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TRAVELLING SEMINAR ON QUALITY CONTROL OF PHARMACEUTICAL PREPARATIONS

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REGISTRATION OF PHARMACEUTICAL SPECIALITIES IN IRAN

by

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In Iran the Division for Pharmaceutical Affairs has to cope with all problems of foreign pharmaceutical preparations and drugs locally produced under royalties or independently.

In the Division a Section deals with registration of all pharmaceutical specialities imported or locally manufactured, and their re-registration after three years. Two advisory Committees are formed one for imported drugs and one for locally produced. These two Committees in their regular meeting are authorized to make decisions on a higher level as the members of the Committees are formed by various experts in the field of pharmacy and medicine and decisions of these Committees in the above mentioned problems are final.

According to the regulations the importation as well as manufacturing of pharmaceutical specialities in the country require a licence from the Division for Pharmaceutical Affairs with the registration of every drug manufactured. Drugs imported should have been manufactured by firms which are recognized by the authorities of the country of origin. A certificate from the responsible authority should also mention that the drug has been sold for at least five years in the country of origin. Exceptions are granted by the Committee according to circumstances.

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For registration of pharmaceutical specialities applications are prepared. The requested information for locally produced speciality should give to the Division for Pharmaceutical Affairs a complete description of the analytical procedure for the pharmaceutical preparation to be registered. The method is to be examined at the laboratory before the registration is granted.

The same consideration applies to imported pharmaceutical specialities and the form concerning their registration includes a request for full information on therapeutic indications, side effects and analytical procedures, etc.... These particulars are to be supplied to the Division for Pharmaceutical Affairs and the Committee for imported pharmaceutical specialities through the local representation.

A copy of the form requesting registration of imported pharmaceutical specialities is enclosed.

APPLICATION FOR REGISTRATION OF IMPORTED DRUG

Date: _____

No.: _____

Applicant: _____

Name: _____

Address: _____

(It is necessary to submit legible and complete answer of all questions together with necessary documents for consideration of the Committee.)

1. Drug Specifications

   1.1 Name

   1.2 Pharmaceutical form

   1.3 Name of the manufacturing laboratory

   1.4 Address of the manufacturing laboratory

   1.5 Country of origin

2. Following documents must be attached:

   2.1 A photostatic copy of the manufacturing permit from the country of origin.

   2.2 A photostatic copy of the sale-permit from the country of origin (submitted by the Ministry of Health or other Authorities) certified by the Iran Embassy.

   2.3 A photostatic copy of the complete and detailed analytical procedures used for checking the final product.

   2.4 Five samples of the preparation for which the permit is requested.

3. Drug's Specification in the Country of Origin

   3.1 Name

   3.2 Formula

   3.3 Sale unit (packing specification)

4. Price

4.1 Unit price for wholesaler in the country of origin.

4.2 Unit price for pharmacy in the country of origin.

4.3 Public price.

4.4 Sale price in Iran.

5. Calculation of the Public Price for Iran

5.1 Export price (should be written in original currency: Rls.)

5.2 Transportation cost.

1. By sea (indicate delivery port)
2. By land (indicate the custom office)
3. By air

5.3 Insurance.

5.4 Custom duties.

5.5 Other expenses should be attached in this list .....Rls.

Delivery (cost) price to the store.

6. Profit

6.1 Profit of the importer.....Rls.

Price for wholesaler

6.2 Estimated profit for wholesaler.....Rls.

Price for pharmacy

6.3 Profit of pharmacy.....Rls.

Public price

7. Expiration date should be guaranteed by the manufacturer and must be printed on the packing.....

8. Estimated minimum consumption for twelve months from the date of clearance from the custom.

Notice

1. In case the drug has not been imported within six months the import licence will be cancelled.
2. The licence can be cancelled if according to the records of the importer the sale of twelve months, after clearance from custom, is less than seventy-five percent compared with the previous estimation.
3. Any change in the specifications of the drug for which the licence had been issued, should be done only after approval.
4. If according to the reports of the control laboratory the specifications of drug or other specifications are different from the application, the importer will be made responsible and the import licence will be cancelled and legal steps will be taken.
5. The importer should obtain a photostatic copy of the result of the analysis of the shipped product and four samples of each consignment should be submitted to the Drug Division for getting the clearance permit.
6. Under special cases air shipment will be allowed with the permission of the Drug Division.

This information has been obtained from the documents and is certified by us.

Name and surname of the Manager of the Company

Name and surname of the technical responsible

Formula of the Pharmaceutical Preparation: _____

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