SCOPE Work Package 8
Lifecycle Pharmacovigilance

Top 10 tips on Safety-related Referrals

2016

SCOPE

Scope

1. Be clear about the scope of the referral – is it restricted to a specific indication, formulation, population; should fixed-dose combination products be included? This will ensure that time and energy isn't wasted on unnecessary work.

Clarity of questions to MAH(s)

2. Make sure all questions to the companies (LoQ, and LoOI) are short, simple and consistent with the scope. Only request information that is essential for your decision – do not ask for anything that is a 'nice to know', getting a second opinion on the draft LOQ will help to ensure that the questions are clear.

Pre-work/time-saving

3. Get some idea of the volume of data you may receive by checking Annex 1 on the referral page of the EMA website, remembering MAHs are not obliged to respond. If possible, familiarise yourself with the key studies/data that are likely to be relevant and do as much 'pre-work' as possible before receiving the MAH responses. This will save you valuable time once the clock has started.

Team working

4. If you are working in a team, hold planning meetings with all relevant parties, including the PRAC rapp, at an early stage. Decide in advance how to organise the work to make best use of skills and avoid duplication of effort. Involving the EMA is particularly important, especially for advice on procedural issues.

Assessment plan

5. Decide at an early stage on your approach for assessing company responses when multiple MAHs are involved. Where the same data is described by multiple MAHs, focus on the most comprehensive, well-considered response – acknowledging other MAHs that have reached the same conclusion and highlighting those that have reached a different conclusion.

Timelines

6. Carefully consider the timetable, including how it fits around holidays, and create your own personal timetable for assessment, bearing in mind that your report will most likely need national expert advice and/or peer review. Give yourself daily milestones for what you will need to have assessed and stick to them.

Quality

7. Consider relevant clinical guidelines, seek peer review or national expert advice and/or consult an EMA scientific advisory body (e.g. (supplemented) SAG or ad hoc expert advisory group)/patient groups/other stakeholders to ensure that your conclusions are compatible with how the drug is used in practice and do not have any unintended clinical consequences for healthcare professionals and patients. If you are not the rapporteur MS, providing timely comments before the PRAC discussion will help to improve the robustness of the final outcome.

Conclusions on data

8. Ensure the conclusions are: clearly explained; justified based on the totality of the data; proportionate to the risk; and within the scope of the referral.

Recommendations

9. Describe the advantages, disadvantages and feasibility of each regulatory option. Bear in mind that substantial changes to the product licence (e.g. removing an indication, route of administration or formulation) may trigger the suspension or the revocation of some products involved in the procedure.

SmPC proposals

10. SmPC proposals should be clear, concise and consistent and serve a purpose. Consider existing wording (e.g. from the SmPC comparison table or for other products in the class) as this can be useful for recommending updates to product information. Ensure that any new proposals are compatible with the rest of the SmPC/PL.