

Republic of Iraq

Ministry of Health
Technical Affairs Directorate
Registration Department

Drug

Registration

Regulations

A/ General

1- According to the pharmaceutical regulations in Iraq, a pharmaceutical product cannot be marketed unless it is registered. Registration is the filing of certain information about the safety efficacy , quality and origin of products to

be marketed in Iraq. Registration should be done by manufacturers , marketing authorization holder, contract manufacturers.

2- Companies required to be registered are:

- Pharmaceutical companies that have one or more of a pharmaceutical factory
- Companies producing General products (Appendix 1)
- Medical appliances and disposables producing companies.
- Laboratory diagnostic kit manufacturers

3- Products that are required to be registered are any pharmaceutical products , vaccines and sera with a therapeutic effect.

a- prescription only drugs (full documentation is required)

b- OTC drugs (Appendix 2) (reduced documentation is required)

* reduced documentation :- no bioavailability or bioequivalence study is required , however dissolution profile to be submitted.

4- Registration of a pharmaceutical product is valid for 5 years but for national pharmaceutical products is valid for 10 years, re-registration will be required thereafter.

5- Anew registration file for registered Product should be submitted prior to major modifications to the formulation, manufacturing process or method of preparation while upon minor modifications only notification with samples is required.

6- Requirements for resubmission of a product for registration after it's refusal depends on the reason of that refusal.

7- Registration of a pharmaceutical product will be revoked whenever new scientific evidence proves facts contrary to the information supplied with the original registration documents.

8- Hospital packs of the registered product could be marketed though not registered, provided that specifications of packaging materials are consistent with the specifications used in the stability data . submit samples of outer packaging with application.

9-The Registrant is responsible for the product quality and the recalling process of the product.

10-The product label can carry the name of its owner/applicant regardless of country and has the right to mention the name of collaborators/ contract

manufacturer in that product.

- 11- Names and copy rights of a product registered by a research company need to be respected and no violation of such copy right that resemble the original product directly or indirectly will be allowed.
- 12- All documents submitted by a pharmaceutical company concerning registration of a product shall be treated as confidential and should not be passed to any other party .
- 13- In the registration of a drug the following priorities shall be followed
first priority :- new chemical entity
second priority :- national drugs.
third priority :- other drugs.
- 14- Inspection of pharmaceutical manufacturing establishments :
 - Legal basis : drug registration system
 - authority : Ministry of Health (MOH) / registration departmentregistration department have the right to inspect any pharmaceutical establishment for compliance with GMP regulations. If an inspection is deemed necessary by the Registration Department, then it will be at the Registrant expense.

B/ Procedure:

- 1- The responsible authority for registration is MOH/ technical affairs directorate/ registration department.
- 2- Registration documents should be submitted to the receiving unit/ communications section of the Registration Department. Documents shall be checked by the pharmacists in that unit and if they meet all of the requirements , then the applicant shall be informed to pay the registration fee , the communication section shall accomplish documents checking within 21 days from submission of pharmaceutical product and 14 days for companies in order to assure that all necessary information is included in the submission.
- 3- Registrant shall pay the applicable fee within 2 weeks of notification from the communication section. Once the fee has been received, documents shall be transferred to the responsible section to be evaluated by the registration committees, if the applicant failed to pay the fee , the registration process shall be delayed pending payment .If the payment is not received within two (2)

months, the Registrant will be required to reapply.

4- Time required for evaluation from the date of full data submission is not more than one year for pharmaceutical products and not more than 90 days for companies.

5- Arabic and English are the accepted languages for the application forms.

6- Scientific data should be in English.

7- During the course of registration and whenever the committee required additional information from the Registrant ,such a request will be made in writing. The Registrant will have up to one year to provide the requested information otherwise the Registrant will be required to reapply.

8- Files to be submitted should be numerated and have a table of contents .

