

PRODUCT RECALL COMPLETION FORM

The filled Product Recall Completion 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**.

1	Details of company	
1.1	Name of company	
1.2	Address of company	
1.3	Name of reporting person	
1.4	Designation	
1.5	Office tel	
1.6	E-mail	
1.7	Signature of reporting person	
1.8	Date	
2	Details of recall	
2.1	Class of the recall	
2.2	Level of the recall	
2.3	Date of recall initiation	
2.4	Date of recall completion	
3	Product details • Additional products can be provided as an attachment	
3.1	Name of product	
3.2	Brunei registration number or other reference number	
3.3	Active ingredient(s)	

Annex IV

3.4	Batch number and expiry date	
3.5	Quantity imported in Brunei Darussalam	
3.6	Quantity remaining in warehouse	
3.7	Quantity sold (please attach sales record)	
3.8	Quantity recalled (Please provide names and address of purchasers and quantities recalled)	
4 Action(s) taken on affected stocks		
<p>The above recall has been completed on (date)_____ and all recalled stocks have been planned for:</p> <p><input type="checkbox"/> Destruction*</p> <p><input type="checkbox"/> Returned to manufacturer/ third party supplier overseas*</p> <p><input type="checkbox"/> Re-introduction into the market upon approval by Ministry of Health</p> <p><input type="checkbox"/> Other actions upon approval by Ministry of Health. Please specify the actions to be taken:</p> <p>_____</p> <p>_____</p> <p>*Approval is not required. Documentary proof of actions to be taken is required to be submitted once the recalled products are destroyed/ returned.</p>		