



## Defective Medicinal products And Dietary Supplements reporting form

Please complete the form as detailed as possible

### 1. Origin of report

1. Name of person / organisation reporting problem	
2. Organisation	
3. Address	
4. Telephone number	
5. Fax number	
6. E-mail Address	
7. Time of report	
8. Date of report	
9. Signature of the applicant	

### 2. Product Details

1. Brand names of affected Product(s)	
2. Generic name(s)	
3. Name of manufacturer/ distributor	
4. Affected batch(es)	
5. Expiry date	
6. Pharmaceutical dosage form	
7. Strength	
8. Pack size	
9. Point of purchase (website, country, pharmacy, etc)	
10. Photo of the product	Attach

### 3. Defect Details

Name of the officer receiving the report .....

1. Source of Problem (e.g. Patient /Hospital /pharmacy /manufacturer).	
2. Defect Description	..... ..... ..... .....
3. Defect Category	<ul style="list-style-type: none"> <li>• Suspect counterfeits</li> <li>• Product contamination</li> <li>• Poor packaging</li> <li>• Product mix-up</li> <li>• Labeling concerns</li> <li>• Therapeutic failures</li> </ul>
Category Descriptor	
1. Manufacturing laboratory controls issues	1.1 Manufacturing laboratory controls issues 1.2 Out of specification test result
2. 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
3. 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
4. Product packaging issue	4.1 product blister packaging issue 4.2 product closure issue 4.3 product commingling 4.4 product container seal issue 4.5 product container seal issue 4.6 product dropper issue 4.7 product outer packaging issue