C/ Requirements for the registration of pharmaceutical companies

1- Company registration form to be filled in one copy signed and stamped by the person responsible on the establishment (appendix 3)

2- GMP certificate published by legalized official authority .

3- Copy of the CPP for at least two of its products released from one of the following authorities: (not required for companies producing general products)

- FDA (USA). Food and Drug Administration
- HPFB (Canada).Health products and Food Branch, therapeutic products Directorate.
- EMEA (EU or any of its countries). European Union, European Agency for the Evaluation of Medical products
- MHLW (Health authority of Japan) .Ministry of Health, Labor, and Welfare, pharmaceutical and Medical Safety Bureau
- GCC central registration in gulf countries

Other wise the company should be inspected by Registration Department

4- Certification letter regarding the boycott with Israel (i.e. Do not comprise any parts, raw materials, Labor or capital of Israeli origin) . It is acceptable to simply specify the country of origin for raw materials. (This certificate should be sign and stamp by the company itself.

5- Registration fee \$1000.

6- Marketing Distributor and companies that responsible for final packaging which do not have actual pharmaceutical manufacturer have No right to Registered

7- Multinational companies are required to register any of their subsidiaries, if they decide to supply any of their products from the said subsidiary .

D/ Requirements for the Registration of Medical Appliances, Disposables producing companies and Laboratory diagnostic kit manufacturers

1- Company registration form to be filled in one copy Signed and stamped by the person responsible on the establishment. (appendix 4)

2- Quality assurance certificate such as ISO 9001, 9002 or equivalent.

3- manufacturer registration certificate in the country of origin officially legalized .

4- Spread data sheet of the company products (catalogue)

5- Certification letter regarding the boycott with Israel.

6- Company registration fee \$ 1000.

Medical Appliances, Disposables products and Laboratory diagnostic kit, theirselves are not require to be register

E/ Pharmaceutical Products registration requirements

1- Registration form to be filled in one copy.(appendix 5) Should be stamped and signed by company.

2- CPP issued by the health authority of the country of origin of the manufacturer legalized officially: from Ministry of Health, Ministry of Foreign affairs and Iraqi Embassy in the country of origin of the manufacturer (including the number and date of registration and that the product is freely sold in the country of origin). e.g.: according to WHO form.

3- Product(s) of significant therapeutic and pharmaceutical value that are not marketed in the country of origin but available in other countries can be exempted from the country of origin stipulation through the submission of an

approval certificate from one of the following authorities (FDA, HPFB, EMEA, EU or any of its countries, MHLW or GCC.)

4- If the product is marketed in the country of origin in a trade name differ from that submitted for registration in Iraq, the company should mention that and explain the reasons for such change. with conformation of similarity in composition and other specifications.

5- Method of manufacturing in detail for the drug product

6- Specifications of the finished products certified by the Q.A./ Q.C. legalized from the health authority or other authorized firm responsible for this subject.

7- Certificate of analysis for the finished products.

8- Quantities and specifications of both active and non-active ingredients which should be according to the latest edition of either BP, Ep, USP, or Japanese .If the product is non- pharmacopoeial submit in-house specification .

9- Specifications of the packaging materials

10- List including countries where the item had been registered including number and date of registration.

11-In process and finished product Q.C. test methods along with the validation of that method unless the product is a pharmacopeial one.

12-Bioavailability or bioequivalence study (with a number of volunteers 18-24) for the following items: (see appendix 6)

13- A certificate stating that the gelatin and other components of animal source are

not of pork origin, and these components are free from contamination with BSE.(issued by the health authority of country of origin of raw material).

14-A certificate stating the safety of blood products from HIV.,HAV ,HDV , HCV.,

HBS, test control methods used to assure that individual blood and pooled samples are tested for the mentioned viruses ,should be submitted.

15-In addition to the above-mentioned requirements, firms producing oral liquid containing propylene glycol must submit a certificate that there is

no

contamination with diethylene glycol in the raw materials used in the production of

these products.

