7. Revision History

Revision	Revision Date	Reason for Revision/Change Request	Revised By
0		Original Release/first draft	

Annex 1: Product Defect Complaint Form

Instructions:

i. This Form is used to report deficiencies/defects of medicines. Problems of this nature are usually found in a single batch(s) of a product.

ii. Do not report ADR on this form

iii. Use a separate form for each product reported

iv. ***Return the completed form to Drug Regulatory Authority. (Fax no. 335803)***

1. Reporter (i.e Person reporting the Defect/Problem)	
Name:	
Occupation/Position:	
Institution/Organization:	
Address:	Telephone: Facsimile:
2. Complainant (i.e patient, customer, and client): **[IF ANY] or Leave it Blank**	
Name:	
Address:	Telephone: Facsimile:
3. Product Details	
Name:	Brand name:

	Generic name:
Composition(with strength):	
Batch no.	
Name & Address of the Manufacturer:	
Expiry Date:	
4. Details of the Product Defect: *(If required, refer Quality Inspection Check Sheet for Pharmaceuticals Annex V,Guideline on Quality Inspection of Medical Supplies, Quality Assurance and Standardization Division, MoH)*	
Description of the Defect/Problem:	
6. Details on Stock Balance and Storage:	
Do you have Stock Balance of the same batch product:	Please circle one: YES/NO If Yes: How many? ……..
Where was the product stored?	Please circle one: Store Room/Dispensary? If Others, give details: .....
Storage Temperature (in degree Celsius)	(Please give the storage temperature as indicated on the thermometer at the time of reporting):…….

This Report was submitted by: (Name):	Signature:	Date:

XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Leave this blank: For DRA's use only:

1. Categorization of the type of Product Defect:

Critical ☐ Major ☐ Minor ☐ Not sure ☐

2. Alert Recall Committee YES ☐ NO ☐

Reviewed by: **(Post Marketing Control Division)**	**Signature:**	**Date of Review:**