Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs and Drug Control

MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 20 / 2012

04 -04-1433 H

26 -02-2012

TO: ALL PRIVATE DRUG STORES

After Compliments,

Sub: Application Form-M
Requirements for marketing approval of Medical Device containing medicinal substances

As you are aware that there are currently a large number of medical devices available in the market. In order to regulate those devices and to have a better control of such devices to ensure their safety and efficacy, we have decided to streamline the requirements for the approval of such devices to be marketed in the country.

As a first stage, we would start the formal registration of medical devices which are containing medicinal substances. In the future, please submit the requirements as per the enclosed Form (FORM-M) whenever you want to register such medical devices containing medicinal substances.

Thanking you and looking forward to your cooperation.

With best regards,

Ph. Mohammed Hamdan Al Rubaie
ACTG. DIRECTOR GENERAL

Encl: a/a

CC: Director, Office of H.E. The Undersecretary for Health Affairs
DDC
SH(Reg)

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MINISTRY OF HEALTH
DIRECTORATE GENERAL OF PHARMACEUTICAL AFFAIRS AND DRUG CONTROL
DIRECTORATE OF DRUG CONTROL

REQUIREMENTS FOR MARKETING APPROVAL OF MEDICAL DEVICES CONTAINING MEDICINAL SUBSTANCES
FORM (M)

-This Application Form to be filled by the applicant by typing **ONLY** (original & one photocopy)
-All the documents submitted with this application should either be in English or Arabic
-Arrangement of the documents in the folder should follow the same sequence followed in this form

Type of application: New ☐ Re-registration ☐

Part I: (*To be filled by local agent*)

1. Name and Address of the Local Agent:

Address	**Administration Office**
P.O. Box: P.C. Tel. No. Fax No. E-mail	

2. Copy of the drug store license:

3. Full description of the device: (Trade Name, Strength & Pack size):

4. Name of the Manufacturer:

5. Name of the Marketer to Oman:

6. Name of the batch releaser to Oman:

Name & Signature of the authorized Pharmacist in the Pharmacy

Stamp of the Pharmacy

Part II (to be filled by the manufacturing company)

1. Information about the manufacturer

1.1 Company information in details	☐	☐
1.2 Manufacturer License	☐	☐
1.3 Legalized GMP or ISO 13485 certificate or other equivalent certificate standard	☐	☐
1.4 If the marketing authorization holder is different from the manufacturer(s), a certificate showing the relation between the two companies (marketing authorization holder & manufacturers)	☐	☐

2. Information about the product

2.1 Trade Name of the device:

2.2 Description of the device:

2.3 Mechanism of action and Instructions for use:

2.4 Purpose of uses

2.5 Dosage Form:

2.6 Pack size:

2.7 Type of packaging material:

2.8 Shelf Life:

2.9 Storage Conditions in figures:

2.10 Potential side effects:

2.11 Warnings:

2.12 Contraindications:

2.13 Clarification whether the device contains animal or human materials:

2.14 The classification of device in the country of origin:

	Yes	No
3. Legalized CE Certificate or declaration of conformity issued from an accredited notified body certifying the conformity to the product standards	☐	☐
4. Composition or component of the device	☐	☐
5. Legalized pack insert (if available), the content of the pack insert should be as per attachment No. (1), 2 specimens of the pack insert are required.	☐	☐
6. Evidence of established procedures and systems for distribution records, complain handling, adverse incident reporting & recall	☐	☐
7. Summary of reported problems with the device	☐	☐
8. Safety and effectiveness data (risk assessment, pre-clinical and clinical studies, process validation studies)	☐	☐
9. Manufacturing process	☐	☐
10. List of countries in which the medical device is approved (Attached copies of approval certificates)	☐	☐
11. Ten samples when required with batch analysis certificate	☐	☐
12. Two specimens of inner, outer packs and labels	☐	☐
13. Quality Control Laboratory requirements as per attachment (2)	☐	☐