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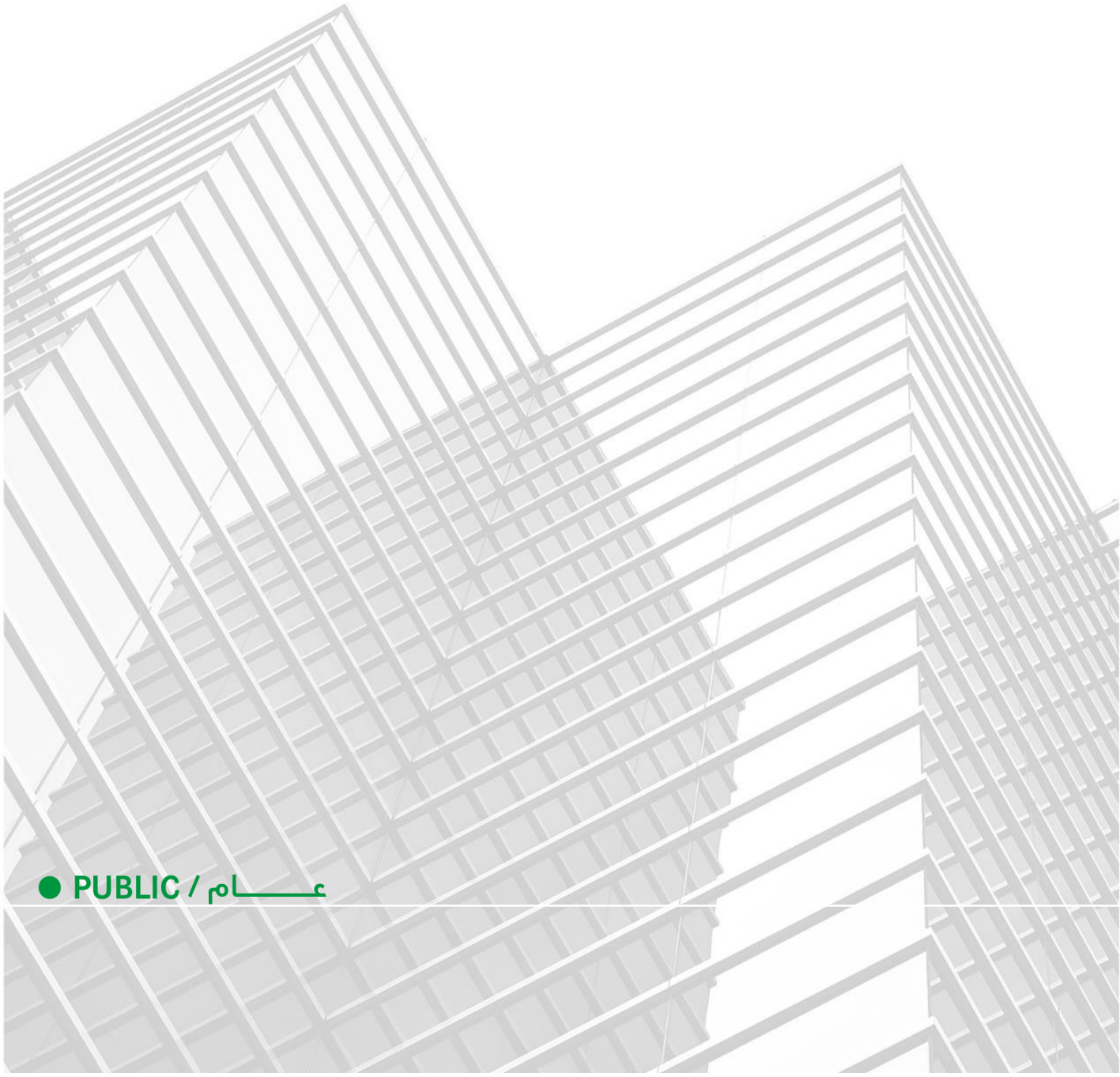
DEPARTMENT OF HEALTH

Policy for Quarantine and Recall of Medical Products



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1. Policy Purpose and Brief

PURPOSE

To standardize the process of quarantine and recall of Medical Products by the Pharmacovigilance & Drugs Education Section at the Department of Health (DOH) from healthcare facility/ market authorized holder, pharmaceutical companies /vendor/supplier/authorized agent/ distributors and stores in the Emirate of Abu Dhabi.

