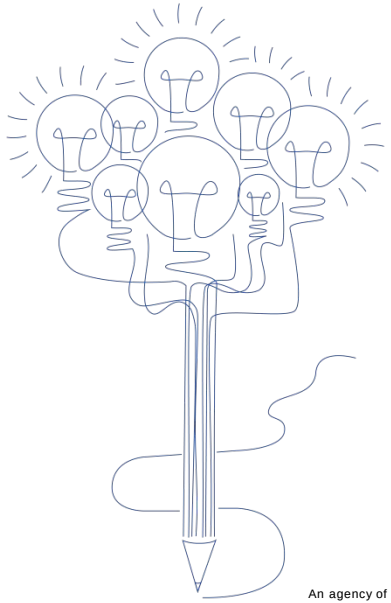
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Advancing patient-centred access to medicines in partnership with healthcare systems

EMA's core recommendations

Human Stakeholders Workshop



Presented by Michael Berntgen on 24 October 2018
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Summary

Contribute to **HTAs' preparedness** and downstream decision-making for innovative medicines

Bridge from evaluation to access through collaboration with **Payers**

Reinforce **patient relevance** in evidence generation

Promote use of high quality **real world data** in decision-making

Develop network competencies and specialist collaborations to engage with **big data**

Deliver real-time **electronic Product Information** (ePI)

Promote **availability and the uptake of biosimilars** in healthcare systems

Further develop **external communications** to promote trust and confidence in the EU regulatory system

Contribute to HTAs' preparedness and downstream decision-making for innovative medicines

- Ensure the evidence needed by HTAs and payers are incorporated early in drug development plans
- Enable information exchange with HTAs to support bridging from benefit-risk to relative effectiveness assessment
- Discuss with HTAs guidance and methodologies for evidence generation and review
- Contribute to the identification of priorities for HTA
- Monitor the impact of decision-maker engagement through reviews of product-specific experience

Bridge from evaluation to access through collaboration with Payers

- Contribute to the preparedness of healthcare systems by creating opportunities for collaboration on horizon scanning
- Enable involvement of payers' requirements in the prospective discussion of evidence generation plans
- Clarify the treatment-eligible patient population included in the labelling, and its scientific rationale
- Participate in discussions clarifying the concept of unmet medical need

Reinforce patient relevance in evidence generation

Coordinate Agency's approach to patient reported outcomes (PROs). Update relevant clinical guidelines to include reference to PROs

While validating PROs, address patients' needs and leverage patients' expertise

Co-develop with EUnetHTA a core health-related quality-of-life PRO to implement in trials and to bridge the gap with comparative effectiveness assessment

Promote use of high-quality real world data (RWD) in decision-making

- Create a sustainable, quality assured, flexible framework delivering rapid access to and analysis of representative, longitudinal RWD throughout a product's lifecycle
- Develop a capacity that will enable the Agency to rapidly and securely access and analyse large amounts of healthcare data
- Accelerate the implementation of a learning regulatory system based on electronic health records and other routinely collected RWD

Develop network competence and specialist collaborations to engage with big data

- Implement the core recommendations emerging from the EMA/HMA Taskforce addressing areas such as harmonisation of data standards, characterisation of data quality, and provision of regulatory guidance as to acceptability of evidence
- Engage proactively with new stakeholders relevant to the Big Data Landscape
- Invest in capacity building across the network to acquire new skills to engage with these emerging areas

Deliver real-time electronic Product Information (ePI)

- Enable real-time interactivity within the Summary of Product Characteristics and Patient Leaflet
- In conjunction with Healthcare Providers and patients, develop a strategic plan to deliver ePI programme
- Enable the reuse of structured medicinal product information by third parties through developing a standardised interface
- Leverage new channels of social media communication

Promote the availability and uptake of biosimilars in healthcare systems

- Further develop strategic communication campaigns to Healthcare Providers and patient organisations to reinforce trust and confidence
- Enhance training of the network and non-EU regulators in the evaluation of biosimilars with extension to all therapeutic areas
- Address regulatory challenges in manufacturing e.g., statistical assessment of CQAs in the comparability exercise and the evolution of multisource biologicals/biosimilars

Further develop external communications to promote trust and confidence in the EU regulatory system

Develop content strategy, particularly in key public health areas and hot topics in regulatory science

- Enhance professional outreach through scientific publications & conferences
- Proactive approach to key public-health areas (e.g. vaccines)
- Improved communications for patients, HTA and payers

Develop more targeted and evidence-based communication facilitated by updated web content and format

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