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DRUG CONTROL AND DISTRIBUTION IN HUNGARY¹

A CASE STUDY

CONTENTS

	<u>Page</u>
The drug supply system	2
Prescribing and drug availability	2
Pricing	3
Drug regulation	3
Criteria and mechanisms for drug registration	3
Labelling, packaging, information for prescribers, advertising	4
Training and education	5

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DRUG CONTROL AND DISTRIBUTION IN HUNGARY

The drug supply system

1. The organization and supervision of the Hungarian drug supply system are the responsibility of the Ministry of Health. The legal basis is furnished by Government acts, especially the Health Act of 1972 and its executive order 16/1972 of the Council of Ministers, decrees and regulations issued by the Ministry of Health, and the authority given to the National Institute of Pharmacy (NIP) in respect of all regulatory measures.
2. Drug manufacture is confined to licensed state-owned manufacturing companies, 75% of the drugs used in Hungary being supplied by those manufacturers. The export and import of pharmaceutical products are carried out exclusively by Medimpex, a joint trading enterprise of the state-owned manufacturing companies. It imports medicaments for domestic consumption.
3. There is just one drug wholesaler in Hungary, the state-owned drug distribution enterprise, GYOGYERT, which is under the direct supervision of the Ministry of Health. GYOGYERT is the key organization in the Hungarian drug supply system; all pharmaceutical products, manufactured in the country or imported, are distributed by it to the pharmaceutical centres and hospitals.
4. The management of community pharmacies is the task of the pharmaceutical centres of the county councils. There are 20 county councils and consequently 20 pharmaceutical centres in Hungary. These centres provide the administrative apparatus for the management and maintenance of the community pharmacies in the county as well as storage depots and analytical and galenical laboratories. Drug substances and medicaments produced by GYOGYERT are distributed by the centres. Pharmacies have the exclusive right to compound, dispense, and sell medicaments over the counter. Hospitals, all of them state-owned, receive their drug supply directly from GYOGYERT.

Prescribing and drug availability

5. Drug prescribing is exclusively reserved to physicians (the limited rights of dentists are regulated separately by ministerial order). The right to prescribe some specified medicaments is restricted to specialists (for example psychiatrists). Some other specified medicaments can be prescribed by any physician on the basis of a diagnosis established by a specialist. A limited number of medicaments can be prescribed and used for inpatients only.
6. The question of prescription drugs is decided by the Ministry of Health. The overwhelming majority of medicaments are prescription drugs. Except for narcotic drugs (including codeine), psychotropic substances and some other sedatives, drugs for parkinsonism, stimulants, antibiotics, glycocorticoids, and some others, prescriptions can be validated by the prescribing physician for three refills during a period of 90 days.
7. The number of medicaments exempted by the Ministry of Health from prescription is about 100. Their ingredients are considered to be relatively safe and they are used mainly for symptomatic treatment. The guiding principle in selection is that the population should have access to drugs for the treatment of any symptom that does not necessitate the immediate intervention of a physician. Examples of such drugs are minor analgesics, antipyretics, sedatives, antacids, antitussives, laxatives, antidiarrhoeal preparations, disinfectants, and antihæmorrhoidal

preparations. The dispensing of these non-prescription drugs is restricted to pharmacists, who must limit the quantity dispensed to a maximum of two weeks' supply.

8. Pharmacies can sell only medicaments, surgical dressings, specified herbal products, medicated food, some specified medical devices and health care products, veterinary medicines, and pre-mixes.

Pricing

9. The population in Hungary is entitled to medical care free of charge and to preferential treatment in relation to medicaments. In conformity with this principle there are no consumer prices in Hungary. At the moment of marketing a consumer fee, that is, the amount actually to be paid by the patient, is established by the Ministry of Health. For the establishment of the consumer fee the Ministry is guided by the principle that the population's contribution should cover 15%-20% of the real cost, this principle being applied in general to all drugs. The actual price of individual medicaments is based on health and social need considerations. Some medicaments (e.g., for diabetes, tuberculosis, epilepsy) are free of charge and so, like hospital treatment itself, are drugs used in hospitals. The actual consumer fee varies between 3 and 10 Forint (at present 50 Ft = 1 US\$).

