APPENDIX 16A *SINGAPORE-SPECIFIC ANNEX (SSA) TEMPLATE*

I Product Information

Product name:	e.g. ABC123
Active ingredient(s):	e.g. safetyzumab

II Safety Concerns

To list the important safety concerns relevant in the Singapore context.

Important identified risks (an untoward occurrence for which there is adequate evidence of an association with the therapeutic product)	e.g. • Drug-induced liver injury (DILI) • Severe cutaneous adverse reactions (SCAR) • Heart failure • Myopathy • Rhabdomyolysis • Elevated liver enzymes (ALT and AST)
Important potential risks (an untoward occurrence for which there is some basis for suspicion of an association with the therapeutic product)	e.g. • Malignant cell growth (haematological malignancy) • QT prolongation • Peripheral neuropathy • Potential medication error/ dispensing error • Unknown safety in special populations (e.g. elderly, immunocompromised patients, patients who are renally impaired or with hepatic dysfunction)

III Description of the Proposed Local Pharmacovigilance (PV) Activities

To describe the PV activities (routine and/or additional), relevant to the local context, that are planned to address the safety concerns.

(A) Routine PV Activities *[required for all products]*

Please refer to the *Guidance for Industry – Post-marketing Vigilance Requirements for Therapeutic Products and Cell, Tissue and Gene Therapy Products* on the respective timelines for the following routine PV activities.

✓	Reporting of local serious adverse reactions to the Vigilance and Compliance Branch, HSA in accordance with stipulated timeline
✓	Timely update on significant safety issues that may influence the overall benefit-risk profile of the product
✓	Timely update on safety-related regulatory actions taken by other agencies, particularly HSA's reference agencies (i.e., Australia TGA, EMA, Health Canada, UK MHRA and US FDA)

(B) Additional PV Activities

Where applicable, to include planned date for such activities. If no additional PV activities are considered to be required, it should be indicated as such (i.e. "Nil").

Examples: Active surveillance programme, post-marketing safety studies (applicable to local context), cohort event monitoring

e.g. To conduct active soliciting of local serious adverse reaction reports associated with the use of ABC123 from physicians who prescribe the product. Solicited local serious adverse reaction reports will be compiled on a quarterly basis and submitted to the Vigilance and Compliance Branch, HSA. (e.g. end of March, June, September, December)

IV Description of the Proposed Local Risk Minimisation Activities (RMAs)

To describe RMAs (routine and/or additional), relevant to the local context, that are planned to address the safety concerns.

(A) Routine RMAs *[required for all products]*

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

(B) Additional RMAs

If no additional RMAs are considered to be required, it should be indicated as such (i.e. "Nil").

Examples: Provision of physician educational materials and patient medication guides, provision of sales data, issuance of Dear Healthcare Professional Letter, implementation of restricted access programme, controlled distribution, pregnancy prevention programme

e.g.

- Physician educational material is developed to highlight the identified safety concerns, signs and symptoms to look out for and to highlight on the potential risk of medication error/dispensing errors
- A patient medication guide is developed to highlight the identified safety concerns, signs and symptoms to look out for and when to seek medical attention
- A Dear Healthcare Professional Letter will be issued to reinforce the significant safety concerns at product launch.

V Additional Information

To list the RMP documents enclosed in this application and to provide other comments (if any)

e.g.
The following RMP documents are enclosed in this application for your perusal:

- Latest version of the approved EU-RMP (i.e. version 2.1)
- Draft physician educational materials and patient medication guides
- Draft Dear Healthcare Professional Letter

REVISION HISTORY

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