SYMPOSIUM ON DRUG EVALUATION AND LICENCING

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Country Statement of Kuwait

by

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COUNTRY STATEMENT

KUWAIT

Dear Sir,

It is a great honour for me to attend this symposium in "Drug Evaluation" and to listen to different views from my colleagues in this symposium, especially from the W.H.O. consultants attending the symposium.

I hope that I will be able to apply the recommendations which will be issued in this concern, in my country as we are about to re-evaluate all the pharmaceutical preparations in Kuwait by applying a new registration system. This will help us to control both quality and quantity of pharmaceuticals in our local market.

I should like to inform you briefly about the structure and activities of the Drug regulatory authorities.

1. Pharmacy Section :

a) Headed by a chief pharmacist

b) 2 Assistants

b-1) one responsible for gov. hospitals

b-2) one responsible for gov. clinics and polyclinics.

Main task for these two:

Report to the head about the routine work, problems liable to be arising, shortage of personnel, discussion of technical points with the pharmacists in hospitals, clinics and polyclinics.

2. Inspection Section :

a) For private section

b) For govt. section

For Private Sector:

- Licencing of pharmacists.
- Licencing of pharmacists through committees under the heading of the Under-Secretary.
- Inspection of the pharmaceutical preparation, send samples to the Quality Control Laboratory where there is doubt.
- Check the narcotics, tranquillisers and localmarket consumption .

For Government Sector:

- Inspection of Government Pharmacies
- Cheek narcotics and tranquillisers in the specified books.
- Check the dispensed pharmaceutical preparation and send any suspected sample to the Quality Control Laboratory.

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3. Drug Manufacturing Plant:

Staff : Head
Production Manager
Production Controller

Sections: One for tablets and capsules
One for suppositories and skin ointments
One for syrup and suspensions.

It is a small unit manufaturing about 35 items for governmental use only. There is no in-process control, but now action is taken to establish it. Raw materials and some of the finished products are analysed in the Quality Control Laboratory for conformity with the authorized pharmacopea. The actual control will be seen properly when the quarantine area is going to be erected.

4. Quality Control Laboratory:

Staff : Head
Deputy

Activities:

- Analysis and control of imported pharmaceutical raw materials.
- Analysis and control of pharmacopoeal products manufactured by the Drug Manufacturing Plant.
- Analysis and control of drugs of M.O.H. submitted through tender committee.
- Analysis and control of pharmaceutical products about to be registered.
- Registration of Medicinal products and drugs which fulfil our registration requirements and sent it to the Preventive Department for Licencing.
- No medicines allowed to be used unless it is registered.

Up to this, I hope that I have successfully given you a brief statement about the Drug authorities and their activities in Kuwait.

Thank you.

Documents and Materials required for registeration a Pharmaceutical company or a Drug preparation .

1- Agency contract issued by the principals (Parent Company) .

2- Certificate of Registeration of the parent Company to manufacture and sell its products freely in the country of origin are issued by the Ministry of Health in that country . This document should also be certified us true by the Kuwait Embassy / Consulate in that country and when this is not possible, by an authorised Arabian Embassy / Consulate in that country .

3- A list of Pharmaceutical products required to be registered (3 Copies).

4- A free sale certificate for each product showing that it is allowed and released for sale in the country of origin .

5- A certificate of composition of the product giving in detail, the Chemistry of the active ingridient / ingridients in the product.

6- Detailed specificatiens and standards laid down by the manufacturer for each product together with its method of analysis in detail. when the product is the subject of a monograph in the Pharmacopoea it is sufficient to refer to the page, edition and name of the Pharmacopoea concerned; since it is issued in Arabic or English. If the Pharmacopoea concerned is not issued in an English or Arabic edition, a Photocopy of the page or pages refferring to product and an Arabic or English translation thereof required .

7- A certificate of sterility and absence of pyrogens wherever it is applicable for eye preparations, parenteral injections and antibiotics in its different dosage forms.

8- 3 samples of the product to be registered should be made availble to the Drug Quality Control Laboratory. This should be adequate to carry out analysis of the product according to the requirements of the specifications and method of analysis in (6) above .

9- When a new drug preparation or product is to be introduced into the market the following additional documents should be supplied :

a) Certification of registeration of the new preparation or product in the country of origin (number and date) .

b) Detailed Pharmaceutical and clinical reports of the product together with published papers in international journals as to the safety and clinical efficacy of the product .

c) Sufficient additional samples of the product to carry out all tests and assay, toxicity and clinical investigations in one of the state hospitals (Kuwait) .

10- Reference sample / samples of the active ingridient / ingridients te be used as standard in the assay of the product when these are not available with the W.H.O. or not mentioned in an official Pharmacopoea .

11- Stability studies in detail for all Pharmaceutical preparation .

12- Dissolution rate studies in detail for tablets and Capsules .

13- Bio - availability studies in detail when it is appliable .

14- Safety and Tolerance studies .

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