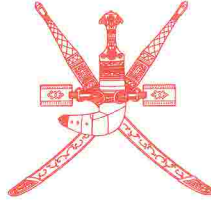


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control
MUSCAT



سلطنة عمان
وزارة الصحة
الديرة العامة للصيد
والرقابة الدوائية
مسقط

Circular No. 60 / 2015

24 -12-1436 H
8 -10-2015

To:

ALL PVT. PHARMACIES / MEDICAL STORES / LOCAL MANUFACTURERS

After Compliments,

SUB: CONTROLLED (NON PSYCHOTROPIC) DRUGS

Further to our previous Circular No. 49/2010 dated 17/4/2010, this is to inform you that the list and the regulations of the controlled non-psychotropic drugs were recently revised by this Directorate. You will find attached the revised list of controlled non-psychotropic drugs in (Annexure 1). The following regulations will be binding for these drugs with immediate effect:

1. IMPORT

A. Import will be allowed against a No Objection letter issued in advance by this Directorate on request only for the following consignments:

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

B. No objection letter will be issued against submission of the enclosed application Form-G (Annexure 2) by the importer. A copy of the institution's LPO should be submitted along with the Application Form. The No Objection Letter shall be valid for a period of ONE YEAR.

C. Imports of 'free medical samples' will not be allowed.

D. A copy of the Delivery Note signed by the receiving party should be submitted to this Directorate on regular basis.

2. PRESCRIPTION AND DISPENSING

All controlled drugs should be dispensed only against prescription as follows:

A. Private sector

- White Prescription
- Dispensed quantities to provide the prescribed dose but not for more than 7 days.

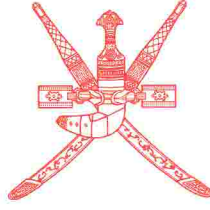
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سِلاطِنَة عُمان
وَزَارَة الصِّحَّة
الذِّمْرِيَّة الْعَامَّة لِلصِّدْرَة
وَالرِّقَابَة الدَّوْلِيَّة
مَسْقَط

- 2 -

- Prescription should not be dispensed after 10 days from the date of its issue.
- Prescription should clearly show the date, patient name, age, sex, stamp of the doctor and the clinic otherwise it should not be dispensed.
- Loose quantities can be dispensed.
- A photocopy of the ID of the customer should be taken before dispensing and should be attached to the prescription in the file.

B. Government sector

- The colour of the Prescription is according to the institutional regulation.
- The full prescribed quantities should be dispensed.
- Prescription should not be dispensed after 10 days from the date of its issue.
- Prescription should clearly show the date, patient name, age, sex, stamp of the doctor and the clinic otherwise it should not be dispensed.
- A photocopy of the ID of the customer should be taken before dispensing and should be attached to the prescription in the file.

C. Any prescription from private or government institution should not be dispensed if it lacks any of the above mentioned information.

D. Pharmacist should mention the dispensed quantity, date and also put his / her stamp and signature at the back of the prescription once it is dispensed.

E. Dispensed prescriptions should be kept for a period of 18 months and thereafter could be disposed off subject to prior approval from this Directorate.

3. STORAGE AND RECORDS

A. All Medical stores, retail pharmacies and local pharmaceutical manufacturers should maintain separate registers for the controlled drug for both saleable stocks and samples as follows:

- Saleable stocks in Medical stores (Annexure 3).
- Saleable stocks in retail pharmacy (Annexure 4).
- Registration/tender samples in Medical store (Annexure 5).

B. The registers should be reviewed, signed and stamped by this Directorate before any data entries are made.

C. The dispensed prescriptions should be entered in the relevant registers within 24 hours from dispensing date.

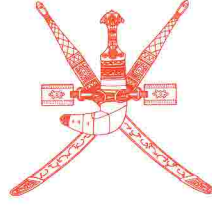
D. At the end of each quarter of each year, all Medical stores, retail pharmacies and local pharmaceutical manufacturers should submit statements/reports on the available stocks of the controlled drugs.

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E. The Quarterly statements should be directly submitted to the Drug Control Department in this Directorate. The reports should be as follows:

- Statement for the saleable stocks available in Medical stores and retail pharmacies (Annexure 6).
- Statement of the stock of registration/tender samples available in the Medical stores (Annexure 7).

Although oral preparations containing Ephedrine, Pseudoephedrine, whether they were in plain or combination formulations like, (pseudoephedrine /triprolidine or (ephedrine/ chlorpheniramine) and others are not included in the list of controlled non-psychotropic drugs and they can be dispensed against normal doctors prescriptions, they should be imported/ exported only against a No objection letter issued by this directorate after submitting the request as per Form G. In addition, a statement showing the trade name, manufacturer, country of origin, quantities imported, quantities sold, opening balance and closing balance should be submitted to the Drug Control Department on a quarterly basis for both retailers and wholesalers.

Please note that all correspondence on this subject be directly addressed to the Director of Drug Control, DGPA&DC.

This revised Circular will be effective from the date of its issue and it supersedes all our previous Circulars in this regard.

Yours faithfully,

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL



Cc: Director, Office of H.E. The Undersecretary for Health Affairs.
Director General, Royal Hospital.
Director General of Medical Supplies.
Director of Rational Use of Medicine
DDC / DPD / DQCL.
Director General of Pvt. Health Est. Affairs – for circulation to all Clinics pls.
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SH (DD) / Head of Cordin. & FU.

