EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Post Licensing Evidence Generation (PLEG)

Feedback from Focus group

3rd Industry Stakeholder Platform on R&D support, 18 May 2018

Presented by Jane Moseley, Scientific Advice

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, starting from an output outlining what comprises PLEG
- To discuss several key areas in the context of seeking scientific advice on PLEG including

Approaches for questions on which scientific advice is sought, along with the appropriate structure of a company position

Types of products where such early engagement on PLEG would be particularly relevant, including optimum timing and opportunities in “Late” parallel consultation

Engagement with EUnetHTA is ongoing.

Note: different to other initiatives e.g. HMA/EMA Big data TF, Registries initiatives

Group members

Name	Affiliation
Jane Moseley (lead)	EMA
Spiros Vamvakas	EMA
Alison Cave	EMA
François Meyer	HAS, France
Anne Willemsen	EUnetHTA

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

Expected output

The aim of the focus group is to deliver recommendations via a 2-page document on how/when considering scientific advice/dialogue/consultation for PLEG

Outline content of the document: a problem statement/discussion was considered essential, followed by a clear message to clarify understanding of the opportunities, value and rationale for undertaking such advices to different stakeholders.

Clearly defining the scope of PLEG (early, late, continuum), and having examples (Regulatory, HTA, parallel) and both positive and negative would be helpful.

To serve as a discussion tool within companies, and for other stakeholders, and to encourage and facilitate further PLEG requests proactively

Data on issues or barriers to seeking SA on PLEG

First step: Collection of feedback from industry and views of EMA and HTAs

To cover:

- How seeking PLEG advice is viewed
- Reasons why not coming for advice
- How barriers and problems may be different depending on the timing and nature of advice

Solutions: reality to be described, myths dispelled, examples, frameworks where these type of advices can be discussed pre-submission, use of HTA collaboration

Types of uncertainties and PLEG requests from decision makers (e.g. report from EMA and EUnetHTA, respectively)

How and when to seek PLEG

To cover:

- The context of a continuum of evidence generation rather as separate pre- and post-licensing.
- Change of mind-set with a move towards recognising the need for more than one dialogue.
- When seeking early advice, be forward thinking, and engage in scenario planning; then revisiting the topic with accumulating evidence, refining what needs to be collected in PLEG.
- PLEG needs to be embedded within evidence generation along drug development, and when making decisions at key mile stones.

Elements to be addressed in the output document

Aim of PLEG (scope) and synergy regulatory/HTA

Problem statement current status

Experience - the types of uncertainties and data request for regulators and HTAs

Cases for seeking PLEG advice early and on a continuum (built on examples)

How to seek advice: options / questions/ timing

What you might be worried about (myth busting)

Other FAQs

Draft to be developed until 3Q18, for discussion at the next platform

Discussion: reflections on issues

Issues/Barriers?

The case for seeking PLEG advice?

Solutions?

Types of products most useful?

How?

When ?

Any questions?

Further information

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