10. The difference between the manufacturer's price and the consumer fee is covered by the Government.

Drug regulation

11. In Hungary the National Institute of Pharmacy is the national drug regulatory agency. Its main responsibilities are as follows:

- selection of materia medica
- authorization of clinical trials in man with substances not previously used as medicines in Hungary
- drug registration
- supervision of drug production and manufacture
- drug regulation, including removal of unsuitable pharmaceutical products from the market
- study of drug utilization and updating of drug therapy
- supervision of drug information and monitoring of adverse drug reactions
- fulfilment of responsibilities within the context of international obligations for cooperation.

Criteria and mechanisms for drug registration

12. Hungary has a selective drug registration system, i.e., pharmaceutical preparations containing the same active ingredients in the same drug dosage form under different brand or generic names are in principle not registered.

13. In Hungary the NIP is authorized by the Ministry of Health to decide, on the basis of the results of pharmacological, toxicological, and clinical tests and following consultations with experts, whether or not the marketing of a new drug meets a health need. The aim is to provide the medical profession and the public with new pharmaceutical preparations of proved therapeutic value and at the same time to avoid the circulation not only of medicaments of doubtful therapeutic value but also of different but practically equivalent medicaments and unnecessary drug combinations. Through the existing selection system the number of registered preparations has been kept under reasonable limits. Other criteria for drug registration are standardized constant quality, relative safety, and efficacy.

14. The process of registration starts with the submission of preclinical data by the manufacturer to the NIP. All the requirements for such data are prescribed by the Institute. The data are scrutinized by the specialized staff of the Institute and evaluated with the aid of outside experts and expert committees. The outcome of a positive scrutiny and evaluation is a decision authorizing clinical pharmacological research in man. Unauthorized human experiments and the supplying to doctors of unauthorized new drug samples are prohibited.

15. Clinical pharmacological tests on man are carried out by specialized units of the Clinical Pharmacological Network, located in clinics and large hospitals. The results are evaluated by the NIP and outside expert committees. In the light of the results a decision is made whether or not to authorize clinical trials.

16. Controlled clinical trials are authorized by the NIP. The first investigators are designated by the Institute, an extension of clinical trials granted after evaluation of the first results by an expert committee. Extension must be requested by the manufacturer. Clinical trials of new non-registered drugs cannot be carried out without the authorization of the NIP.

17. Evaluation of the clinical results by expert committees and formal approval of the therapeutic suitability of the new drug by the NIP are a prerequisite to registration. The manufacturer must submit his application for registration to the NIP. The format for the presentation of chemical, analytical, dosage, and biological data, the proposed control methods, the description of stability tests, etc. is prescribed in detail by the NIP. All the data are carefully evaluated and checked experimentally in the NIP's laboratories. At the time of registration the official quality specification of the drug preparation is established by the NIP.

Labelling, packaging, information for prescribers, advertising

18. Advertising pharmaceuticals to the general public is strictly prohibited in Hungary. The sources of information on drug use are different for patients and for practitioners. Information for patients is contained in labels and package inserts. Registration of a pharmaceutical preparation also includes prescription of the text of the label by the NIP and approval of the text of the package insert.

19. Information for practitioners is contained in leaflets, brochures of the manufacturer, and advertisements in medical and pharmaceutical periodicals intended for health professionals exclusively. The pharmaceutical industry must send information to every physician and pharmacy on each new drug at the time it is marketed. Authorization by the NIP is required for the texts of the leaflets and brochures mentioned and for the advertisements published in medical or pharmaceutical periodicals.

20. There is no sales representative system in Hungary. The manufacturers are authorized to maintain person-to-person contact solely with clinicians conducting clinical trials with their products.

21. The NIP's own drug information services comprise publications and management of the network of pharmacists specialized in drug information.

22. A small book, Guide for drug prescribing, containing all the necessary information on the Hungarian materia medica (composition, indications, contraindications, doses, side-effects, interactions, etc.) is published every two or three years. A periodical is also published and distributed free of charge; it contains information on new drugs, new indications, etc.

23. About 50 pharmacists working in pharmacies are trained by the NIP in drug information. They work in different parts of the country as information centres for physicians and pharmacists. They are independent of the pharmaceutical industry, consequently the lectures and information they give are objective and completely free of commercial bias.

Training and education

24. Pharmacists are trained in the pharmaceutical faculties of two medical universities, one in Budapest, the other in Szeged. Organization of the postgraduate education of pharmacists is the task of the department of pharmacy of the postgraduate medical school, which is based on the NIP. Postgraduate training covers 12 special branches of pharmacy.

25. Pharmacy technicians are trained in special secondary schools. Their postgraduate education is also organized by a special school.

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