



نتقدم بثقة
Moving Forward
with Confidence



To:

Director General of Royal Hospital
Director General of Khoula Hospital
Director General of Medical Supplies, MOH
Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)
Director General of Primary Health Care, MOH
Director General of Specialized Medical Care, MOH
Director General of Quality Assurance Centre, MOH
Director General of Health Services in all Governorates
Director of Rational Use of Medicine (MOH)
Hospital Director (Al Nahda Hospital)
Hospital Director (Al Massara Hospital)
Hospital Director (Sultan Qaboos Hospital)
Director General of the Public Authority for Civil Defence & Ambulance
The Head of Medical Services in SQU Hospital
The Head of Medical Services in Royal Oman Police
The Head of Medical Services in Ministry of Defence
The Head of Medical Services in The Diwan
The Head of Medical Services in The Sultan's Special Force
The Head of Medical Services in Internal Security Services
The Head of Medical Services in Petroleum Development of Oman
The Head of Medical Services in LNG Oman
Director of Pharmacy of Sultan Qaboos Comprehensive Cancer Care & Research Centre
Director of Pharmacy & Medical Stores in all Governorates (for distribution pls.)
Marketing Authorization Holders & Pharmaceutical Companies
ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No. 102 Dated 22/7/2024 regarding the **MONITORED MEDICINES (MM)**.

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Head of Narcotic Drugs & Psychotropic Substances committee
- Head of Narcotic Drugs & Psychotropic substances Inspection Team
- Section Head (Controlled Drugs)
- Director of Drug Control Department, DSC
- Director of Pharmaceutical Licensing Department, DSC
- Director of Pharmacovigilance & Drug information Department, DSC
- Director of Medical Device Control, DSC
- Director of Central Quality Control Lab, DSC

1



Circular No. 102/2024

16 -01-1446 H
22 -07-2024

Sub: Monitored Medicines (MM).

Reference to our previous Circular No. 189/2023 dated 3/09/2023, this is to inform you that the list and regulations of the monitored medicines (MM) were recently revised by Drug Safety Center. The revised list and regulations are attached.

INTRODUCTION:

Monitored Medicines (MM) are Prescription Only Medicines (POM) that are being monitored particularly closely by the Drug Safety Center (DSC). These medicines undergo additional restrictions on their import, prescribing, dispensing, stock management, records and disposal.

Annexure (1) includes all (MM) that require implementation of all paras below (1, 2, 3, 4). It also includes preparations containing **Ephedrine**, **Pseudoephedrine**, **Phenylpropanolamine** which should be imported only against No Objection Certificate (NOC).

The restrictions are described as follow:

1. IMPORT

1.1 Import will be allowed against a No Objection Certificate (NOC) issued in advance by (DSC) on request only for the following consignments:

- 1) Samples for registration purpose.
- 2) Samples for government tenders.
- 3) Consignments to supply the private market, Government and semi-government institutions.



1.2 NOC letter will be issued against submission of an online application through MOH e-portal. A copy of the institution's letter of purchase order (LPO) should be submitted along with the online application, if the consignment is for government tenders/a specific private health institution.

1.3 The application for NOC should only be submitted by government Health Institution or Licensed Drug Store.

1.4 NOC Letter will be valid for one year only, and it can be used for multiple imports.

1.5 Applications for Samples for government tenders/registration purpose, do not require submission of LPOs.

1.6 Imports of 'Free Medical Samples' for (MM) will not be allowed.

1.7 Approval to release a shipment containing (MM) is only against an e-portal request supported with necessary documents including the NOC and one clearance invoice for each request.

1.8 If the biologicals were derived from blood, a plasma certificate should be submitted upon clearance.

1.9 Delivery Notes signed by the receiving party should be maintained and submitted to MOH upon request.

2. PRESCRIPTION & DISPENSING:

2.1 MM should be dispensed only against a valid white prescription & clearly shows the below:

- Name of Patient
- Patient ID number
- Patient registration file number
- Age
- Sex
- Department
- Health institution/establishment stamp
- Treatment details:
- Drug Generic Name



نتقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman Vision

- Quantity to be dispensed (in numbers and letters)
- Dose & frequency for use.
- Date of prescription
- Name, stamp & signature of prescriber.

2.2 Some of the (MM) should be prescribed only by certain specialties. As shown in remarks column in (Annex 1)

2.3 For prescriptions issued by private establishments, the dispensed quantities should not exceed the dose of 30 days.

2.4 For prescriptions issued by government health institutions, the full prescribed quantities can be dispensed.

2.5 Validity of the prescription is 10 days from the date of issue.

2.6 Pharmacist should mention the total quantity dispensed, the date and his / her stamp with the pharmacy seal on the prescription.

