



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Post Licensing Evidence Generation (PLEG)

Feedback from Focus group

4th Industry Stakeholder Platform on R&D support, 23 Nov 2018

Presented by Jane Moseley, Scientific Advice

An agency of the European Union



Objectives of PLEG focus group

The objectives of this group are

- To identify issues and barriers to seeking scientific advice on PLEG, and discuss potential solutions
- To discuss several key areas in the context of seeking scientific advice on PLEG
- Key issues: communication and clarification on terminology/process/potential
 - Approaches for timing, Types of products, discussions of issues
- Engagement with EUnetHTA is crucial
 - Note: different to other EMA initiatives e.g. HMA/EMA Big data TF, Registries initiatives



Group members

Name	Affiliation
Jane Moseley (lead)	EMA
Spiros Vamvakas	EMA
Peter Arlett	EMA
Xavier Kurz	EMA
Alison Cave	EMA
Chantal Guilhaume	HAS, France EUnetHTA ED secretariat
Anne Willemsen	EUnetHTA

Name	Affiliation
Alexa Hunter	Merck KgaA
Anja Langeneckert	F. Hoffmann-La Roche Ltd
Catherine Cohet	GSK
Christelle Lamoril	Sanofi Aventis
Emma Du Four	AbbVie
Geert Preuveneers	Merck
Karin Van Baelen	Janssen Pharmaceutical
Simon Bennett	Biogen
Solange Corriol Rohou	AstraZeneca
Virginia Acha	MSD

Draft Paper being developed by the PLEG focus group

- The paper will be the output of a focus group, derived from the EMA Industry R&D platform,
- Aim of the paper is to serve as a discussion tool for medicines developers and other stakeholders, to encourage and facilitate proactive PLEG scientific advice discussions on remaining scientific questions: personal opinions of authors with disclaimers
- Work in progress, with the objective to finalise the document in Q1 2019, and have it published in a peer-reviewed scientific journal
- Process
 - 4 x TCs completed, Active engagement by participants, Iterative drafts and comments
 - For Discussion in EUnetHTA Wp5 Dec18
 - Next TC Jan 8/9 TBC



Any questions?

Further information

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