Risk Management Plan – Philippine-Specific Annex

Version number:

Related EU- RMP or global/core RMP version:

1. INTRODUCTION / PRODUCT OVERVIEW
   1.1. Product information
      - *Active ingredient(s)*
      - *Product Name*
      - *Pharmaceutical form(s) and strength(s)*
      - *FDA Registration No(s). (if applicable)*
   1.2. Indication(s) and Target Population(s)

2. SAFETY SPECIFICATION
   2.1 *Important Identified Risks*
   2.2 Important Potential Risks
   2.3 Missing Information

3. PHARMACOVIGILANCE PLAN
   3.1. Routine Pharmacovigilance Activities
      - *Reporting of adverse reactions and signal detection*
      - *Update on significant safety information*
      - *Update of actions taken by other regulatory agencies*

   3.2. Additional Pharmacovigilance Activities
      - *Additional pharmacovigilance activities applicable to local context with planned date for such activities (attach the protocol in Section 6. References)*
      - *Discuss if there are no local additional pharmacovigilance activities to be implemented*

Additional activity	**Objectives**	**Safety concerns addressed**	**Status**	**Planned submission date**
Additional activity (with complete title and protocol ID)	*Provide the objective of the such activity*	*Safety concerns being addressed by such activity*	*Status of the activity (ongoing, planned)*	*Proposed date of submission to FDA Philippines*
…	…	…	…	…

4. PLANS FOR POST-AUTHORIZATION EFFICACY STUDIES

Planned local post-authorization efficacy studies.

Mark N/A if no such studies are required.

Post-authorization efficacy study	**Status (planned, on-going)**	**Summary of Objectives**	**Planned submission date**
Study (with complete title and protocol ID)	*Status of the activity (ongoing, planned)*	*Provide the summary of objectives of the study*	*Proposed date of submission to FDA Philippines*
…	…	…	…

5. RISK MINIMIZATION MEASURES

5.1. Routine Risk Minimization Measures

- *Provisions of warning & precautions in the package insert*
- *Updates of labeling & packaging of products*

5.2. Additional Risk Minimization Measures

- *Additional risk minimization measures applicable to local context with planned date for such activities*
- *Discuss if there are no local additional risk minimization measures to be implemented*

Safety Concerns or Missing Information	**Routine Risk Minimization Measures**	**Additional Risk Minimization Measures**
List of safety concerns being addressed	*Include details of exact wording for package insert proposed for this safety concern*	*Include details of additional measures for this safety concern to be undertaken in the Philippines*
…	*…*	*…*

6. REFERENCES

6.1. List of Reference/s, if applicable

6.2. Attachment(s)

- *Study protocols for planned local additional pharmacovigilance activities or study protocol for local Post-Authorization Efficacy Studies*
- *Proposed local RMP materials such as educational materials, flyers, etc.*

7. PERSON RESPONSIBLE FOR THIS RMP AND CONTACT DETAILS

Identify the person responsible for the implementation of activities as indicated this RMP. It is usually the QPPV of the MAH in the Philippines.

8. VERSION HISTORY