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جناب آقای دکتر شیبانی
رئیس محترم سندیکای صاحبان صنایع داروهای انسانی ایران

سلام علیکم

بااحترام، به پیوست یک نسخه بروشور "راهنمای صدور مجوز برای تاسیس کارخانه های تولید داروهای شیمیایی، گیاهی و لوازم پزشکی" در کشور عمان، واصله از وزارت امور خارجه جهت استحضار و بهره برداری مقتضی ایفاد می گردد.

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OBJECTIVES

Develop a clear, unified procedure for licensing a local manufacturing plant for Human Medicines, Herbal Medicines and Medical Devices.

Provide a reference document for applicants for licensing a local manufacturing plant and for all other relevant bodies.

PREFACE

Good manufacturing practice is a professional system based on approved principles and standards to ensure the quality, safety and effectiveness of the products.

In order to provide high-quality health care, the Ministry of Health in the Sultanate of Oman, through its future Health Strategy (Health 2050), are seeking to establish an approved mechanism to enhance medical security and the health system sustainability in providing appropriate and cost-effective medicines by encouraging local manufacturing companies. This in turn will help in reducing expenditure on the import of medical supplies, especially with the continuous increase in prices globally.

Directorate General of Pharmaceutical Affairs and Drug Control, which is the authorized body in the Ministry of Health, for the implementation of the Ministry strategical plans in this area, encourage investments in local pharmaceutical industry and demonstrate all the steps that the investor must follow.

In this context, this guide presents all the necessary steps for the licensing of local manufacturer for the production of human medicines, herbal medicines, medical devices from the submission of the application to the completion of the industrial establishment and the start of production according to the internationally approved principles and standards in the field of good manufacturing practices. The Directorate is committed to make direct follow-up and facilitate all procedures.

DEFINITIONS

Ministry: Ministry of Health (MOH)

Directorate: Directorate General of Pharmaceutical Affairs & Drug Control (DGPA&DC)

Concerned Section: Pharmaceutical Industry Section

GMP Committee: Good Manufacturing Practice Committee

Medicine (Human/Herbal): One substance or more used to diagnose, prevent or treat human diseases

Equipment & Medical devices: Any instrument, apparatus, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for diagnosis, prevention, monitoring, treatment, alleviation of disease, compensation for an injury, control of conception and more.

4. An initial approval valid for one year will be issued for accepted application. It can be extended if justified.

Third: Documents

1. Application form for initial approval of manufacturing plant. (Attachment 1).
2. A summary of the feasibility study (if any).

PHASE II: CONSTRUCTION

First: Conditions

1. Plant design and layouts should be in accordance with the international good manufacturing practice requirements and (ISO 13485) for Medical devices.
2. The owner should assign a consultant or technical body specialized in the pharmaceutical/medical devices industry to follow up of the layouts assessment with the concerned section at the Directorate and hereafter, plant construction and other technical affairs.
3. Plant construction to be started only after layouts approval by the Directorate.
4. Any changes in the approved layouts has to be approved first by the Directorate.

Second: Procedures

1. The GMP committee will assess layouts within 30 working days calculated from the date of its submission to the concerned section.
2. Layouts approval and permission for construction.
3. Owner has to notify concerned section upon completion of the construction. The plant shall then be inspected within 30 working days from the date of receipt of the notification, in order to confirm the compliances of the construction with the approved layouts.
4. Issuance of manufacturing plant license.

Third: Documents

1. CV summary for all consultants and technical personnel assigned, stating their qualifications & experiences.
2. Layouts should be in A1 paper explaining the following details:
   - Site plan.
   - Warehouse area.
   - Quality Control area
   - Production area.
   - Personnel movement.
   - Material movement.
   - Heating Ventilation & Air Conditioning (HVAC) system, stating the classes of the different areas and their pressures differentials.
   - Water system.
3. Details of the manufacturing site, as well as the type of the surrouding factories.

PHASE III: FINAL APPROVAL

First: Conditions

1. Sources of raw materials have to be approved by the Directorate.
2. All the necessary documents (e.g. Site master file, SOPs...etc.,) has to be prepared in accordance with the international good manufacturing practice or other relevant references.
3. Inspection of the plant during the production of the pilot scale batches.
4. Company will be allowed to manufacture production batches only after issuance of GMP certificate and payment of the stated fees.

Second: Procedures

1. Payment of stated fees for the issuance GMP certificate.

2. Company has to notify the concerned section in a period not less than 30 days about the date intended to start manufacturing the pilot batches.
3. An assigned team from the directorate will inspect the plant on the date stated by the company to verify its compliance to the good manufacturing practices requirements.
4. The inspection team has to submit its report to the concerned section within a period not exceeding 21 working days from the date of the inspection.
5. In the case of observations, the report has to be forwarded to the company to carry out the necessary corrective measures and to submit a compliance report supported with relevant documents and photographs.
6. The inspection team evaluates the response of the company (within a period of not more than 21 working days). In case it fulfil all the GMP requirements, the final report prepared by the inspection team will be presented to the concerned committee for making the decision, not later than 15 working days.
7. A GMP certificate valid for 2 years will be issued from the directorate.

Third: Documents

1. Copy of the company Site Master File
2. Copy of the documented evidence for the payment of the stated fees.

***NB:** To complete company registration and its products after getting the GMP certificate, please refer the link: https://www.moh.gov.om/ar/web/dgpadc/resources

ANNEXURE

Attachment (1): Template for the Initial approval application.

REFERENCES

Official Gazette No. (1118) / Royal Decree No. 35/2015

ATTACHMENT (1)

Application for Initial Approval for Manufacturing Plants for Human Medicines, Herbal Medicines & Medical Devices

- All the documents submitted with this application should be in either English or Arabic.
- Arrangement of the documents in the folder should follow the same sequence followed in this form.