EMA
EUROPEAN MEDICINES AGENCY

HMA
Heads of Medicines Agencies

POLAND25.EU

Theme 6: Sustainability of the European medicines agencies network

Ensuring available resources to support its scientific and regulatory decision-making

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Theme 6 – general considerations

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

- Reference to environmental sustainability
- Include knowledge management in the scope of digital transformation (goal 1, objective 3)
- An explicit reference to AI being in the scope of potential shared initiatives (goal 2, objective 6)
- Include support for regulatory systems of EU candidate countries (goal 3, objective 10)
- Reinforce the wording on stakeholder engagement (goal 3, objective 11)

To be considered in implementation actions

- Use revised regulatory fees to increase the number of well-trained assessors
- Call for improved resourcing
- Training
- Streamlined processes, automation and efficiency

Theme 6 – Goal 1 (capacity & capability of the network)

Reinforce the scientific and regulatory capacity and capability of the network

1. Ensure the network has the capacity and capability to support innovation and the use of new methodologies, AI and data analytics and to be equipped for the new pharmaceutical legislation
2. Explore ways to improve efficiency by creating centres of excellence and allocating NCA resources more strategically
3. Build the network's capability to carry out the digital transformation of its scientific and regulatory processes, ways of working and tools

Theme 6 – Goal 1 (capacity & capability of the network)

To be considered in implementation actions

- Initiatives to facilitate use of external experts, use of specific research networks and wider stakeholder cooperation, to increase capacity and capabilities in specific areas of innovation
- Resourcing improvements also for off-patent medicines and veterinary medicines
- Continue advancement of MNATs
- Explore more agile ways of working
- Develop joint understanding of scientific, regulatory and digital technology aspects

Other comments

- Prioritise developing capabilities in specific areas, e.g. for ‘other methodologies’ for transition away from testing on animals or pharmacovigilance
- Foster a culture of proportionality in clinical trial assessment to improve efficiency and reduce duplication
- Prioritise the sustainability of the network by ensuring growth in capabilities (already included)
- Safeguard checks and balances (remains)
- Efficient resource allocation (already included)
- Maintaining capacity for current workload (remains)

Theme 6 – Goal 2 (shared operating model)

4. For human medicines, prepare for the implementation of new legislation combined with the modernisation and consolidation of IT systems
5. For veterinary medicines, continue to build on the progress achieved in implementing the veterinary regulation and align IT solutions across sectors
6. Explore opportunities for shared data, process and technology initiatives and establish a model for joint EMA/HMA sponsorship for such initiatives
7. Contribute to the implementation of the new EMA fee regulation and regularly monitor and adjust the cost-based system for fees and NCA remuneration

Theme 6 – Goal 2 (shared operating model)

To be considered in implementation actions

- Consider minimum requirements for IT Network Partners
- Take into account user experience
- Consider experience with digitalisation of variations for veterinary medicines
- Foster more clinical research in veterinary domain
- Improvements to Union Product Database (UPD)
- Early onboarding of NCAs
- Ongoing streamlining of variations framework
- Regular monitoring and adjustments under fee regulation

Theme 6 – Goal 2 (shared operating model)

Comments outside the remit of medicines agencies

- Streamlining of various frameworks to improve efficiency and speed
- Legislation update to account for technical advances
- Advanced IT models for predicting impact of new legislation (new legislation process not complete)

Other comments

- Expansion at EU level of some national level initiatives on sharing data, processes and technology
- Emphasis of importance of PMS (addressed in theme 2)
- Simplification and streamlining (already covered)
- Additional public funding for regulators
- Importance of PMS / SPOR master data (addressed in theme 2)

Theme 6 – Goal 3 (engagement and convergence)

Strengthen public and stakeholder engagement and global convergence with international partners

8. Enhance capacity of the network through international convergence, information and work sharing and multilateral cooperation
9. Together with the European Commission, strengthen international collaboration to perform legal duties relating to inspections and to face global challenges related to new methodologies and continuous manufacturing
10. Support the establishment of the African Medicines Agency, strengthening cooperation between European, African and international partners
11. Develop and implement a framework for communication and engagement to address information needs of the public and counter mis/disinformation

Theme 6 – Goal 3 (engagement and convergence)

To be considered in implementation actions

- Collaboration with stakeholders to ensure that right information on medicines and health threats arrives to European citizens (regulators, developers, clinicians and academia share a common goal to fight mis-/ dis-information)
- Accessible communication in lay language on use of new sources of data and AI, on AMR
- Broader training access and financial compensation for patients
- International experience sharing and harmonisation efforts in specific areas, e.g. on non-animal approaches
- Explore expanding reliance approach
- Strengthened communication channels and improved predictability of regulatory updates
- Cover veterinary medicines in international cooperation related to inspections
- Support European Commission’s work on free trade agreements

Theme 6 – Goal 3 (engagement and convergence)

Comments outside the remit of medicines agencies

- Legislative changes for single global development of off-patent (‘follow-on’) medicines

Other comments

- Strengthened international cooperation and alignment (already included); EU as a model for international convergence
- Transparency (already included)
- Providing right information to stakeholders (already included)
- Cover off-patent medicines in the international cooperation (already in place)