EMA
EUROPEAN MEDICINES AGENCY

HMA
Heads of Medicines Agencies

POLAND25.EU

Theme 2: Leveraging data, digitalisation and artificial intelligence

Improving decision-making, optimising processes and increasing efficiency

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Theme 2 – general considerations

Potential changes to the goals, objectives or narrative of the strategy

- Reinforced reference to compliance with data protection laws
- More explicit link to European Health Data Space (EHDS)
- Reference to SPOR master data (incl. PMS)
- Reflect public engagement on digital tools, such as ePI
- Cybersecurity

To be considered in implementation actions

- Work of HMA-EMA Network Data Steering Group to maximise interoperability, exchange and use of data, evidence generation and utilisation of AI (*workplan will support implementation of Theme 2 in EMANS to 2028*)
- Develop data exchange mechanisms with data providers
- Promote adoption of digital tools by stakeholders
- Goals to include enhancing services to stakeholders
- Global collaboration
- Training and sharing of best practices/ learnings
- SPOR master data

Theme 2 – Goal 1 (data for decision-making)

Maximise the generation, interoperability, use and exchange of data to support EU decision-making

1. Embed the use of EU healthcare data from diverse populations in the network's processes and pilot the use of novel types of data (e.g. synthetic data, patient experience data or data for personalised medicine, e.g. genomic data)
2. Ensure a high level of interoperability, standardisation and quality of data addressing potential biases and ethical considerations, and ensure that the network data assets are appropriately managed

Theme 2 – Goal 1 (data for decision-making)

To be considered in implementation actions

- Develop guidance and provide clarity on required quality, access and use of data / evidence generation
- Support to EHDS and any other EC legislative initiatives
- Develop comprehensive strategy on use of data, including synthetic data
- Foster availability of more extensive data, including in specific areas (e.g. OTC medicines, patient experience data) and from other (non-medicine) regulatory frameworks
- Consider centres of excellence for novel data types
- Include diverse populations and types of evidence; accurate representation and bias avoidance
- Consider implications of data use on off-patent (follow-on) medicines
- Appropriate data management to generate trust, boost confidence and show example
- Apply ethical standards
- Maximise interoperability, according to FAIR principles

Theme 2 – Goal 1 (data for decision-making)

Comments outside the remit of medicines agencies

- Development and implementation of EHDS beyond the elements within the remit of regulators

Other comments

- Safeguarding evidence standards + consideration of data limitations (always applied)
- Protecting intellectual property and commercial data (always considered)
- Maintain the responsibility of the applicant for data/ evidence generation

Theme 2 – Goal 2 (digitalisation, experimentation and innovation)

Leverage digitalisation, experimentation and innovation to deliver optimised regulatory processes

3. Reinforce the network's digital infrastructure in line with the Network Portfolio Vision to drive the digital transformation of the network's scientific and regulatory processes
4. Foster a culture of continuous experimentation and innovation across the network

Theme 2 – Goal 2 (digitalisation, experimentation and innovation)

To be considered in implementation actions

- Consider resource implications
- Strengthen digital infrastructure at EU level
- Ensure transparency and sharing of learnings
- Consider predictability of digital upgrades to allow stakeholders to prepare
- Work on eliminating duplications and towards more integrate systems for optimised efficiency and seamless integration
- Digital technology for authoring, submission and assessment
- Engage with stakeholders for implementation
- Foster wide participation of partners
- Implement the tools and solutions with an aim to avoid delays to innovation and spare resources
- Note the key role for Regulatory Optimisation Group (ROG)

Theme 2 – Goal 2 (digitalisation, experimentation and innovation)

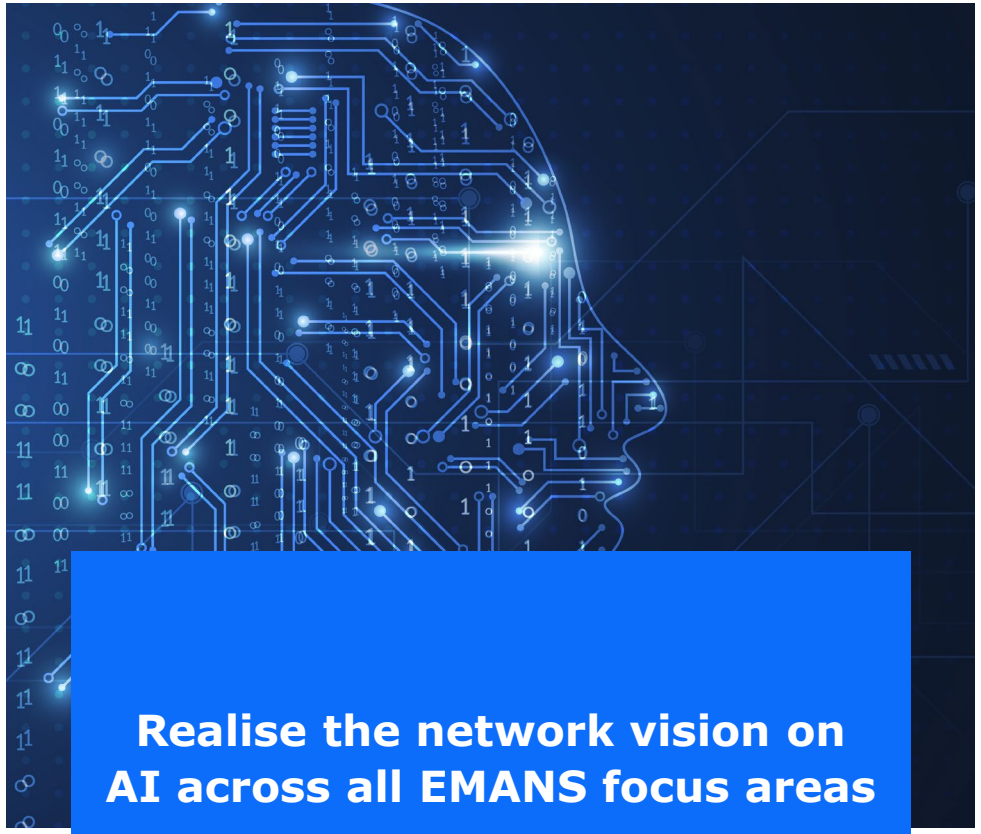
Comments outside the remit of medicines agencies

- Focus first on implementation of EHDS at national level (for elements beyond the remit of regulators)
- Measures dependent on conclusion of the EU Pharma legislation review

Other comments

- Additional, more detailed explicit references suggested (e.g. IDMP, FHIR, IRIS)

Theme 2 – Goal 3 (artificial intelligence)



Realise the network vision on AI across all EMANS focus areas

5. Leverage experimentation and technological advances in AI to support the digital business transformation of the EU network
6. Harness the potential of AI throughout the medicines' lifecycle

Theme 2 – Goal 3 (artificial intelligence)

To be considered in implementation actions

- Strict and transparent governance & safeguards (also for building trust); plan for addressing bias; clear guidance; Independent oversight
- Regularly revisit the plans due to rapid developments
- Consider resource implications; aims to include efficiency gains and capacity building
- Consider centralization / avoiding overlaps of efforts
- Particular importance of stakeholder cooperation and transparency (incl. on when AI has been used)
- Consider application for innovative development approaches (e.g. without / with limited use of animals)
- Consider extensive Pharmacovigilance data analysis
- Implementation of Artificial Intelligence Act
- Consider starting with ‘low risk’ medicines (e.g. generics and biosimilars)
- Explore also for post-approval CMC changes

Other comments

- An offer made to cooperate from a group of stakeholders with supervisory role in a related area