## Appendix II: Pharmaceutical Product Reporting Form (Part I) And Recall Notification Form (Part II)

**Note:**

Part I of this form should be used to report a problem with medicines and allied substances in quality, safety or efficacy, which are thought to have arisen during their manufacture, storage, or handling. Problems of this nature may require laboratory investigation by ZAMRA.

Part II of this form should be completed when a decision of recall is established.

When the reported problem may lead to a Class I or II recall, it should be reported to the Authority by telephone within 24 hours, and followed by email or letter of Part I of this form.

If a Class I or II recall is required, parts I and II of this form should be reported to the Authority immediately by telephone and followed by email or letter.

The manufacturer, marketing authorisation holder, local responsible person, distributor or importer should submit the available information to the Authority as soon as the recall decision is made, rather than waiting until ALL applicable information in part II is this form available.

For a problem that may lead to a Class III recall, Part I of this form should be reported to the Authority by letter or email within 72 hours.

If Class III recall is required, Parts I and II of this form should be submitted by letter or email to the Authority.

Contact information for the Authority:

**The Director General**
**Zambia Medicines Regulatory Authority**
**Plot No. 2350/M Off Kenneth Kaunda International Airport**
**PO Box 31890**
**Lusaka, Zambia**
**Tel: +260 211 432 350 / 432 351**
**Email: pharmacy@zamra.co.zm**

Use a separate form for each pharmaceutical product reported.

**Pharmaceutical Product Problem Report Form (Part I)**

| **DETAILS OF THE PROBLEM** | |
|---|---|
| Reporting company: | |
| Name of contact person: | Position: |
| Name of the organisation | |
| Address: | |
| Email: | |
| Telephone (office): | Mobile: |
| Pharmaceutical product problem occurred in Zambia? If not, location of the problem: | |
| Nature of the problem: | |
| Date of complaint received: | |
| Source of complaint | Patient □ customer □ retailer □ self-inspection □ |
| | Other (specify) |
| Number of similar reports received: | |
| Description of the problem (use separate sheet if this space is not enough) | |
| Results of tests/Investigation on the suspect product or other samples | |
| Has the manufacturer or distributor been contacted? Yes □ No □ (If yes, please provide company names) | |

| |
|---|
| Other relevant information (Attach photo, package insert, and press release of any overseas authority of the product if any) |

| **DETAILS OF THE PRODUCT** | | | |
|---|---|---|---|
| Name of the product (on marketing authorisation certificate) | | ZAMRA MA Number: | |
| Active ingredient and strength: | | | |
| Indications (Attach additional sheet if this space is not enough): | | | |
| Dosage form: | | Pack size: | |
| Batch number: | | Expiry date: | |
| Distribution of products: | Wholesale □ | Hospitals □ | Health centers □ |
| | Pharmacies □ | Drug stores □ | Health shops □ |
| | Clinics □ | Others (specify) | |
| **Manufacturer** | | | |
| Name: | | | |
| Address: | | | |
| Tel (office): | Email: | Manufacture date: | |
| Batch size: | Quantities of batches manufactures: | | |
| Date and quantity released: | | Quantity on hold: | |
| Quantity distributed: | | Local: | |
| | | Overseas: | |
| **Importer** | | | |
| Name: | | | |
| Address: | | | |
| Tel (office): | Email: | Import date: | |

<table>
<tr><td colspan="2">Quantity of batch imported:</td><td colspan="2">Quantity on hold:</td></tr>
<tr><td colspan="4">Date and quantity released</td></tr>
<tr><td colspan="2" rowspan="2">Quantity distributed:</td><td colspan="2">Local:</td></tr>
<tr><td colspan="2">Re-exported:</td></tr>
<tr><td colspan="4">Local distributor (please attach distribution list)</td></tr>
<tr><td colspan="4">No. of local distributors:</td></tr>
<tr><td colspan="4">Name:</td></tr>
<tr><td colspan="4">Address:</td></tr>
<tr><td colspan="2" rowspan="2">Contact person:</td><td colspan="2">Tel (office):</td></tr>
<tr><td colspan="2">Tel (mobile):</td></tr>
<tr><td colspan="2">Quantity on hold:</td><td colspan="2">Quantity distributed:</td></tr>
<tr><td colspan="4">Exporter</td></tr>
<tr><td colspan="4">Has the product been exported? YES □ NO □<br>If yes, specify the country/countries:</td></tr>
</table>

