EMA
EUROPEAN MEDICINES AGENCY

HMA
Heads of Medicines Agencies

POLAND25.EU

Theme 1: Accessibility

Facilitating access to medicines in the EU

Michael Berntgen (EMA)

Theme 1 – general considerations

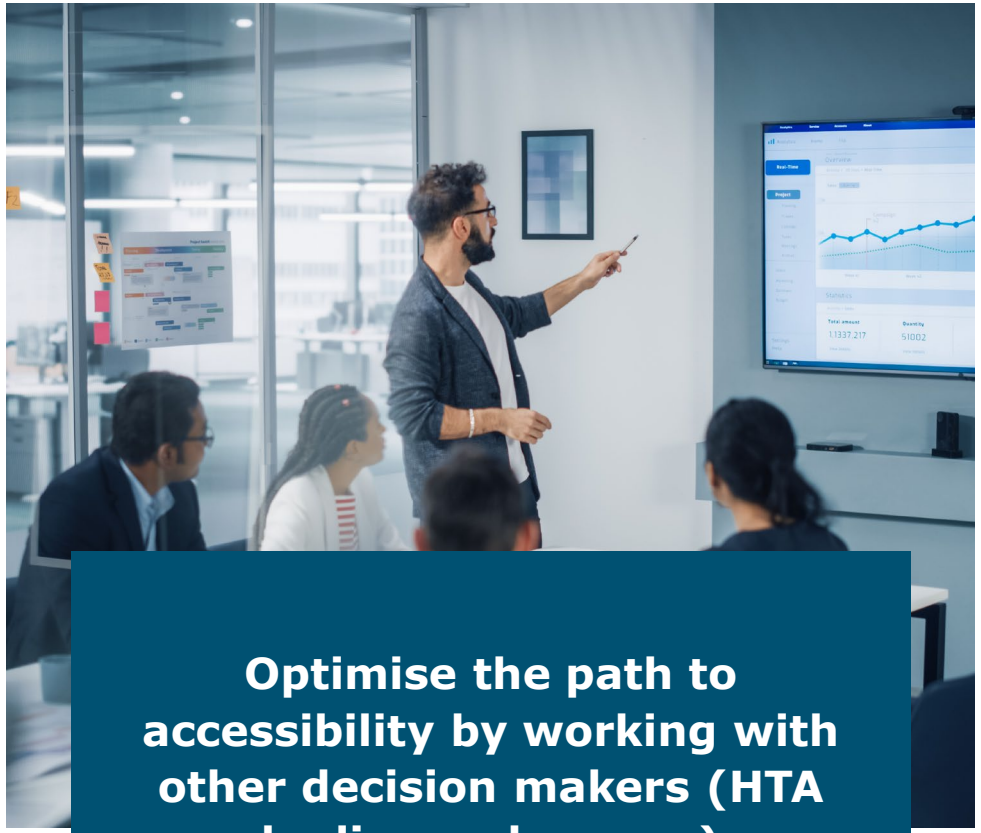
Potential changes to the goals, objectives or narrative of the strategy

- Clarity of the separation of the remits of regulators and HTA bodies
- Emphasis on both innovative and off-patent medicines being subject to enhanced communication and other activities to support accessibility

To be considered in implementation actions

- Consider relevance expedited pathways for faster access to (priority) medicines
- State of the art communications with patients and HCPs
- Guidance and improved public awareness of (complex) generics and biosimilars
- Consider specific accessibility needs for medicines for children
- Highlight the impact of accessibility on health outcomes
- Accessibility challenges of repurposed medicines

Theme 1 – Goal 1 (path to accessibility)



Optimise the path to accessibility by working with other decision makers (HTA bodies and payers)

1. Contribute to the successful implementation of the HTA Regulation
2. Foster the generation of robust scientific evidence to serve different decision makers (regulators, HTA bodies and payers)
3. Enhance communication with other decision makers about the scientific considerations leading to regulatory outcomes

Theme 1 – Goal 1 (path to accessibility)

To be considered in implementation actions

- Cooperate with healthcare professionals, patients and other stakeholders for successful implementation of the new HTA regulation
- Better integration of different types of evidence needs and different methodologies
- Appropriate / manageable (data) requirements; data generation remains responsibility of the developer
- Strengthening of transparency on evidence that is supporting regulatory decisions
- Early interactions also for off-patent medicines
- Contextualise regulatory and HTA outcomes: focus on information that needs to be exchanged between regulators and HTAs

Theme 1 – Goal 1 (path to accessibility)

Comments outside the remit of medicines agencies

- Involvement of stakeholders and other partners in the HTA process
- Legal obligations for product launch/ engaging in pricing and reimbursement process
- Operational steps of the HTA process according to the HTA regulation and implementing acts
- Imposition of evidence requirements outside the needs for regulatory decisions and supervision
- Opt-out [from HTA regulation] for known substances

Other comments

- Extend collaboration with HTA bodies and payers to NITAGs
- Horizon scanning to also cover off-patent developments
- Avoidance of overly restrictive evidence requirements

Theme 1 – Goal 2 (engagement with policy makers)

Deepen engagement with healthcare policy makers on initiatives and research relevant to sustain health technology accessibility

4. Contribute to initiatives exploring the perspective different stakeholders have about unmet medical needs and how they inform considerations about clinical significance, significant benefit and major contributions to patient care
5. Conduct research to better understand accessibility for medicines addressing unmet needs and how evidence requirements affect decision outcomes
6. Continue collaborative work on methodologies for the generation of evidence that is also relevant for health technology assessments

Theme 1 – Goal 2 (engagement with policy makers)

To be considered in implementation actions

- Multi-stakeholder discussions on scientifically sound recognition of unmet medical needs with an aim to foster innovation and better accessibility
- Develop metrics for comparison of accessibility, including for the impact of early access schemes
- Particular focus on patient involvement; prioritisation of and guidance on patient experience data
- Promoting public trust in biosimilar medicines
- Explore commonalities on methodologies, e.g. patient experience data, novel clinical trial designs and endpoints, without forcing alignment
- Use all available sources of evidence on accessibility
- Explain uncertainty management and risk acceptance
- Attention to rare diseases, paediatric medicines and other specific areas

Theme 1 – Goal 2 (engagement with policy makers)

Comments outside the remit of medicines agencies

- Purely economic / pricing considerations (e.g. cost-containment policies)
- Fostering competitiveness through the HTA Regulation implementation
- Inequality in access across countries

Other comments

- Multistakeholder discussion on the concept of innovation
- Challenges of horizontal legislation