EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA-EUnetHTA work plan 2017-2020

Commission Expert Group on Safe and Timely Access to Medicines for Patients ("STAMP")

8 December 2017

Presented by Michael Berntgen (EMA) and Michelle Mujoomdar (EUnetHTA)

Dialogue between regulators and HTA bodies in Europe

- The collaboration between EMA and EUnetHTA started in 2010 based on a mandate of the High-level Pharmaceutical Forum
- EMA and EUnetHTA hold regular bilateral meetings on topics of mutual interest and publish reports from these interactions
- A first joint work plan was established for 2012-2015 (under Joint Action 2) and a report on the work plan delivery was published
- The Reflection paper on synergies between regulatory and HTA issues on pharmaceuticals was adopted by the HTA network in November 2016
- On 13 November 2017 a new EMA / EUnetHTA work plan 2017-2020 (under Joint Action 3) was published (press release)

Activities in the EMA-EUnetHTA work plan 2017-2020 (1/3)

Topic area	Activity
Early Dialogue / Scientific Advice	• Design and implement a single, common, European procedure for Parallel Consultation (previously known as parallel scientific advice/early dialogue)
	• Facilitate learning and understanding of evidence needs
"Late dialogues" / peri-licensing advice	• Gaining experience with peri-licensing advice on post-licensing data generation plans with a focus on specific products (e.g., ATMPs) or regulatory processes or tools (e.g., CMA, Adaptive Pathways, or PRIME)
	• Optimise utilisation of post-licensing evidence generation for decision making
Information exchange between regulators and HTA bodies	• Timely provision of the outcome of the regulatory assessment to support joint REA production
	• Respecting the remit and perspectives of both regulators and HTABs, create a mechanism for reciprocal learning opportunities between regulatory reviewers and HTA assessors.
	• Further optimisation of the regulatory output to facilitate uptake of regulatory outcome by HTAB

Activities in the EMA-EUnetHTA work plan 2017-2020 (2/3)

Topic area	Activity
Methodologies to identify the treatment eligible population	• Share experience on how regulators define therapeutic indications and the impact of their wordings in HTABs' definition of the treatment-eligible population.
	• Mutual understanding of the extrapolation concept, including its application for the paediatric population
Significant benefit vs. added therapeutic value for orphan medicines	• Understanding of the similarities and differences between the concepts of significant benefit and added therapeutic value in the context of orphan drugs
	• Exchange on product specific reviews at time of authorisation
Unmet medical need and therapeutic innovation for priority setting	• Explore how HTABs and regulators interpret the concepts of unmet medical need and therapeutic innovation
	• Explore opportunities to collaborate on monitoring of new medicines' approvals ("horizon scanning")
Patient and clinician engagement	• Share respective practices and experiences related to the involvement of patients and clinicians in activities
	• Assess the feasibility of developing a shared pool/list of contacts

Activities in the EMA-EUnetHTA work plan 2017-2020 (3/3)

Topic area	Activity
Shared understanding of methodological approaches for design, analysis and interpretation of clinical trials and observational studies	• Provision of guidance on evidence needs for regulators and HTA bodies, through therapeutic-area-specific guidance, methodological guidance, non-product specific qualification advice and opinions, workshops.
	• Better utilization of patient-reported outcomes as part of evidence generation plans
Population-specific or Intervention-specific areas	• Address the specific needs for paediatric medicines
	• Share practices and experiences with combination products/companion diagnostics
	• Share information and experiences with ATMPs

Next steps post-publication of the work plan

- Identification of contributors from both EMA and EUnetHTA for the various activities and gradual activation
- Support to the mapping exercise by the Synergy group in relation to the reflection paper through the work plan
- Progress monitoring of the various actions as part of the regular EMA/EUnetHTA collaboration
- Topics identified for the next EMA/EUnetHTA bilateral: Concepts of significant benefit and added value, Opportunities for collaboration on horizon scanning, The concept of evidence transfer (also known as “extrapolation”), and Principles for the wording of the indication

Thank you for your attention

Further information

Michael.Berntgen@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Follow us on **@EMA_News**