SYMPOSIUM ON DRUG EVALUATION AND LICENCING

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THE STRUCTURE AND ACTIVITIES OF THE DRUG REGULATORY AUTHORITIES IN THE SUDAN

by

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Up to 1962 Pharmaceutical Products were losely finding their way into the Sudanese market without restrictions,but soon after the emergence of the pharmacy and poisons Act 1963 and the impose of restrictive laws on registration, the free flow of pharmaceuticals into the country was checked.

In fact the Sudan now has strict and exacting regulations governing the importation, manufacturing, and sale of pharmaceutical products. Importation of products may take place only through approved parties such as agents and manufacturers.

The basic regulations governing the importation, registration and sale of pharmaceutical specialties, medicinal preparations and allied procuts are contained in The Pharmaceutical regulations which took effect in 1974.

The decrees of 1963 and the amended form 1974 make mandatory the registration with the board of pharmaceutical products sold in the Sudan. According to the law it shall be unlawful to manufacture, import, distribute, sell, offer for sale, receive for resale,purchase, administer, transport or possess any brand of drugs which has not been registered.

A person wishing to register any brand of drug shall file with the board an application in the prescribed form, filling in all particulars required and enclosing the following:-

(i) Ten Fully packed orignal samples of that brand of drug;

(ii) A copy of all claims made by the manufacturer for that brand of drug;

(iii) A full description of the clinical and other tests upon which the claims are based;

(iv) A registration fee for each product;

(v) Submition of a free sale certificate

(vI) Certificate of registration in other countries especially U.S.A. and European Countries

(vll) Certificate from the Health Authorities in the manufacturing country certifying that the firm is obliged with good manufacturing practice and in conformity with the W.H.O. recommendations. Failing to submit such a certificate, the reasons should be explained and send with the application.

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(vlll) Method of analysis and a certificate of analysis.

(lx) Method of manufacturing.

(x) Any other relevant information that the board may in any case require.

The board may register any brand of drug and issue a certificate of registration in the prescribed form subject to any restrictions the board may see fit to impose. It also may, for reasons to be stated in writing the board may refuse to register or refuse to renew the registration of any brand of drug or cancel the registration of any registered brand of drug, which is, in their opinion unsuitable for registration at the time.

A certificate of registration granted shall expire after 24 months, but may be renewed, on application for renewal being made in the prescribed form, accompanied by a renewal fee not later than 30 days before the expiry date shown on the certificate.