SYMPOSIUM ON DRUG EVALUATION AND LICENCING

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Country Statement of Egypt

by

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Different regulations governing pharmaceutical practice were present in Egypt in the twenties; but a complete law was issued only in 1941. The law was changed in 1955 when a more comprehensive law was issued and is still valid.

The 1955 law requires that a licence should be obtained for any pharmaceutical establishment, whether it is a pharmacy, drug store or factory. Each of these should be directed by a licenced pharmacist, and a pharmacist responsible for quality control should be present in each manufacturing firm.

Records are required to be kept in each firm and government inspectors are authorized to inspect and take samples for analysis.

Production: In 1963 the pharmaceutical factories in Egypt were nationalized. The small firms were closed and only larger ones remained. Certain foreign firms were given licence to open factories in Egypt, and the local production developed to cover 85 per cent of the consumption. The local factories produce their own brand products as well as several international products under licence. Several international firms are starting their activities at the present time. Apart from an American firm already starting production, a Japanese firm for large vol. parenterals and a Spanish firm for eye drops and ointments have been given licences.

Quality Control: It is required now that the head of quality control in each firm should be responsible directly to the chairman or head of the company. Analytical laboratories are present in each firm and final products are not released except after being accepted by the quality control.

On a central governmental level, the National Organization for Drug Control and Research (NODCAR) was established in 1976 to combine two previous set-ups namely the Ministry of Health laboratories and the Drug Research and Control Centre.

Samples are presented to NODCAR for analysis from:

1. New drugs submitted for registration.
2. Local pharmaceutical production for batch release or simply for checking.
3. Pharmacies.
4. The Customs where imported products should be accepted by NODGAR before release.

Inspection and sample collection is done by well trained inspectors from the Ministry of Health. Closer cooperation between inspection and NODCAR is being discussed, since the conditions of production are not yet related to laboratory results.

Registration of New Drugs:

Every product should be registered at the Ministry of Health authorities before being allowed on the market. Registration is valid for ten years and has to be repeated, if still needed, after that period.

The authorities require that an application should be submitted in several duplicates including complete formula, references, claims, toxicity studies, clinical studies, specifications and methods of analysis. The application does not at the present time require extensive information to be submitted, changes are being expected in the registration forms to require more data about chronic toxicity, bioavailability, degradation products and stability, etc.

If the drug is imported it is required that it should be accepted by the country of origin.

The registration fees are now nominal but will be increased in the near future.

Evaluation: Committees for evaluation of new drugs are present in the Ministry of Health, there are also several specialized sub-committees.

The committees study the files and the presented data, and may ask for further information if required. Clinical trials are often done by specialists in university hospitals or in other hospitals.

Laboratory investigation is done at NODCAR where specifications are revised and methods of analysis are verified. Apart from chemical and microbiological experiments, biological testing on laboratory animals may be repeated.

The policy of the registration committee has changed during the last few years and apart from efficacy and safety, the price and the presence of competititve local products are factors taken into consideration. The result of investigations done by control authorities in other countries is also taken into consideration. Factory inspection is not yet considered as an important parameter in new drug evaluation.