The Drafting group is co-chaired by EMA (Melanie Carr) & HMA (Svens Henkuzens).
- The Drafting group is composed of a Coordination Team and leads of the 6 Theme Teams for the strategic areas.
- EMA provides administrative and communication support.
- A kick-off meeting was held on 18 December 2019 and work has started.



EMRN Strategy to 2025

High level Project timeline



Network Strategy to 2025 – Drafting Process

Current Status

- ✓ The Drafting group have had two successful meetings since the start of the year.
- ✓ Each Theme Team have so far undertaken a high level environmental analysis and uncovered challenges, opportunities and future trends per Theme area
- ✓ In addition, the main goals within each Strategic areas are under discussion.
- ✓ The document is currently being drafting and peer reviewed by both HMA and EMA representatives within the Drafting group.
- ✓ Initial input has been sought from HMA Working Groups and Task Force and EMA Committees and Working Parties.
- ✓ A final draft will be ready in mid-April for endorsement by HMA and EMA Management Board, ready for the two-month public consultation.

Route to joint strategy to 2025: stakeholder consultation

EMRN strategy to 2025: Stakeholder consultation

Early engagement



➤ **Goals:**

- Provide overarching presentation on key themes and timelines for consultation process and publication of final strategy
- Gather stakeholders' initial views during the drafting phase

➤ **Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP)**

- 3 March 2020 – PCWP/HCPWP joint meeting covering in total 44 European organisations

➤ **Industry stakeholders together with academia and veterinary stakeholders**

- 4 March 2020 – HMA Stakeholder meeting in the margins of 99th HMA meeting

EMRN strategy to 2025- Stakeholder consultation

Public consultation



➤ **Goals:**

- Promote transparency and allow similar level of inclusivity/equal opportunity as for previous Network strategy
- Stimulate visibility, awareness and positive perception of the proposed Network strategy

➤ **HMA/EMA multi-stakeholder launch meeting - 4 May 2020**

- Present final draft EMRN strategy document and rationale for what is expected as an end product; provide opportunity for stakeholders to formulate initial considerations

➤ **2-month public consultation (4 May to 3 July 2020)**

- Release final draft EMRN strategy immediately after launch meeting together with a predefined template for submission of comments (EUSurvey)
- Summary of comments published separately at the time of publication of final EMRN strategy (September/October 2020)

Presentations of the 6 topic themes

EMA Strategy Reflection to 2025

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Questions for stakeholders early engagement meetings

EMRN strategy to 2025: Stakeholder early engagement meetings

General questions for stakeholders:

Can you identify any gaps in the themes and issues being proposed for the next Network Strategy?

Is there any missing challenge that should be addressed in the next 5 years?

Are there any planned or ongoing initiatives that you would like to flag to the drafting group?

Theme 2: Data analytics, digital tools and digital transformation

What are your expectations in relation to regulatory standards for the use of AI and machine learning?

- How do we ensure transparency in relation to study results, statistical methodology and algorithms, and what are your considerations in relation to ensuring high data security and ethical standards?

Are there specific issues we need to take into consideration in relation to the use of data analytics within veterinary medicines and human medicines respectively?

- How do we as regulators support the introduction of a streamlined approach to data analytics within veterinary medicines and human medicines across borders within EU/EAA?

Route to joint strategy to 2025: next steps

EMRN strategy to 2025

Next Steps (1/2)

- Next joint strategy drafting group meeting on 18 March:
 - Review input from HMA working groups and EMA scientific committees/working parties
 - Collaborate with IT colleagues to align telematics and business strategies
 - Review feedback from Stakeholder early engagement meetings of 3 & 4 March
- Mid-April Draft strategy will be finalised by drafting group and will be circulated to HMA and EMA Management Board for endorsement via written procedure.

EMRN strategy to 2025

Next Steps (2/2)

Stakeholder consultation:

- Invitations for next stakeholder meeting on 4 May will be circulated in April
- Multi-stakeholder consultation launch meeting on 4 May will take place at EMA (remote participation also possible)
- Following the launch meeting, the final draft strategy will be published on both EMA and HMA websites for 2 months public consultation.
- EU survey tool will be used to collect feedback

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