16-If alcohol is used in the formula, specify its percentage and state the reasons for

such percentage.

17-Any scientific studies (pharmacological, clinical, toxicological and antidotes

studies).must be submitted For new chemical entity drugs .

18-Stability studies derived from tests on the final dosage form in its final and marketed container and packaging. Data submitted are obtained from accelerated

study at least according to WHO requirements (3 different temp. for 3 batches

including real time study whenever its available) . Additionally , published and/ or

recently obtained experimental supporting stability data may also be submitted. (e.g.: On the stability of the active ingredients and related formulations).

* once the product has been registered, additional stability studies are required whenever modifications are made to the formulations manufacturing process, packaging or method of preparation.

* Firms must to submit the validated test method for stability studies (i.e. stability- indicating method) .

19-In case of manufacturing by contract whether importing the finished and packed , bulk products to be packed or semi finished to be processed and packed , the GMP certificate of the contract manufacturer of the relevant product is required.

20-In case of under license arrangement the applicant should submit an official letter from the mother company conforming its approval to export this item to Iraq .

21-For herbal products and food supplements (any product of plant or animal origin that may improve the welfare of health in human being without a known toxic or adverse effects) , all the mentioned above requirements are required except what is mentioned at number 12. and in addition to:

A / A certificate confirm that there are no dangerous side effects for the herbal products legalized by authorized firm responsible for this subject.

B/ Study including the chronic and acute toxicity of herbal products.

C / A certificate confirm that the herbs used in the formula of herbal product are free

from contamination, of radiation, and pesticides legalized officially .

22-Registration and analysis samples required are as stated in (appendix 7)

23- Companies who wish to register their products should submit all the requirements

for analysis (International reference standards for the active components and the

related substances). For non pharmacopoeia products submit enough active constituent(s) of working standard quality to conduct all required tests a minimum

of three times. Detailed method of analysis for this (these) component(s) should

also be submitted In addition to the required chemicals and equipments.

243- If there is more than one pack (individual pack, hospital pack) submit sample for

one and mentioned it in the registration form.

Samples of the primary label and outer carton must be in Arabic and English (if space is available) otherwise in English as follows:

Primary Label :

- Trade name and generic name
- Strength
- Quantity of Active Ingredient
- Route of Administration
- Storage Conditions
- Dosage form (tablet, suppository etc.)
- Manufacturers name and address
- Expiration Date
- Date of Manufacture
- Batch Number

Outer Carton:

All above listed requirements plus special instructions for use.

For non-prescription drugs mention the normal adult dose and pediatric dose (if

applicable) and the main indication .

Inner Leaflets :

Samples of inner leaflets (should be same as approved one in country of origin) including : (to be written in English and Arabic)

- Trade Name and generic name
- Strength
- Name and Quantity of active Ingredient
- Name and Quantity of Inactive Ingredient
- Dosage form
- Rout of Administration
- Dosing Information
- Manufacturers Name and Address
- Cautions
- Precautions
- Drug Interaction
- Indication
- Side Effects .
- Storage conditions.

25 For national pharmaceutical products , all the mentioned above requirements to be submitted except what is mentioned at no. 2,3 ,12.

26- Registration fee \$ 165 for each product.

* Registration fee for the national products is 2500 ID.

27-Re-registration is required after five years and ten years for national products

The re-registration requirements are as follows :

- 1- Sample of the finished product.
- 2- Cpp issued by the health authority of the country of origin of the manufacturer
- 3- Specifications of finished product .
- 4- Formula
- 5- Specifications of the active and inactive ingredients
- 6- A letter from the manufacturer company declaring that there are no changes made on the Formula , manufacturing method and the specification (active and inactive ingredient and finished product) . signed and stamped

by the manufacturer company.

7- Re registration fee \$100

The committee has the right to ask for any additional informations or documents about the product especially for those which where registered for long time .