2.7 Dispensed prescriptions should be kept for a period of 6 months and presented to MOH upon request.

3. STOCK MANAGEMENT & RECORDS:

3.1 Drug stores, pharmacies and local pharmaceutical manufacturers should maintain comprehensive records for all receipts, storage, issues and distribution of the MM.

3.2 It is recommended to use electronic records. However, non-electronic records are also acceptable, depending on the capability of the establishment.

3.3 Records are no longer required to be stamped by DSC. Verification and matching of the records with the available stocks will be carried out by the DSC inspection team.

3.4 Submission of (MM) quarterly statements is no longer required.

3.5 The records may also be submitted to the DSC upon request.



- 3.6 The record should be kept for 12 months from the last day of entry.
3.7 The records should comply with the below mentioned specifications:

a. **Electronic Records:**

- Should have Access control
- Allow data retrieval
- Allow traceability of data and data editing.
- Maintain data security
- Searchable.
- System validation and maintenance to assure its performance.
- System should allow immediate data update after each transaction
- Reports should be generated according to template 2,3 & 4.

b. **Non-Electronic (paper) Records:**

- Relevant templates shown in Annex 2, 3 and 4 should be printed and compiled in form of register.
- For stocks in medical stores, template in (Annexure 2) should be used.
- For stocks in pharmacy, template in (Annexure 3) should be used.
- For Registration/tender samples in medical store, template in (Annexure 4) should be used.
- The title of the register and name of the Institution, branch, ward should be mentioned on the cover of the register.
- The register should be securely compiled in a way to avoid loss of pages (Non-spiral). the register should Indexed.
- Pages should be numbered sequentially.
- The transactions should be entered into the relevant registers within 24 hours.



بتقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman Vision

4. DISPOSAL:

Each Institution should contract with specialized company to destruct unusable/expired medicines according to para 17/article 37 & para 6/article 34 from the **Ministerial Decision 113/2020** Issuing the Executive Regulation of the Law Governing the Practice of the Pharmacy Profession and Pharmacy enterprises. Confirmation of disposal by the 3rd party company should be maintained and submitted to DSC upon request.

All correspondence regarding this matter should be directly addressed to the Director of Drug Control, DSC.

This Circular will be effective from the date of issuance and supersedes Circular No. 99 dated 30/6/2024.

Yours faithfully,

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL



Annexure (1)

S/No	Description	Remarks
1	Vaccines	Medical Stores should distribute vaccines to the private health establishment that are qualified by the Directorate General of Disease Surveillance and Control. The list will be available on the MOH website and updated on regular basis.
2	Biologicals	All biologicals should be imported against NOC, however, for biologicals derived from blood, a <u>plasma certificate</u> should be provided upon clearance.
3	Dextromethorphan	-
4	Xanthine derivative in Paed. Syrup form only (e.g. caffeine, theophylline, theobromine)	-
5	Isotretinoin	To be dispensed only against prescriptions issued by Specialists/Consultants in Dermatology.
6	Acitretin	To be dispensed only against prescriptions issued by Specialists/Consultants in Dermatology.
7	Tretinoion	-
8	Misoprostol	Prescriptions from Private health establishments, should be strictly prescribed by Specialists/ Consultants (Obstetric/Gynecologist) for in-patients at Private Health Establishments with labor services.
9	Carisoprodol containing products	-
10	Mycophenolate	To be dispensed only against prescriptions issued by Specialists/Consultants.
11	Anabolic steroids (Nandrolone, <u>Oxandrolone</u>, <u>Mesterolone</u>)	-
12	Growth Hormone	-

13	Hydroxychloroquine	Allowed to be prescribed by specialist/consultant at private health institutions strictly, only for the treatment of Rheumatoid Arthritis, Systemic and Discoid Lupus Arrhythmia.
14	Topical Preparations containing plain/combination: <ul style="list-style-type: none"> • clobetasol • Betamethasone • fluocinolone 	To be dispensed only against the prescriptions issued by Specialist/Consultant.
15	Hydroquinone topical preparation 4% and above	To be prescribed by specialist/consultant dermatologist.
16	Ethyl Chloride Spray	-
17	Tropicamide	To be dispensed only against prescriptions issued by Ophthalmologists.
18	Heberprot-P	Restricted to health establishments providing diabetic foot care/treatment
19	Ketamine	To be dispensed against a valid prescription.
20	Esketamine	This medicine must only be prescribed in hospital with Psychiatry Specialty and must be used under the supervision of a health care professional in a healthcare setting.
21	Preparations containing Ephedrine, Pseudoephedrine, Phenylpropanolamine (plain or combination formulations).	These medicines are not (MM). However, they should be imported against NOC.

