EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# EMA: Update on current initiatives relevant to HTA

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An agency of the European Union

# Dual roles for regulators, HTA bodies, payers

## Enabler

## Access

To be discussed later by J Moseley

- Early dialogues
- PRIME
- Adaptive Pathways pilots, ADAPT SMART
- Early REA, information sharing

## Gatekeeper

## Sustainability

## Controls

- (Early) Late dialogues
- Registries
- Drug utilisation – effectiveness of risk minimisation
- Wording of indication

# PRIME (PRIority-MEdicines)

EU Medicines Agencies Network Strategy to 2020:

- Lend strong support to medicines that offer a major therapeutic advantage over existing treatments, or benefit patients with no treatment options → launch of PRIME
- offer early, proactive and enhanced scientific and regulatory support to enable accelerated assessment and patient access
- **Collaboration with HTA bodies (and payers) will be paramount** to achieve goal – **need to discuss resource prioritisation?**

# Adaptive Pathways (AP) Pilots

Goal: provide real-life case studies about potential pathways of product development (incl. HTA, reimbursement considerations) for timely access to medicines; involving all stakeholders.

Rules of the game: non-binding, safe-harbour brainstorming; only existing regulatory tools to be used.

Current status: ~60 products submitted; 20 selected; in-depth discussion with sponsors, HTAs, patient groups ongoing.
**Continue AP pilots in voluntary but more structured format ("broad scientific advice" - with HTA bodies) to better manage resource constraints; 6 applications to date.**

# ADAPT SMART

IMI ADAPT SMART Consortium: 22 companies, EMA, HTAs (EUnetHTA), EU patient orgs, academics, (payers)

Goal: facilitate availability of "Medicines Adaptive Pathways to Patients"

Themes: Evidence generation throughout the life cycle; designing the right pathway; decision-making, sustainability & implications for stakeholders

Current status: operational, culture-clash, payers are sceptical, but progress is evident

**Continued engagement from HTAs is key for success**

# EUnetHTA's pilot projects on rapid REA* of pharmaceuticals

Aim: reduce time lag between regulatory and reimbursement decisions, reduce divergences across HTA bodies → enable speedy access for patients

Road block: sharing of extracts of final CHMP assessment reports before official Commission decision, informing applicant accordingly

**Solution: Data Sharing Arrangement can (hopefully soon) be established between EMA and individual HTA bodies.**



*REA: Relative Efficacy Assessment

# "Late dialogues"

Next frontier: collaboration on post-launch data generation

Aim: one (set of) studies for regulators and HTA bodies (payers); including real-world evidence, which is currently an underutilised resource; to enable refined and extended benefit-risk assessment as well as value assessment and pay-for-performance schemes

**Door now open for (parallel) scientific advice on post-authorisation studies, risk management planning, etc**.

# Registries

*Initiative for patient registries; Strategy and pilot phase [15 September 2015, EMA website]:*

- facilitate the use of existing patient registries
- capacity-building exercise
- input from PARENT
- explore "the extent to which patient registries … **might be suitable for answering HTA–related questions**"

# Drug utilisation studies

The predictive value of regulatory *and* health technology assessments is context-dependent. Drug utilisation (off-label, prescription creep) is key for *realised* benefit-risk *and* value-for-money, budget impact.

*PRAC* strategy on measuring the impact of Pharmacovigilance activities [11 January 2016; EMA website]*: "Analysis of drug prescription/utilisation patterns overtime will be used .."

**Collaboration with national HTA bodies (and payers, as applicable) is welcome and needed**.



*PRAC: EMA Pharmacovigilance Risk Assessment Committee

# Wording of indication

*HTA network paper on regulatory–HTA interaction, draft [22 April 2016]:*

"Differences between populations for which the treatment is covered by health care systems and the labelled indication coming from the marketing authorisation process may take place." → reasons and implications are well understood.

*Report on EMA-EUnetHTA 3 year work plan 2012-2015:*

"**Continuous collaboration on possible criteria and on general aspects of indication wording in the SmPC*.**"



*SmPC: Summary of Product Characteristics = "label"

# Conclusion:

- There are many domains where (untapped) HTA-regulatory synergies could be realised to mutual benefit.
- HTA-regulatory collaborations need to reflect appropriate balance between the *enabler* and the *gatekeeper* roles to ensure effective, well-aligned and sustainable healthcare systems in EU.
- How can EUnetHTA be involved systematically in these EMA activities? “Observer status" and/or other forms of formal and informal collaboration? To be discussed.

# Thank you

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