



Medicines Control Authority of Zimbabwe

LEF 63

LICENSING AND ENFORCEMENT DIVISION

MEDICINE, VACCINE OR MEDICAL DEVICE PRODUCT PROBLEM/DEFECT FORM

To be completed by Manufactures and/or Applicants

Reporting Applicant (reporting the problem of medicine to MCAZ)		
Name of contact:	Position/ Occupation	
Organization :		
Address :		
E-mail address :		
Tel: (office)	(mobile)	Fax:
Product problem occurred in Zimbabwe? If not, location of problem:		
Nature of the problem:		
Date of receiving complaint :		
<input type="checkbox"/> Patient <input type="checkbox"/> Customer <input type="checkbox"/> Retailer <input type="checkbox"/> Self-inspection		
Source of Complaint		
<input type="checkbox"/> Other: _____		
Number of similar reports received		

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Description of the problem (use separate sheet if space is inadequate)	
Samples submitted for analysis to MCAZ at manufacturer's cost if required and method of analysis	
Results of tests/ investigation on suspect or other samples:	
Has manufacturer/ distributor been contacted? <input type="checkbox"/> No <input type="checkbox"/> Yes (please write down their names)	
Other relevant information (attach photos, package insert and press release of external national regulatory agencies of the product if any)	
DETAILS OF THE PRODUCT	
Name of the product (as in product registration certificate)	Zimbabwe Registration Number
Active Ingredients & Strength:	
Indications :	
Dosage form :	Pack size :
Batch number:	Expiry date:
Distribution of products <input type="checkbox"/> Public Hospitals <input type="checkbox"/> Private hospitals <input type="checkbox"/> Pharmacies <input type="checkbox"/> Medicine stores <input type="checkbox"/> Public Clinics <input type="checkbox"/> Private doctors <input type="checkbox"/> Others (specify)	
Manufacturer	
Name :	
Address :	

Tel :	Fax	Manufacture date:
Quantity of the batch manufactured		Date and quantity released
Quantity on hold		Quantity distributed: local external
Importer		
Name:		
Address :		
Tel :	Fax :	Import date :
Quantity of the batch imported :		Date and quantity released
Quantity on hold:		Quantity distributed: local re-exported
Local Distributors (please attach distribution list)		
No. of local distributors		
Name :		
Address :		
Contact Person :	Tel (office & mobile)	
Quantity on hold :	Quantity distributed: local re-exported	
Exporter		
Has the product been exported outside Zimbabwe? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, specify the exported countries.		

Contact no. _____ (Mobile):

Date:

Signature of Reporter: