Annex II

**MEDICINAL PRODUCT DEFECT REPORTING FROM LICENSED MANUFACTURER/ LICENSED WHOLESALER/ LICENCED IMPORTER/ PRODUCT LICENCE HOLDER TO MINISTRY OF HEALTH**

The completed Medicinal Product Defect Reporting Form and any other accompanying documents must be submitted to **Pharmacovigilance Section, Department of Pharmaceutical Services, Ministry of Health** via hard copy or e-mail at **productdefect.pharmacy@moh.gov.bn.**

The information denoted (*) are mandatory to fill in.

| **1** | **Summary of product defect notification** | |
|---|---|---|
| 1.1 | Product defect classification* | ☐ Critical ☐ Non-critical |
| 1.2 | Is there a need for a product recall?* | ☐ Yes ☐ No ☐ Not determined<br><br>*If yes, please complete the following:*<br><br><u>Class of Recall</u><br>☐ Class 1 ☐ Class 2 ☐ Class 3<br><br><u>Level of Recall</u><br><br>☐ Consumer/ Public ☐ All points of sale/ retail/pharmacy<br><br>☐ Wholesale/ Importer ☐ Manufacturer<br><br>Date of initiation of recall<br>_____ |
| **2** | **Company and contact details** | |
| 2.1 | Date of notification to Ministry of Health* | |
| 2.2 | Company type* | ☐ Licensed Manufacturer<br>☐ Licensed Wholesaler<br>☐ Licenced Importer<br>☐ Product Licence Holder |

| | | |
|---|---|---|
| | | ☐ Others (please specifiy):_____ |
| 2.3 | Name of company* | |
| 2.4 | Company address* | |
| 2.5 | Name of reporting person* | |
| 2.6 | Designation* | |
| 2.7 | Office tel* | |
| 2.8 | Email* | |
| 2.9 | Signature of reporting person* | |
| 2.10 | Name of contact person(if it different from the reporting person) | |
| 2.11 | Designation | |
| 2.12 | Office tel | |
| 2.13 | Email | |
| **3** | **Product details**<br>• Additional products can be provided as an attachment<br>• Please also attach the distribution list of the affected batch(es), if applicable. | |
| 3.1 | Name of product* | |
| 3.2 | Brunei registration number or other reference number | |
| 3.3 | Active ingredient(s)* | |
| 3.4 | Dosage form(s)* | |
| 3.5 | Strength(s)* | |
| 3.6 | Pack size(s) | |
| 3.7 | Manufacturer* | |
| 3.8 | Address of manufacturer | |
| 3.9 | Where is the product supplied to? | |
| 3.10 | Batch numbers and expiry dates | |

| | | |
|---|---|---|
| **4** | **Nature of defect(s)** | |
| 4.1 | Date of first detection of defect* | |
| 4.2 | If defect is detected in Brunei Darussalam, indicate the place of first detection of the defect. | |
| 4.3 | If the defect is detected outside of Brunei Darussalam, please state the country | |
| 4.4 | Details of the defect* (*please provide investigation and medical assessment if available. Investigation reports should provide justification on the defect classification*) | |
| 4.5 | Was there a local serious adverse reaction associated with the defect? | ☐ Yes ☐ No ☐ Not known |
| 4.6 | If yes, was an adverse effect report submitted to Ministry of Health? | ☐ Yes (date of submission of report to MOH) _____<br>☐ Pending<br>☐ Not known |
| **5** | **Actions taken/proposed market actions (please attach CAPA) report if needed)** | |
| 5.1 | Actions taken and proposed actions to be taken (include actions taken in overseas market for the affected product) | |
| 5.2 | Other relevant information | |