EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Key points from session 3 – Industry perspective

Workshop on Haemophilia Registries
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Rapporteurs: Karri. Penttilä, EMA: Irene Papadouli/Glenda Silvester

Presented by Karri. Penttilä on 2 July 2015
BPWP member

An agency of the European Union

Aim of Session:

From the Industry viewpoint, what are the strengths and weaknesses of registries for providing data on specific products and on a product class, and how could this be improved?

Discussion questions

Industry perspective on strengths and weaknesses of registries from the perspective of providing safety and efficacy data on specific products and on a product class, and consideration of approaches/initiatives to strengthen this.

- Disease-specific registries follow the journey of the patient over the long-term, where each patient will usually receive more than one product during the period of investigation. What difficulties does this pose for Industry in interpreting findings from registries? How could such difficulties be addressed?
- How can Industry facilitate the work of registries?
- What could be appropriate facilitation options e.g. technical tools, electronic diaries, apps etc?

Key points: Summarising key points from discussion

Registries:

- Better collaboration of all stakeholders is needed
- Lack of access to adequate data set/information
- In an ideal world, funding path from public health domain for whole registry rather than from industry (with industry support for specific topics)
- Overlap of reporting e.g. interference with mandatory AE reporting (physicians / industry)
- Problems with non-interventional studies
  - low interest (10% in one case) of recruiting patients
  - Centralized lab testing not mandatory, influence to e.g. inhibitor testing?

Key points: Summarising key points from discussion

- Industry must not be able to identify individual patient from registry data (already in place e.g. in UK)
- Are all patients allowed to participate in registries in addition to clinical trials? Which registry (ies)?
- EHC letter about patient data availability from clinical trials: Industry need to consider and come back with an answer (solvable?)
- Pharmacoeconomic data important to industry
- Industry wants to be active partner not just a money giver
- From industry's point of view it is important to know what are the regulators expectations for hemophilia registries (models from other registries) – industry`s role?
- FDA workshop includes registries, PPTA preparing for this with an Industry group