

**MEDICINES CONTROL AGENCY**

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| **Recall Information Form (PART 1)** |
| **DETAIL OF THE PROBLEM** |
| **Reporting Company / Entity** |
| Name of contact | Position/ Occupation |
| Organisation |
| Address |
| E-mail address |
| Tel (office) (mobile) | Fax |
| Product problem occurred in The Gambia? If not, location of problem: |
| **Nature of the problem** |
| Date of receiving complaint |
|  Patient  Customer  Retailer  Self-inspectionSource of Complaint Other:  |
| Number of similar reports received |
| Description of the problem (use separate sheet if space is inadequate) |
| Results of tests/ investigation on suspect or other samples |
| Has manufacturer/ distributor been contacted?  No  Yes (please write down their names) |
| Other relevant information (attach photos, package insert and press release of oversea authority of theproduct if any) |

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| **DETAILS OF THE PRODUCT** |
| Name of the product (as in product registration certificate) | MCA Registration number |
| Active Ingredients & Strength |
| Indications |
| Dosage form | Pack size |
| Batch number | Expiry date |
| Distribution of products  CMS  Hospitals  Private Pharmacies  Private Clinics RMS  Health Centres  Others (specify) |
| **Manufacturer** |
| Name |
| Address |
| Tel | Fax | Manufacture date |
| Quantity of the batch manufactured | Date and quantity released |
| Quantity on hold | Quantity distributed: |
| **Importer** |
| Name |
| Address |
| Tel | Fax | Import date |
| Quantity of the batch imported | Date and quantity released |
| Quantity on hold | Quantity distributed:  |
| **Local Distributors (please attach distribution list)** |
| No. of local distributors |
| Name |
| Address |
| Contact Person | Tel (office & mobile) |
| Quantity on hold | Quantity distributed: |
| **Exporter** |
| Has the product been exported outside The Gambia?  Yes  NoIf yes, specify the exported countries. |

Name of Reporter: Contact no. (mobile):

Signature of Reporter: Date:

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| **RECALL INFORMATION FORM (PART 2)** |
| **RISK ASSESSMENT** |
| Type of hazard  Safety  Quality  Labelling  Compliance Issue Other (specify) |
| Evaluation of Health Hazard to users (e.g. effects on users, possibility of occurrence) (attached expert advice if any) |
| Proposed recall classification  Class I  Class II  Class III |
| **PROPOSED ACTION (WITH AGREEMENT OF MCA PRIOR ACTION)** |
| Recall start date | Proposed recall end date |
| Hotline(s) for enquiry |
| Hotline(s) operating hours: Mon- Fri Sat Sun & PH |
| Responsible officer of recall | Tel (office & mobile) |
| Proposed recall level  Wholesale  Retail  Consumer |
| Location of recall spots *(For Consumer level recall only)* |
| Operating hours and duration of the recall spots *(For Consumer level recall only)* |
| Means of Refund at the recall spots  Money  Credit Note  Replacement  Other |
| Conditions of Refund at the recall spots |
| Proposed recall strategy (use separate sheet if space is inadequate) |

Name of Reporter: Contact no. (mobile):

Signature of Reporter: Date: