Health Authority – Abu Dhabi			
Document Title:	Policy for Recall of Drugs and Healthcare Products		
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Applies to:	Healthcare Facilities and Professionals Licensed by HAAD in the Emirate of Abu Dhabi		
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1. PURPOSE

To standardise the process of recall of drugs and healthcare products by the Drugs and Medical Products Section at the Health Authority Abu Dhabi (HAAD) from the healthcare facility/market/vendor in the Emirate of Abu Dhabi.

2. POLICY STATEMENT

2.1. Drugs and Medical Products Section at HAAD is responsible for issuing, ordering, reporting and monitoring drug/ medical products and healthcare product recalls in the Emirate of Abu Dhabi.

2.2. This policy encompasses all types of drugs and healthcare products, which have been identified or suspected to have deficiencies.

2.3. Drugs and healthcare products identified or suspected to have deficiencies must immediately be withdrawn and held from use by healthcare facilities or from the market in the Emirate of Abu Dhabi, until HAAD commissioned investigation is completed.

2.3.1. A Deficient product is any product that does not comply with quality specification (as per UAE adopted pharmacopeias or manufacturer's approved specifications) or is contaminated, counterfeit, fake, mislabeled, and presents efficacy, quality or safety issue that may harm patients.

2.4. Once HAAD investigation of the suspected drug/ healthcare product is completed and recall is issued (Class II and III), compliance by all stakeholders is mandatory and the process of recall must be completed within 3 weeks after the issuance of the recall.

2.5. For Class I (Critical), HAAD declared recalls will be effective immediately after the issuance of the recall (Appendix 1).

2.6 All stakeholders must comply with this policy; non-compliance may result in sanctions and penalties being imposed by HAAD which may range from warnings, fines, other disciplinary actions, or to closure of facilities.

3. SCOPE

For consumer protection, patient safety and quality of care, recalls are processed and issued for drugs and/or healthcare product which fail to comply with any article of UAE pharmacy law and is applicable at all levels of drugs and healthcare products

handling, including supply chains, retail, healthcare facilities, pharmacies, and where deficiencies are identified during inspections, post marketing surveillance and/or through customer complaints.

4. TARGET AUDIENCE

4.1. Healthcare professionals and healthcare facilities licensed by HAAD in the Emirate of Abu Dhabi
4.2. Market authorisations holders
4.3. Abu Dhabi and Federal Government entities, in particular the Ministry of Health (MOH)

5. PROCEDURE

5.1. Healthcare facilities must inform HAAD immediately as they become aware of information that indicates or suggests that a drug or medical product is deficient or is suspected of being deficient;
5.2. All healthcare professionals working in healthcare facilities must first inform the head of their pharmacy department about any suspected product. Deficient and suspected products must be put on hold and not be used or recommended for use until HAAD investigates and issues final decision about the concerned product.
5.3. Healthcare facilities must report information on the deficient or suspected drugs or medical products by completing the reporting form (Appendix 2) and faxing/sending it to HAAD. Reports may also be submitted via mail, e-mail and telephone. HAAD recommends that report originators must ensure that the information was received by Drugs and Medical Products Regulation section of HAAD. Contacts information is listed in the reporting form.
5.4. Upon receiving the notification, HAAD will undertake the following:
    5.4.1. Based on the type of quality concern about suspected products, HAAD may immediately request all healthcare facilities to cease prescribing, dispensing and/or administering the deficient product or suspected. In such cases, HAAD will also inform the MOH, and ensure that the information has been received;
    5.4.2. Start an investigation about the deficient or suspected product and follow up with responsible parties. Inform the market authorisation holder, manufacturer and/or representing party in Abu Dhabi, and provide them with a set time to address any quality concern and also request them to quarantine the product under investigation, where necessary. HAAD investigation comprises:
        5.4.2.1. Collect and test samples, if needed. Where it requires so, compliance with HAAD request is mandatory;
        5.4.2.2. Gather evidence based data and make recommendations about the appropriate action to be taken as necessary for individual products;
        5.4.2.3. Determine whether complete recall of a product from Abu Dhabi market is required and issue such a recall, subject to authorized delegate's approval;
        5.4.2.4. Inform the MOH about any decision to recall drugs and medical products.
5.5. Market Authorisation Holders must manage all reported quality, efficacy or safety issue about their products in accordance with GMP, pharmacy law and regulations in Abu Dhabi and HAAD policies and standards. They must submit to HAAD supportive evidence based information and must ensure that they execute all necessary actions to avoid risk of harm to patients and the community posed by deficient and/or suspected products. Deficient products must be recalled swiftly from the market. Market authorization holders are responsible and accountable for effecting the necessary product recalls once issues by HAAD, including removal from the market, follow-up checks to assure that recalls are completed successfully, and final reporting

to HAAD and MOH on completed product recalls.

