

**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-inspection  Source 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 the  product 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  No  If 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: