



MEDICINES CONTROL AGENCY

54 Kairaba Avenue, Pipeline, The Gambia. Tel.No. +220 4380632, www.mca.gm

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		
Source of Complaint	<input type="checkbox"/> Patient <input type="checkbox"/> Customer <input type="checkbox"/> Retailer <input type="checkbox"/> Self-inspection	
	<input type="checkbox"/> 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? <input type="checkbox"/> No <input type="checkbox"/> Yes (please write down their names)		
Other relevant information (attach photos, package insert and press release of oversea authority of the product if any)		

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 <input type="checkbox"/> CMS <input type="checkbox"/> Hospitals <input type="checkbox"/> Private Pharmacies <input type="checkbox"/> Private Clinics <input type="checkbox"/> RMS <input type="checkbox"/> Health Centres <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:
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? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, specify the exported countries.	

Name of Reporter: _____ Contact no. (mobile): _____

Signature of Reporter: _____ Date: _____

RECALL INFORMATION FORM (PART 2)	
RISK ASSESSMENT	
Type of hazard <input type="checkbox"/> Safety <input type="checkbox"/> Quality <input type="checkbox"/> Labelling <input type="checkbox"/> Compliance Issue <input type="checkbox"/> Other (specify)	
Evaluation of Health Hazard to users (e.g. effects on users, possibility of occurrence) (attached expert advice if any)	
Proposed recall classification <input type="checkbox"/> Class I <input type="checkbox"/> Class II <input type="checkbox"/> 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 <input type="checkbox"/> Wholesale <input type="checkbox"/> Retail <input type="checkbox"/> Consumer	
Location of recall spots (<i>For Consumer level recall only</i>)	
Operating hours and duration of the recall spots (<i>For Consumer level recall only</i>)	
Means of Refund at the recall spots <input type="checkbox"/> Money <input type="checkbox"/> Credit Note <input type="checkbox"/> Replacement <input type="checkbox"/> 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: _____