EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Post-authorisation safety studies (PASS)

Encouraging joint studies

Industry Stakeholder platform - Operation of EU pharmacovigilance legislation

Presented by Irene Rager on 12 January 2015
Head of Service E Procedure Management Department

An agency of the European Union

Background

Article 22a (1) of Directive 2001/83/EC:

1. After the granting of a marketing authorisation, the national competent authority may impose an obligation on the marketing authorisation holder:

(a) to conduct a post-authorisation safety study if there are concerns about the risks of an authorised medicinal product. If the same concerns apply to more than one medicinal product, the national competent authority shall, following consultation with the **Pharmacovigilance Risk Assessment Committee**, **encourage** the marketing authorisation holders concerned to **conduct a joint post-authorisation safety study**; […]

Implication

- Joint studies to be always encouraged if more than one MAH involved
- PRAC/EMA to find a way to systematically support joint studies
- Timely facilitation key as often challenging deadlines
- Simple process to be implemented which supports MAHs in coming together

Realisation proposal

- EMA will highlight to MAHs at point of imposition that joint study is strongly recommended and will encourage a joint business venture, offering the following:
  - Explanation of the reasons why a joint study is the most effective way to address the underlying question(s) to be addressed by the PASS
  - Clarification of the fee benefit
  - Offering to act as a platform for exchange of contact details for companies interested in a joint study (i.e. collect response in a listing and make it available to all interested parties after a deadline of 2 weeks)
- If needed (criteria to be developed), EMA will additionally organise a webinar/TC, where interested companies are introduced to each other and have the opportunity to interact and raise questions

Thank you for your attention

Further information

irene.rager@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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