EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Encouraging joint PASS submissions

12th industry stakeholder platform - operation of EU pharmacovigilance

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Encouraging joint PASS - Regulatory grounds

GVP Module VIII Rev 3 :

If safety concerns apply to more than one medicinal product, the Agency or the national competent authority shall, following consultation with the PRAC, **encourage** the marketing authorisation holders concerned to conduct a **joint PASS** [DIR Art 22a, REG Art 10a] Requests to the marketing authorisation holders should contain the justification for the request of a joint study and may include core elements for the study protocol. The national competent authority or the Agency should support interactions between the concerned marketing authorisation holders and providing suggestions for the joint study proposal.

Encouraging joint PASS – It makes sense

- Meaningful engagement with committees at the time of imposition – making sure the study is feasible, meaningful and proportionate.
- Optimising workload and resources
- Ensuring representation across the EU – maximise sample size
- Protecting public health – timely start of the study

Joint PASS: What can competent authorities do?

Model for facilitating joint PASS

Sharing contact details

For all procedures imposing a PASS in more than 1 MAH (i.e. Referral, PSUSA)

Webinar

- To introduce MAHs to each other
- To provide background information to the study objectives and desired PASS deliverables

Joint PASS: Recent experience

- ***Example 1 - Valproate***
- ***Example 2 - Diane***
- ***Example 3 - Direct Acting Anti-Virals (DAAVs)***

Example 1 - Valproate

- Risk minimisation measures such as educational materials aimed to better inform patients and healthcare professionals on the risks and a drug utilisation study to assess the effectiveness of the proposed risk minimisation measures.

- ✓ Letter encouraging exchange of contact details - 20 responses were received representing 80% of the MAHs involved
- ✓ 15 representatives attended the TC/Webinar representing around 90% of the MAHs.
- ✓ There was already a consortium organised and lead by Sanofi (in total 18 MAHs)
- ✓ **4 additional MAHs joined the consortium**

Example 2 – Diane-35

- A protocol for the drug utilisation study to characterise prescribing practices for the medicinal products during typical clinical use in representative groups of prescribers and to assess main reasons for prescription.
- A PASS to evaluate the effectiveness of the risk minimisation activities.

- ✓ Consortium organised and lead by Bayer (in total 14 MAHs)
- ✓ Successful collaboration among MAHs
- ✓ Results evaluated by PRAC in 2016 – fulfilment of the conditions
- ✓ **Meaningful evaluation of the risk minimisation measures**

Example 3 – DAAV

- A prospective PASS to evaluate the recurrence of hepatocellular carcinoma associated with DAAVs

- ✓ Consortium lead by Gilead (in total 5 MAHs)
- ✓ All MAHs attended the TC/Webinar including MAHs for products under initial MAA reviews
- ✓ Early discussions held with PRAC Rapporteurs shortly after CHMP opinion, meaningful feedback in preparation for Art 107n protocol submission
- ✓ **Timely start of the study key due to risk of patient depletion**

Thank you for your attention!

Further information

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