Health Sciences Authority

SINGAPORE-SPECIFIC ANNEX (SSA)

The Singapore-Specific Annex (SSA) describes a product's proposed risk management plan (RMP) to be implemented in Singapore. An SSA must be submitted as part of all New Drug Application type 1 (NDA-1) dossiers.

A) PRODUCT OVERVIEW

1. Product name	
2. Active ingredient(s)	
3. Company's name	

B) SAFETY CONCERNS

Please list the safety concerns relevant to the Singapore context in the appropriate boxes below. State "Nil" if there are none.

4. Important identified risks (Adverse reactions with adequate evidence of an association with the product that could impact its benefit-risk balance)	
5. Important potential risks (Safety concerns with suspected but unconfirmed association with the product that could impact its benefit-risk balance)	
6. Missing information (Clinically significant gaps in knowledge about the product's safety profile or its use in particular patient populations)	

C) PROPOSED LOCAL PHARMACOVIGILANCE (PV) ACTIVITIES

Routine PV activities should be conducted for all products.

Additional PV activities may be necessary for products requiring extra level of monitoring to ensure that their benefit-risk profiles remain acceptable for the approved indication(s).

See Annex for examples of routine and additional PV activities.

7. Are you proposing any additional PV activities locally?

No

Yes

Please provide further details below (e.g. type/title of activity, safety concerns addressed, milestones and due dates), or provide an attachment (to indicate below) describing the details.

D) PROPOSED LOCAL RISK MINIMISATION ACTIVITIES (RMA)

Routine RMA should be conducted for all products.

Additional RMA may be necessary for products requiring extra level of risk minimisation to ensure that their benefit-risk profiles remain acceptable for the approved indication(s).

See Annex for examples of routine and additional RMA.

8. Are you proposing any additional RMA locally?

No

Yes

Please provide further details below (e.g. type of RMA, safety concerns addressed), or provide an attachment (to indicate below) describing the details. The proposed local RMP materials should be submitted in the application dossier (see Q10).

E) SUPPORTING DOCUMENTS

9. I have submitted the following reference RMP(s) in the application dossier *(tick all that apply)*
EU-RMP US REMS Company Core RMP Others (please specify) _____
10. I have submitted the following proposed local RMP materials in the application dossier *(tick all that apply)*
Not applicable Educational materials Others (please specify) _____
11. [Only applicable for therapeutic products] I do not have any outstanding RMP documents to submit for this application
Yes No. I commit to submit the full set of RMP documents within 40 working days from the date of application acceptance for evaluation *(only applicable for applications submitted via the full or abridged route)*

Date of Submission (dd/mm/yyyy)

Name and Designation

Signature *(Note: Once the signature is inserted, the document is locked and no further edits can be made)*

ANNEX

PHARMACOVIGILANCE (PV) ACTIVITIES

Routine PV activities include:

- Monitoring of the safety profile of registered products, including signal detection and evaluation
- Reporting local **serious** adverse events to HSA in accordance with the stipulated timeline
- Providing timely notifications to HSA on significant safety issues that may influence the overall benefit-risk profile of the product
- Preparing the product's Periodic Benefit-Risk Evaluation Reports (PBRER). HSA may request for the submission of PBRER for selected products on a routine or ad hoc basis

Additional PV activities can include:

- Conducting and submitting the results of post-market safety studies e.g. monitoring of long-term safety from clinical studies
- Conducting active surveillance programmes
- Regular review and submission of data from established local or overseas patient registries

RISK MINIMISATION ACTIVITIES (RMA)

Routine RMA include:

- Provision of warnings and precautions in the package insert
- Timely safety updates to labelling and packaging

Additional RMA can include:

- Provision of physician and/or patient educational materials
- Issuance of Dear Healthcare Professional Letter
- Implementation of controlled access programme
- Implementation of pregnancy prevention programme