SCOPE

For consumer protection, patient safety and quality of care, quarantine and recalls are processed and issued for medical products which fail to comply with any article of UAE pharmacy law and is applicable at all levels of medical products handling, including supply chains, retail, healthcare facilities, pharmacies, and where deficiencies are identified during inspections, post marketing surveillance and/or through customer complaints.

2. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	Class I- (Critical)	A dangerous or defective product that could cause serious health problems or death
2.2	Class II- (Major)	A product that might cause a temporary health problem, or pose a slight threat of a serious nature
2.3	Class III- (Minor)	Recalls of products that are unlikely to cause any adverse health reaction, but that violate the labeling or manufacturing regulations
2.4	Deficient product	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
2.5	DOH	Department of Health
2.6	GMP	Good Manufacturing Practices
2.7	Market Authorization Holder	The legal person authorized to market a specific medical product within the country and is responsible for all marketing, promotion and follow-up aspects of the product within the country

2.8	Medical Product	All drugs, medical devices or healthcare products
2.9	MOHAP	UAE Ministry of Health and Prevention
2.10	PVE	Pharmacovigilance and Drugs Education
2.11	Quarantine	The status of starting or packaging materials, intermediates, or bulk or finished products isolated physically or by other effective means while a decision is awaited on their release, rejection or reprocessing.
2.12	Recall	The process of withdrawing the entire medical product or a batch from it, due to a defect in the product or to verify the validity of a report on critical adverse or side effect, or any other reasons stated by the authority requiring product withdrawal. Withdrawal may be by the manufacturer, distributor, importer, by an order of the concerned authority or by MOHAP.
2.13	Specifications	Defined as a list of tests, references to analytical procedures, and appropriate acceptance criteria that are numerical limits, ranges, or other criteria for the tests described. It establishes the set of criteria to which a new drug substance or new drug product should conform to be considered acceptable for its intended use

3. Policy Content

3.1 Pharmacovigilance & Drugs Education section at DOH is responsible for issuing regulatory actions (quarantine and recalls), monitoring the safety & effectiveness of the medical products in the Emirate of Abu Dhabi.

3.2 This policy encompasses all types of medical products, which have been identified or suspected to have deficiencies.

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

3.4 Once DOH investigation of the suspected medical products is completed and quarantine or recall is issued (Class II and Class III), compliance by all stakeholders is mandatory and the recall process must be effective immediately &the recall report must be completed by marketing authorizing holder /vendor/supplier/authorized agent etc. **within 3 weeks** after the issuance of the recall (Class I, Class II and Class III) unless otherwise justified.

3.5 For Class I (Critical), DOH declared recalls will be effective immediately after the issuance of the recall (Class I, Class II and Class III) and the recall report must be completed by marketing authorizing holder /vendor/supplier/authorized agent, etc. **within 1 week**, unless otherwise justified.

4. Policy Roles and Responsibilities

4.1. Healthcare Facilities & Healthcare professionals

4.1.1 Healthcare facilities must inform DOH immediately as they become aware of information that indicates or suggests that a medical product is deficient and/or suspected of being deficient.

4.1.2 All healthcare professionals working in healthcare facilities & handling medical products must first inform the head of their department about the medical product that is deficient and/or suspected deficient. Deficient and/or suspected deficient products must be quarantined and not be used or recommended for use until DOH investigates and issues a final decision about the concerned product.

4.1.3 Healthcare facilities must report information on the medical product that is deficient and/or suspected deficient by completing:

4.1.3.1 Defective Medicinal products & Dietary Supplements reporting form (refers to the DOH Standard on Reporting Medication Errors & Suspected Quality Problems Related to Medicinal Products and Dietary Supplements) or via the link(put the number of the refence here)https://www.doh.gov.ae/en/resources/Reporting

4.1.3.2 Medical Device Reporting Form refers to the DOH Standard on Medical Device Reporting (MDR) Appendix 1&2 or via the link(put the number of the reference. here) https://www.doh.gov.ae/en/resources/Reporting

4.1.3.3 Reports shall be submitted via e-mail to PVE@doh.gov.ae where an email reply should be received within 2-5 business days. DOH recommends that report originators must ensure that the information was received by PVE via documenting the PVE email reply for each case.

4.1.4 The facility in charge is responsible for the implementation of DOH regulatory action of a medical product (Quarantine, recall, suspension of quarantine, etc.).

4.2. DOH Pharmacovigilance and Drug Education Section

4.2.1 Upon receiving the notification, DOH PVE will undertake the following:

4.2.1.1 DOH PVE section may immediately request all healthcare facilities through PV focal points to cease prescribing, dispensing and/or administering the deficient and/or suspected of being deficient. In such cases, a DOH PVE section will also inform the Higher National Committee of Pharmacovigilance, and ensure that the information has been received.