5.6. Market Authorisation Holders must report to HAAD and MOH all voluntary recalls of any drug or medical product from the market in the Emirate of Abu Dhabi.

5.7. HAAD may decide whether or not to inform the public about all approved recalls of drugs and medical products in the Abu Dhabi Market.

7. DEFINITIONS AND ABBREVIATIONS

	Policy Provider and Regulation
DMP	Drug and Medical Products
HAAD	Health Authority, Abu Dhabi
HCF	Health Care Facility
CEO	Chief Executive Officer
DD	Division Director
TLDR	Team Leader Drug Regulation
USP, BP, EP	United States, British, European pharmacopeias (respectively)
MOH	Ministry of Health
GMP	Good Manufacturing Practices
Market Authorization Holder	Responsible party who register the drug with MOH
Drug /Medicine	Is a pharmaceutical product taken to cure and/or ameliorate any symptoms of an illness or medical condition, or may be used as prophylaxis, that has future benefits but does not treat any existing or pre-existing diseases or symptoms
Health Care Product (HCP)	In this policy a HCP are all products and medical devices that could harm the patient if they are deficient. Such products are used in diagnosis of illnesses, delivery and preparation of drugs (e.g. diagnostic kits, buffers for drug reconstitution, water for injection etc.), does not include cosmetic products (soap, shampoo etc.)
Specifications	Are the specific quality tests to control the strength, purity, and the physio-chemical characteristics of a drug. Specifications are available in monographs of adopted pharmacopeia in UAE (USP, EP, BP). In the absence of such monographs, the standard specifications are those presented by the manufacturers and approved by MOH.

APPENDIX 1

Definitions - Classification of Recalls

Class I- (Critical)	Recalls of dangerous or defective products that predictably could cause serious health problems or death. Examples of products that could fall into this category are counterfeit drugs, drugs identified to have serious adverse reactions, undeclared allergens, and a label mix-up on a lifesaving drug, or a defective artificial heart valve.
Class II- (Major)	Recalls of products that might cause a temporary health problem, or pose only a slight threat of a serious nature. Examples of drugs with perceptible change of odor, color, broken tablets, missing labels, expired drugs, products with defects such as leaks, and pinholes.
Class III- (Minor)	Recalls of products that are unlikely to cause any adverse health reaction, but that violate the labeling or manufacturing regulations. Examples might be a container defect (plastic material delaminating or a lid that does not seal); packages with illegible printing of critical information such as lot number and expiry date.

APPENDIX 2

RECALL FORM: PPR/DMP/DR/P0001/07

SAMPLE REPORTING FORM*

1. Origin of the sample: (facility where sample was taken, address, telephone and contact person)
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2. Date of sampling:
……..

3. Information about the sample:
Trade or Brand name of the sample……
Generic or INN name with dosage strength……..
Dosage form (tablet, capsule, etc..) ……
Batch/Lot number: …… ……..
Expiry date:……Manufacturing date:……
Registration or License number (if applicable) ……
Name and address of the Manufacturer: ……
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4. Number of sample units taken: ……..
…… ……

5. Brief comments about the sample (s):
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6. Name and signature of person(s) who collected the sample

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7. Name and signature of the person who completed the report form

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Contact information		
Address:	Health Authority – Abu Dhabi PO Box 5674 Abu Dhabi -UAE	
Telephone	02- 449-3333	Main
	02- 419-3267	Drugs & Medical Products Regulation Section
	800 424	Poison Information Center
Fax	02-444-312	
E-mail	PDIC-HAAD@haad.ae	

* This Sample Reporting Form must always be kept with the collected sample. The sample collected must be stored under the manufacturer's conditions until it reaches the Health Authority-Abu Dhabi. For any information please contact HAAD.