Name of Reporter …… Position ……

Contact Number …… Date ……

Signature of the reporter ……

**Recall Notification Form (Part II)**

<table>
<tr><th colspan="3">RISK ASSESSMENT</th></tr>
<tr><td colspan="3">Types of Hazards: Quality □ Safety □ Efficacy □<br>Other □ (specify)</td></tr>
<tr><td colspan="3">Evaluation of hazards to users (i.e., effect on users, possibility of occurrence) (Attach expert advice where applicable)</td></tr>
<tr><td colspan="3">Proposed recall classification: Class I □ Class II □ Class III □</td></tr>
<tr><td colspan="3">Proposed action (with agreement of ZAMRA)</td></tr>
<tr><td colspan="2">Recall start date:</td><td>Proposed recall end date:</td></tr>
<tr><td colspan="3">Hotline(s) for inquiries:</td></tr>
<tr><td>Hotline(s) hours of operation:</td><td>Mon-Fri:</td><td>Sat, Sun, public holiday:</td></tr>
<tr><td rowspan="2">Person responsible for recall:</td><td colspan="2">Tel (Office):</td></tr>
<tr><td colspan="2">Tel (Mobile):</td></tr>
<tr><td colspan="3">Proposed level of recall: Wholesale □ Retail □ Consumer □</td></tr>
<tr><td colspan="3">Locations of recall spots (Customer level recall only):</td></tr>
<tr><td colspan="3">Means of refund at recall spots: Cash □ Replacement □<br>Other □ (specify)</td></tr>
<tr><td colspan="3">Proposed recall strategy (use separate sheet if this space is not enough)</td></tr>
</table>

Name of Reporter …… Position ……

Contact Number …… Date ……

Signature of the reporter ……

## Appendix III: Customer Reply Form

| | |
|---|---|
| To | |
| Attention | |
| Email | |
| Postal Address | |
| Subject | |
| From | |
| Contact Person | |
| Telephone (office) | |
| Email | |

We **DO** □ **DO NOT** □ have stock that is subject to this recall.

We have reported and returned all the stock on hand to ……

(Supplier)

Stock Received:

| **Batch No.** | **Quantity** |
|---|---|
| | |
| | |
| | |

Unused stock subject to recall (currently in quarantine)

| **Batch No.** | **Quantity** |
|---|---|
| | |
| | |
| | |

Any other relevant details:
……
……
……

I declare that the information provided by me in this reply form is complete and true to the best of my knowledge.

Signature …… Date ……

## Appendix IV: Post Recall Report Form (Final Report)

| DETAILS OF RECALLED PRODUCT | |
|---|---|
| Product name: | Marketing Authorisation No.: |
| Active ingredient and strength: | |
| Dosage form: | Package size: |
| Batch No.: | Expiry date: |
| Reason for recall: | |
| Extent of distribution: | |
| Imported/manufactured quantity: | |
| Quantity distributed in Zambia: | No. of consignees: |
| Quantity exported: | Countries: |
| Action taken by the product owner (i.e., MAH, LRP, importer, distributor etc.) | |
| Result of recall: | |
| Returned quantity: | Outstanding quantity: |
| Used or sold quantity by the consignees: | |
| Quantity of stock not located: | |
| No. of recall reply forms received from consignees and all stock returned/reported: | |
| Disposal plan: Destroy □ Return to overseas manufacturer □ Other □ (Specify) | |
| Details of disposal method: | |

Name of reporter …… Position ……

Contact Number …… Date ……

Signature of the reporter ……

## Appendix V: Document Related to Submission of Analytical Report

### Accredited Test

The laboratory performing the tests should obtain accreditation on the specific test method in accordance with the international standards, e.g., ISO 17025. The Licensee shall submit the raw data and quality control data for the tested samples to substantiate the validity of test results. These data could facilitate the evaluation of the test result by the ZAMRA.

### Non-Accredited Test

In case accreditation of the specific test could not be arranged, the analytical report might be considered acceptable if the laboratory has obtained appropriate accreditation in the area of pharmaceuticals or pharmaceutical products, and be able to provide necessary documentation to prove its competence in respect to its quality control and technical aspects in performance of the specific chemical tests.

Basically, the information should include, but is not limited to, the following:

- Detailed method (including standard preparation procedure, sample preparation procedure, instrument parameters, and quality control procedure);
- Raw data and quality control data for all tested samples shown in the report (including chromatograms, mass spectra and calculation);
- Validation summary for the method used (including method linearity, limit of detection, limit of quantitation, method bias, precision, and measurement uncertainty);
- Reference material used and purity verification summary; and
- Relevant proficiency test participation.