4.2.1.2 Start an investigation about the deficient and/or suspected deficient medical product and follow up with responsible parties.

4.2.1.3 Inform the market authorization holder, manufacturer and/or representing parties in Abu Dhabi, and provide them with a set time to address any quality concern and request them to quarantine the product under investigation, where necessary. DOH investigation comprises:

4.2.1.3.1 Collect and test samples from other DOH concerned staff (Healthcare Facilities Quality Division, Drug & complementary Medicine safety), if needed. Compliance with DOH requests is mandatory.

4.2.1.3.2 Gather evidence-based data and make recommendations about the appropriate action to be taken as necessary for individual products.

4.2.1.3.3 DOH regulatory actions (Quarantine, Safety Alert, Field Safety Notice, Field Safety Corrective Action, Safety Update etc.) concerning Abu Dhabi healthcare facilities will be determined by the investigation's results and concerned authority will be informed with the regulatory decision taken by DOH if required (MOHAP Pharmacovigilance Section).

4.2.1.3.4 A DOH PVE section will determine whether a complete recall of a product from the Abu Dhabi market is required, subject to authorized delegate's approval (MOHAP Pharmacovigilance Section).

4.3. Market Authorization Holders

4.3.1 Must manage all reported quality, efficacy or safety issue about their products in accordance with GMP, pharmacy law and regulations in Abu Dhabi and DOH policies and standards. They must submit to DOH PVE section supportive evidence-based information and must ensure that they execute all necessary actions to avoid the risk of harm to patients and the community posed by deficient and/or suspected deficient medical products.

4.3.2 Responsible and accountable for effecting the necessary product recalls once issues by DOH (Deficient products must be recalled immediately from the market.), including removal from the market, follow-up checks to assure that recalls are completed successfully, and final reporting to DOH on completed product recalls within the specified time in point 3.4 & 3.5 unless otherwise justified.

4.3.3 Must report to DOH all voluntary recalls of any medical product marketed in the Emirate of Abu Dhabi.

The decision of announcing recall actions will be made by the DOH based on the necessity.

5. Policy Scope of Implementation

This policy applies to:

- Healthcare professionals and healthcare facilities licensed by DOH in the Emirate of Abu Dhabi.
- Pharmaceutical companies, market authorizations holders & their subsidiaries, suppliers, agents, etc.

6. Enforcement and Compliance (Consequences/sanction of not applying policy by related stakeholder)

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

7. Monitoring and Evaluation (Key success factors)

Monitoring and evaluation systems are in place to evaluate the effectiveness, outcomes and impact of this Policy and where necessary adopt changes to ensure continuous improvements within the health system.

8. Relevant Reference Documents

No.	Reference Date	Reference Name	Relation Explanation / Coding / Publication Links
1	May 2023	Federal Law No. (8) of 2019 regarding Medical Products, Pharmacy Profession & Pharmaceutical Facilities	https://www.doh.gov.ae/en/about/law-and-legislations
2	August 2023	GOOD PHARMACEUTICAL STORAGE & DISTRIBUTION PRACTICES (GS&DP) 2006	**https://mohap.gov.ae/assets/feb883b4/moh%20uae%20good%20storage%20practices%20english_637731958228485210_638191348690902824.pdf.aspx**
3	May 2023	Recalls Background and Definitions | FDA	https://www.fda.gov/safety/industry-guidance-recalls/recalls-background-and-definitions
4	May 2023	Singapore Health Science Authority, Regulatory Guidance, Guidance for Industry product defect and recall procedures for therapeutic products and cells, tissue and gene therapy products	**https://www.hsa.gov.sg/docs/default-source/hprg-vcb/product-defect-and-recall/guidance_defect-and-recall-reporting_1mar2021.pdf**
5	August 2023	PHARMACY GUIDELINES Version 1, Dubai Health Authority	**https://www.dha.gov.ae/uploads/112021/f6eb62ac-f666-4cce-9a2f-47788a25f565.pdf**

9. Revision List (Changes)			
Issue No.	**Revision Date**	**Clause No.**	**Revision Explanation (changes)**
6	**Sep 2023**	**Standards**	https://www.doh.gov.ae/en/resources/standards.aspx
7	**Sep 2023**	**Pharmacovigilance**	**https://www.doh.gov.ae/en/resources/Reporting**