C. Annex III: Bangladesh Specific (BSA) for PSUR

<Cover Page>

NAME OF THE MEDICINAL PRODUCT(S) COVERED

INTERNATIONAL BIRTH DATE (IBD): <Date>

BANGLADESH REGISTRATION DATE (BBD): <Date>

DATE OF SUBMISSION: <Date>

INTERVAL COVERED BY THIS REPORT:

From <date> to <date (i.e. data lock point)>

DATE OF THIS REPORT:

<Date>

OTHER INFORMATION:

<Other identifying or clarifying information if necessary>

MARKETING AUTHORISATION HOLDER'S NAME AND ADDRESS:

<Name>

<Address>

<E-mail address> (contact person for the PSUR procedure)

NAME AND CONTACT DETAILS OF QPPV:

<Name>

<Address>

<Telephone number>

<Fax number>

<E-mail address>

SIGNATURE (QPPV or designated person): <Signature>

<PSUR Content >

I. Product Overview in Bangladesh

Submission Number (PBRER Cover Period)	e.g. First submission (DD/MM/YYYY – DD/MM/YYYY)
Product Name	
Active Ingredient(s)	
Dosage Form	
MAH/DAR No	
Product Category	e.g. New drug product/ Biologics/Others

II. Summary of Safety Changes

a. Actions Taken in the Reporting Interval for Safety Reasons

Brief tabulated summary of significant actions related to safety that have been taken in any countries during the reporting interval, relating to marketing experience by the MAH, or authorities.

<Suggested format>

Action(s) taken by	Description of the action(s) taken	Status of the action(s) taken
US FDA	MAH was requested to include liver injury in the Warnings and Precautions section of the US PI.	Updated US PI was approved on DD/MM/YYYY

b. Changes in Reference Safety Information (RSI)

Brief tabulated summary of changes in RSI during the reporting interval.

<Suggested format>

Version (Date)	Description of changes	Applicable to Bangladesh (Yes/No)
3.0 (DD/MM/YYY	Update to the Warnings and Precautions section regarding the risk of heart failure	Yes

c. Action(s) Taken or Planned in Bangladesh

State whether or not a specific action has been taken or is planned for Bangladesh, pertaining to the actions taken or RSI changes listed above in II(a) and II(b). If any actions are taken in Bangladesh, the status of the actions should be listed.

<Suggested format>

Type of action/plan	Details
Safety-related	
Non safety-related	

III. List of Signals Evaluated

To list all signals that were closed (e.g. the evaluation was completed) during the reporting interval as well as ongoing signals that were undergoing evaluation, at the end of reporting interval.

The description(s) of the signal evaluations are not to be included.