B. Annex II: Bangladesh -Specific Annex for RMP

TEMPLATE FOR RISK MANAGEMENT PLAN (RMP)
BANGLADESH- SPECIFIC ANNEX (BSA)

I. Product Overview in Bangladesh

Date of Submission	DD/MM/YYYY
BSA Version Numbe r	Current BSA version number eg. V1
Product Name	
Active Ingredient(s)	
Dosage Form	
DAR Number	
Date of First Registration Approval in Bangladesh	
Product Category	e.g. New drug products /Biologics /Others
Marketing Authorization Holder (MAH)	
Details of QPPV(name, designation, email, telephone number)	
Approved Indication(s)	

II. Changes from Previous RMP Version

Brief summary of significant safety-related changes from the previous RMP submission. This section may not be applicable for the first RMP submitted post-registration

III. Summary of Changes to the BSA Over Time

Brief tabulated summary of safety-related changes to the BSA over time.

<Suggested format>

Date of Submission	BSA Version Number	Description of Change
DD/MM/YYYY	V1	First BSA submitted post-registration
DD/MM/YYYY	V2	

IV. Safety Specification: Summary of Safety Concerns

To list the safety concerns in relation to the approved indication(s) in Bangladesh.

<Suggested format>

Important identified risks	Heart failure
Important potential risks	Liver injury Peripheral neuropathy
Missing information	Bone fracture

V. Pharmacovigilance Plan

To describe the pharmacovigilance activities (routine and/or additional), relevant to the Bangladesh context, that are planned or carried out to address the safety concerns.

Routine pharmacovigilance activities are required for all products.

If no additional pharmacovigilance activities are deemed necessary, it should be indicated as 'nil'.

a. Routine Pharmacovigilance Activities

To describe routine activities that are planned or carried out in Bangladesh.

b. Additional Pharmacovigilance Activities by Safety Concern

<Suggested format>

Safety Concerns	Pharmacovigilance Activities	Additional Information
Important identified risks • Heart failure	Additional: PASS [study title]	
Important potential risks • Liver injury • Peripheral neuropathy	Additional: Nil	
	Additional: Nil	
Missing information • Bone fracture	Additional: Nil	

VI. Risk Minimization Plan

To describe the risk minimization activities/measures (routine and/or additional), relevant to the Bangladesh context, that are planned or carried out to address the safety concerns.

Routine risk minimization activities are required for all products.

If no additional risk minimization activities are deemed necessary, it should be indicated as 'nil'.

a. Routine/Additional Risk Minimization Activities by Safety Concern

<Suggested format>

Safety Concerns	Risk Minimization Activities	Additional Information
Important identified risks • Heart failure	Routine: Prescription-only medicine; Labelling in local PI: 'Section XX Special warnings and precautions for use' and 'Section XX. Undesirable effects'; Labelling in Packaging Leaflet: 'Before you start to use it' and 'Side effects'. Additional: DHPC letter & educational materials	
Important potential risks • Liver injury • Peripheral neuropathy	Routine: Prescription-only medicine; Labelling in local PI: 'Section XX Special warnings and precautions for use' and 'Section XX. Undesirable effects'; Labelling in Packaging Leaflet: 'Before you start to use it' and 'Side effects'. Additional: educational materials	
Missing information • Bone fracture	Routine: Nil Additional: Nil	

VII. Additional Information

To list the RMP documents enclosed in this submission and to provide other comments (if applicable).

If the additional risk minimization activity includes a Patient Alert/Reminder Card, the following information are required:

Patient Alert/Reminder Card Checklist

- Product name and Active Ingredient
- Dosage form
- Introduction

This patient alert/reminder card contains important safety information that you need to be aware of before, during, and after treatment with Product Name.

Show this card to any doctor, pharmacist, dentist or other healthcare professional involved in your treatment.

- Content Information

To be aligned with latest approved package insert.

- Warding and Contraindication
  - When to seek immediate attention
  - Contraindication
  - Information on pregnancy

- Additional Advice

Please make sure you also have a list of all your other medicines with you at any visit to a doctor/ pharmacist.

Keep this card for 'X number' months after treatment is completed since side effects may occur after your last dose.

- Treatment details
- ADR reporting

If you notice any side effects, talk to your doctor or pharmacist. You may report any adverse drug reactions directly to the National Regulatory Authority at the official website

- Additional information (for biologic/biosimilar products only):

All ADR reports for biologics/biosimilar should include Brand name, active ingredient, and batch number for traceability purposes.

- Version and month & year of update