SYMPOSIUM ON DRUG EVALUATION AND LICENCING

EM/SYM.DRG.EVL.LIC./9 CYPRUS

Alexandria, 30 October - 2 November 1978

19 September 1978

A BRIEF STATEMENT ON THE STRUCTURE AND ACTIVITIES OF THE DRUG REGULATORY AUTHORITY IN CYPRUS

by

Mr E.I. Kkolos *

---

* Chief Pharmacist, Ministry of Health, Nicosia

A brief statement on the structure and activities of the drug regulatory authority in Cyprus

The Chief Pharmacist of the Ministry of Health is the officer responsible for the administration, organization and supervision of Pharmaceutical Services in Cyprus. He is also the Registrar of the Drugs Council and the Pharmacy and Poisons Board. At the Head Quarters he is assisted by the Inspector of Pharmacies and his assistants, the Secretary of the Tender Board and the Pharmacists responsible for the examination of the applications for the issue of manufacturing or marketing licences, and for the control of narcotics and psychotropic substances.

2. At present medical care in Cyprus is provided by the Public Health Services and the Private Sector.

Private Sector: The private sector provides medical care, including drugs, to about 50% of the population. Drugs used by the private sector are subject to registration under the Drugs (Control of Quality, Supply and Prices) Law No.6 of 1967.

For the manufacture or marketing of a pharmaceutical preparation, a manufacturing or marketing licence has to be issued by the Drugs Council.

The Drugs Council consists of:

(a) the Director-General of the Ministry of Health, ex-officio;

(b) the Government Analyst, ex-officio;

(c) the Chief Pharmacist, ex-officio;

(d) two registered medical practioners in the public service of the Republic, appointed by the Council of Ministers;

(e) one registered veterinary surgeon in the public service of the Republic, appointed by the Council of Ministers;

(f) two registered medical practitioners in private practice, appointed by the Council of Ministers;

(g) three pharmacists in private practice, appointed by the Council of Ministers.

The Director General is the Chairman of the Drugs Council. The powers and duties of the Drugs Council are exercised by the Chief Pharmacist who is also the Registrar.

The manufacturing licence is issued after the Drugs Council is being satisfied that the premises, personnel and equipment fulfil the requirements of good manufacturing practice. Cyprus agreed to participate in the

Certification Scheme on the Quality of Pharmaceutical Preparations moving in International Commerce.

A marketing licence for a pharmaceutical preparation is issued after the Drugs Council is being satisfied about the safety of the preparation and the valitidy of the submitted documents. The documents submitted should include information about the exact composition and purity of the preparation, clinical trials indicating the action and toxicity of the active ingredients, data about the dosage, indications, labelling and stability of the preparation and a Free Sale Certificate proving that the preparation is on free sale in the country of manufacture.

Together with the application for the issue of a marketing or manufacturing licence samples are submitted for analysis by the Government Analytical Laboratory.

Importation of non registered drugs in Cyprus is prohibited. Invoices are endorsed by the office of the Chief Pharmacist.

Applications for the issue of manufacturing or marketing licences are initially examined by the Pharmacists at the office of the Chief Pharmacist and then by two subcommittees, one for the veterinary drugs and the other for drugs for human use and then submitted to the Drugs Council for final approval.

Since 1971 there have been issued 47 manufacturing licences and 6,823 marketing licences but out of 6,823 only about 4,000 preparations are marketed.

In 1977, 23 applications for the issue of a marketing licence were rejected and 7 marketing licences were revoked.

Public Health Sector: The Public Health Services provide medical care free of charge, including drugs, to about 50% of the population in the non occupied by the Turkish army area.

The drugs used by the Public Health Services have been selected by the Drugs Committee of the Ministry of Health which consists of Specialist Doctors and Pharmacists. A catalogue of the approved drugs is distributed to all Doctors and Pharmacists of the Public Health Services. The number of Drugs in this catalogue is about 500 and is considered to satisfy the needs of the Public Health Services with regard to diagnosis, treatment and prevention of diseases. This catalogue is subject to revision every year.

Drugs are purchased by generic name, through tenders and have to be registered in Cyprus or freely sold in the country of manufacture. Each consignment of a Pharmaceutical preparation purchased by the Public Health Services is analysed by the Government Analytical Laboratory in order to safeguard good quality. Drugs

have to conform to the British Pharmacopoeia or European Pharmacopoeia specifications, or in case specifications are not laid down by these Pharmacopoeia to those prescribed in other official monographs.

Prescribing, use and issue of drugs is subject to control by the inspectorate branch of Pharmaceutical Services, of the Ministry of Health.

3. Control of Narcotic Drugs, Psychotropic Substances and Poisons.

Cyprus is a party to the Single Convention on Narcotic Drugs 1961, and the Convention on Psychotropic Substances, 1971.

Narcotics drugs and psychotropic substances are controlled under the Narcotic Drugs and Psychotropic Substances Law and Poisons under the Pharmacy and Poisons Law. The import and export licences and the quarterly and annual reports to WHO are prepared by the office of the Chief Pharmacist. Prescribing, issue and use of narcotic and psychotropic substances are under strict control by the inspectorate branch. It is considered that Cyprus has no problem of drugs abuse.