Medicines Control Authority of Zimbabwe

LEF 80

LICENSING AND ENFORCEMENT DIVISION

REPORT ON MEDICINAL (PHARMACEUTICAL) PRODUCT DEFECT OR PROBLEM

To be completed by Pharmacists, Pharmacy Technicians, Medical Practitioners, Nurses, Veterinary Surgeons and other Distributors of Medicines.

<table>
<tr><td colspan="4">1. Product Name (Brand and Generic)</td></tr>
<tr><td>2. Description of the Device</td><td>3. Intended Use</td><td>4. Size/Type of Container</td><td>5. Registration No.</td></tr>
<tr><td colspan="2">6. Batch Number</td><td colspan="2">7. Expiry Date</td></tr>
<tr><td colspan="4">8. Name and Address of Manufacturer</td></tr>
<tr><td colspan="4">9. Name and Title of Reporter</td></tr>
<tr><td colspan="4">10. Your Practice Location and Address of Hospital, Clinic, Retail Surgery etc.</td></tr>
<tr><td colspan="2">11. Phone Number</td><td colspan="2">12. Date Problem Occurred or Observed</td></tr>
<tr><td colspan="4">13. If requested will the actual product involved be available for examination by MCAZ.
YES NO</td></tr>
<tr><td colspan="2">14. Signature of Reporter</td><td colspan="2">15. Date</td></tr>
<tr><td colspan="4">16. Defects/Problem Noted or Suspected (see TABLE below)</td></tr>
</table>

NATURE OF DEFECT OR PROBLEM
*(Specify only on what is applicable using the space provided in the **Comments** section below)*

NATURE OF DEFECT OR PROBLEM	COMMENTS
Presence of foreign material	
Unusual odour	
Colour Changes	
Fungal Growth	
Suspected Contamination	
Parenteral Solution- Leaks, particulate matter, discolouration etc	
Wrong label, wrong packaging, wrong strength	
Lack of therapeutic response	
Other (specify)	

Return To: The Director-General
Medicines Control Authority of Zimbabwe
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P O Box 10559
Harare
Fax: (04) 736980 Tel: 708255/792165/ 2901327-31
E-mail: mcaz@mcaz.co.zw

For Office Use Only

Report Number: ……..

Date Received: ……