



EUROPEAN
MEDICINES
AGENCY



AIM

Healthcare and
social benefits
for all



esip
EUROPEAN SOCIAL INNOVATION PLATFORM

MEDEV
Medicine Evaluation Committee



Mechanism of Coordinated Access
to Orphan Medicinal Products

Agenda EMA – Payer Community meeting

18 June 2019, 09.00-16.00 CEST

Zorginstituut Nederland (ZIN), Willem Dudokhof 1, 1112 ZA DIEMEN

Co-chairs: Payer Community: Ad Schuurman (am) / Evert Jan van Lente (pm)
EMA: Harald Enzmann (am) / Hans-Georg Eichler (pm)

Timing	Preliminary draft agenda	Name (speakers in bold)
9:00	1. Joint welcome by ZIN's Chair of the Board and EMA's Executive Director	ZIN: Sjaak Wijma EMA: Guido Rasi
9:20	2. Introduction and adoption of draft agenda	Chairs
9:30	3. Tour de table	All
9:40	4. Prospective planning of evidence generation for orphan medicinal products – opportunities for multi-stakeholder dialogue, MoCA, non-product specific, process orientated.	Payers: Evert Jan van Lente Patients: Simone Boselli Industry: Wills Hughes-Wilson EMA: Spiros Vamvakas, Michael Berntgen, Dinah Duarte
10:40	5. (High) Unmet medical need (based on: "Unmet medical need: an introduction to definitions and stakeholder perceptions")	Payers: Jocelyn Stokx EMA: Jordi Llinares-Garcia , Dinah Duarte
11:10	6. Wording of indication, labelling and assessment report (Reference: letter MEDEV/AIM/ESIP and answer EMA).	Payers: Michael Ermisch , Robert Sauermann EMA: Harald Enzmann, Hans Hillege , Michael Berntgen, Jordi Llinares-Garcia
12:30	Lunch break	
13:30	7. Horizon Scanning for pharmaceuticals (References: BENELUXAI tender for ISH, draft TISP recommendations, www.horizonscangeneesmiddelen.nl)	Payers: Eveline Klein Lankhorst , Niels Speksnijder EUnetHTA: Giovanni Tafuri EMA: Michael Berntgen , Tony Humphreys, Corinne de Vries
14:30	8. Post-licensing evidence: filling evidence gaps and impact on decision making Recent experiences: CAR-T project (ZIN); Qualification of registries (EMA); Registry initiative (EMA) Use of Post-licensing evidence for decision making, i.e. benefit/risk evaluation and access decisions (e.g. managed entry agreements).	Payers: Lonneke Timmers , Dimitra Lingri EMA: Spiros Vamvakas , Jordi Llinares-Garcia, Xavier Kurz
15:30	9. AOB and Closing remarks	Chairs