EUnetHTA-EMA Collaboration

HTAi 2018 – Vancouver
RICC Workshop

François Meyer, HAS, WP5 Lead Partner

EUnetHTA-EMA Collaboration

- 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)
- In November 2017 a new EMA / EUnetHTA work plan 2017-2020 (under Joint Action 3) was published

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

HTA-Regulatory Interactions in Canada and Europe

Michelle Mujoomdar, PhD
Director, Scientific Affairs

4 June 2018

HTAi Vancouver

CADTH

Disclosure

- CADTH is funded by federal, provincial, and territorial ministries of health.
- CADTH has application fees for three programs:
  - CADTH Common Drug Review; CADTH pan-Canadian Oncology Drug Review; CADTH Scientific Advice
- Travel expenses paid (CADTH representation): IMI PREFER Stakeholder Advisory Group meeting – Oct 2016 (travel expenses paid by University of Uppsala)
- Engaged as an individual external expert: European Commission (June 2016 – Aug 2016; May 2018 – Aug 2018) and ZIN (April 2018 – May 2018)

Health Canada

- Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health
- Five core roles:
  - Leader / Partner
  - Funder
  - Information provider
  - Service provider
  - Guardian / regulator

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Products regulated by Health Canada

- Biologics
- Consumer goods
- Foods
- Medical devices
- Natural health products
- Pesticides
- Pharmaceuticals
- Toxic substances

Minister of Health Mandate Letter (October 4, 2017)

Office of the Prime Minister

Cabinet du Premier ministre

Ottawa, Canada K1A 0A2

Dear Ms. Petitpas Taylor:

I am honoured that you have agreed to serve Canadians as Minister of Health.

We promised Canadians real change – in both what we do and how we do it. Canadians sent a clear message in the last election, and our platform offered a new, ambitious plan for a strong and growing middle class. Canadians expect us to fulfill our commitments, and it is my expectation that you will do your part in delivering on those promises to Canadians.

We made a commitment to grow our economy, strengthen the middle class, and help those working hard to join it. We committed to provide more direct help to those who need it by giving less to those who do not. We committed to public investment to spur

Regulatory Review of Drugs and Devices (R2D2)

- Proposed changes to the regulatory system to:
  - make it more efficient
  - support timely access to therapeutic products
  - build better linkages within the health care system as a whole

Regulatory Review of Drugs and Devices (R2D2)

- Aligned reviews for certain drugs
- Early scientific advice to manufacturers (drugs and medical devices)
- Expanding priority review pathways for drugs that meet health care system needs
- Building better access to digital health technologies
- Renewal of the Special Access Programme
- Strengthening the use of real world evidence for drugs and medical devices
- Public release of clinical information

CADTH Evidence Driven.

ACMTS Preuves à l'appui.