Agenda EMA – Payer Community meeting

19 September 2017, 10.00-16.00 BST

European Medicines Agency, 30 Churchill Place, London, Room 3F

Co-chairs: Payer Community: Ad Schuurman (am) / Menno Aarnout (pm)
EMA: Harald Enzmann (am) / Hans-Georg Eichler (pm)

Item	Preliminary draft agenda	Name (italic = no reply yet)
10.00-10.10	1. Welcome by EMA's Executive Director	Guido Rasi
10.10-10.15	2. Introduction and adoption of draft agenda	Payers: Ad Schuurman EMA: Harald Enzmann
10.15-10.40	3. Tour de table	All
10.40-11.50	4. Multi stakeholder Late & Early dialogue additional participant: MoCA Steering Group	Payers: Ann Bucsics EMA: Spiros Vamvakas
11.50-12.00	Short break	
12.00-12.45	5. Horizon Scanning for pharmaceuticals Synopsis of KCE report /Full KCE report	Payers: Irina Cleemput, Aldo Golja EMA: Michael Berntgen
12.45-13.40	Lunch break	
13.40-14.40	6. Indication and Labelling, general aspects	Payers: Martin van der Graaff EMA: Kristina Dunder
14.40-15.15	7. Indication and Labelling, specific aspects a) Cross-references within the SmPC b) Information on the use of medicines in the elderly	 Payers: Michael Ermisch EMA: Kristina Dunder EMA: Francesca Cerreta
15.15-15.45	8. Create clarity on the several definitions of unmet medical need (see Annex)	Payers: Menno Aarnout EMA: Jordi Llinares-Garcia
15.45-16.00	9. AOB and Closing remarks	Payers: Menno Aarnout EMA: Hans-Georg Eichler

Objectives per agenda point in the Annex on the next page

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ANNEX: Objectives for agenda points

4.	**Late & Early dialogue** There are opportunities in exploring a potential collaboration between EMA, MoCA, and others on product-specific dialogue on data generation. In this meeting we will discuss the possible organisation of a few pilots, prepared by MoCA. Early dialogue, clarity on data requirements, agreement on research and data collection, common registry, discussion value framework, etc. See how we can improve the late dialogues, making better use of the post licensing space. What are the expectations from payers, HTA, patients, companies (SME) and EMA for such engagement?
5.	**Horizon Scanning** Payers seek exchange of information on (upcoming) dossiers and assessments, for the purpose of horizon scanning. Information needs from payers are synthesized in the KCE report. Which information is EMA collecting? Which opportunities might arise for EMA to provide relevant information? Vice versa look for possibilities how HTA and payer databases can be used by EMA.
6.	**Indication and Labelling (general)** Payers frequently express the view that the wording of indications in the drug label is unclear, or too broad. Indication wording is too ambiguous or of insufficient granularity to underpin appropriate payer decisions. It might be good to jointly explore if and how this concern could be addressed. Even when the risk/benefit is positive in all possible (sub)indications/subgroups, it is important for payers to get information on subgroup-specific levels of evidence/efficacy. Could EMA reasoning on these decisions be made explicit in the publicly available assessment report? Explanations not only on which populations were approved, but also considerations on non-approved indications are useful. This is also needed to advise physicians in providing appropriate care.
7.	**Indication and Labelling (specific)** **A:** Payers ask for more clarity on the meaning and status of cross-references within an SmPC. Engagement of payers in the design of the SmPC is desirable. **B:** The efficacy and safety of medicines are hardly investigated in elder, multimorbid patients. Which information can be found in the regulatory documents? How could this lack of clinical data be worded in the labelling?
8.	Create clarity on the several different definitions of unmet medical need, possibly for different purposes (market authorisation, HTA, Pricing and reimbursement, appropriate care).

Useful links:

European Medicines Agency (EMA)

Association Internationale de la Mutualité (AIM)

European Social Insurance Platform (ESIP)

Medicine Evaluation Committee (MEDEV)

Mechanism of Coordinated Access to orphan medicinal products (MoCA)

European network for Health Technology Assessment (EUnetHTA)

Accelerated Development of Appropriate Patient Therapies, a Sustainable, Multi-stakeholder Approach from Research to Treatment-outcomes (ADAPT SMART)

EMA support for early access