Pharmacovigilance Planning Checklist

Background: Ensuring that you have a pharmacovigilance plan in place is an important post-marketing activity. Pharmacovigilance is defined by the World Health Organisation as the science of detecting, assessing, understanding and preventing adverse effects or any other medicine/vaccine related problem.[1] To ensure the safety of medicines on the market, it is important for marketing authorization holders (MAH) and regulators to collect reported safety information from the public. The information gathered in this process contributes to the continued monitoring of the risk-benefit profile of the medicine. A pharmacovigilance plan is prepared by the MAH and details the process by which they plan to identify and evaluate safety information on a marketed medicine. The plan is typically submitted to the regulatory authority with the application for marketing authorization, although it may be prepared for an approved medicine with an identified new safety concern or proposed new indication.

Prepare a pharmacovigilance plan (per the ICH E2E Guideline or country-specific guideline) covering the following topics:

- ☐ A safety specification summary, including:
  - important identified and potential risks of the medicine
  - unanswered safety questions for continued investigation
  - non-clinical and clinical information
- ☐ A summary of ongoing safety issues and significant identified risks, potential risks, and missing information.

  NOTE: *Missing information refers to gaps in knowledge about the safety of a medicinal product for certain anticipated utilization (e.g., long-term use) or for use in particular patient populations for which there is insufficient knowledge to determine whether the safety profile differs from that characterized so far.*[2]
- ☐ Routine pharmacovigilance practices, including details of pharmacovigilance systems and processes, processes for preparing regulatory reports (ADRs, PSURSs, etc.), systems for continuous monitoring of the safety profile of the product, including signal detection and issue evaluation, and processes for updating labelling and notifying regulatory authorities.[3]
- ☐ An action plan for safety issues.[4]
  - The structure of the action plan should include the safety issue, objectives of the proposed action, rationale of the proposed action, monitoring of the safety and proposed action, and milestones for evaluation and reporting.
- ☐ Any additional pharmacovigilance data, such as that from clinical trials, post-authorization studies, drug utilization studies, patient registries, prescription event monitoring, etc.[5]
- ☐ Any applicable pharmacovigilance data privacy practices.

[1] https://www.who.int/teams/regulation-prequalification/regulation-and-safety/pharmacovigilance#:~:text=Pharmacovigilance%20is%20the%20science%20and,they%20are%20authorized%20for%20use

[2] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-v-risk-management-systems-rev-2_en.pdf

[3,4,5] https://database.ich.org/sites/default/files/E2E_Guideline.pdf