Appendix 1 - Defective Medical products & Dietary Supplements reporting form

(Please fill all the information as detailed as possible)

1. Origin of Defect / Report

1.	**Source of defect**	☐ Patient ☐ Hospital ☐ Pharmacy ☐ Others
	Specify, If others	
2.	**Name of Complainant**	
3.	**Name of Organization**	
4.	**Address of Organization**	
5.	**Telephone / Fax number**	
6.	**E-mail Address**	
7.	**Date & time of reporting**	_____/_____/_____, _____:_____ DD MM YYYY HH MM
8.	**Signature of Complainant**	

2. Defective Product Details:

1.	**Brand Name**			
2.	**Generic Name**			
3.	**Dosage form**			
4.	**Strength**		**Pack size**	
5.	**Batch number**			
6.	**Manufacturing date**		**Expiry date**	
7.	**Name of manufacturer/ Distributor**			
8.	**Point of Purchase** (Pharmacy, website, outside country etc.)			
9.	**Photo of Defect / Product**	Attach photo along with this document / email		

3. Defect Details:

1.	**Defect Description**	

	Defect Category	Category Descriptor
2.	☐ **Manufacturing laboratory control Issues**	☐ 1.1 Manufacturing laboratory controls issues ☐ 1.2 Out of specification test result
	☐ **Product contamination and Sterility Issues**	☐ 2.1 Product contamination chemical ☐ 2.2 Product contamination microbial ☐ 2.3 Product contamination physical ☐ 2.4 Product contamination with body fluid ☐ 2.5 Product sterility lacking ☐ 2.6 Suspected transmission of an infectious agent via product
	☐ **Product Label Issues**	☐ 3.1 Physical product label ☐ 3.2 Product barcode issue ☐ 3.3 Product expiration date issue ☐ 3.4 Product identification number issue ☐ 3.5 Product label issue ☐ 3.6 Product label on wrong product ☐ 3.7 Product lot number issue
	☐ **Product packaging issues**	☐ 4.1 Product blister packaging issue ☐ 4.2 Product closure issue ☐ 4.3 Product commingling ☐ 4.4 Product container issue ☐ 4.5 Product container seal issue ☐ 4.6 Product dropper issue ☐ 4.7 Product outer packaging issue ☐ 4.8 Product packaging issue ☐ 4.9 Product packaging quality issue
	☐ **Product Physical Issues**	☐ 5.1 Product coating issue ☐ 5.2 Product deposit issue ☐ 5.3 Product dosage form issue ☐ 5.4 Product gel formation ☐ 5.5 Product physical issue/ Malfunction
	☐ **Other Issues**	☐ 6.1 Suspected efficacy issue ☐ 6.2 Suspected product degradation ☐ 6.3 Deviation in storage criteria's ☐ 6.4 Missing/Extra quantities of Dosage form (Tablets, Capsule, Liquids in bottles and ampoules) ☐ 6.5 Any issues which are not mentioned above (Specify below) …… ……
3.	**Is the problem associated with any adverse event?**	☐ Yes ☐ No
	Specify, If yes	

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Allotted Complaint Number: DOH/DCMS/QD/_____/_____			
Name of the officer receiving the report		Signature & Date	