Middle Articles

CONTEMPORARY THEMES

Legislation on Medicines

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Ever since the first *British Pharmacopoeia* was published in 1864 Governments in this country have been active in establishing standards for the purity and strength of medicines and in preventing their adulteration and misdirection in such a manner as to deceive the public. Various Food and Drug and Therapeutic Substances Acts have provided considerable legal protection for the population in those respects, and the Cancer and Venereal Diseases Acts and the Pharmacy and Medicines Act 1941 prevented the deception of the public by advertisements of quack nostrums for the treatment of serious disorders. Lastly, various Poisons Regulations and Dangerous Drugs Acts, which among other things prohibited the sale over the counter of certain drugs without a prescription, were so successful that, till recently at any rate, the incidence of addiction to potent narcotics and other psychotropic drugs in this country was so rare as to be a matter of almost incredulous envy in other parts of the world.

This mass of legislation was achieved within the context of a bewildering number of statutes, while the multiplicity of organizations with varying degrees of authority over medicines—some reporting to the Home Office, others to the Ministry of Health, the Board of Trade, the Ministry of Agriculture, the Privy Council, and so forth—made our legislation on medicines somewhat chaotic and in need of consolidation. Further, till 1968 no statute in the United Kingdom required the premarketing approval of medicines on the grounds of their safety, and anyone could market any product no matter how inadequately tested or dangerous without seeking an independent official opinion regarding its safety and the adequacy of the conditions under which it was produced or stored.

Safety of Drugs Committee

Following the thalidomide disaster the Health Ministers, on the advice of a subcommittee under Lord Cohen of Birkenhead of the Standing Medical Advisory Committee, established the Safety of Drugs Committee in 1963 as an interim measure until comprehensive legislation on medicines could be enacted and become operative. The Committee constituted an entirely voluntary arrangement and was official only in the sense that its members were appointed by the Health Ministers who also provided its finance, accommodation, and secretariat. Despite the complete absence of legal sanctions (there were, it is true, some strong unofficial ones) the Association of the British Pharmaceutical Industry and the Proprietary Association of Great Britain promised, before the Committee started to function on 1 January 1964, that their members would not submit for clinical trial or market a new drug against its advice. This promise was loyally observed.

The Committee had three subcommittees: that on toxicity evaluated data derived from studies on animals and healthy human volunteers, determining whether the evidence justified testing the drug on patients; that on clinical trials assessed

the evidence from such trials to establish the drug's safety for marketing; and that on adverse reactions monitored the undesirable effects of the drug after marketing. These subcommittees reported to the main Committee which took all ultimate decisions and notified the firms whether there was any objection to the marketing or clinical trial of a drug for the purposes proposed.

So far as possible the Committee attempted to solve problems by voluntary compliance and mutual agreement and owing to the co-operation of industry this seemed to work reasonably well and with a minimum of procrastination. It might therefore be asked why the Government should have sought to effect through legislation what was being accomplished satisfactorily through the Committee's voluntary arrangements with the pharmaceutical industry. There are however, many reasons for the new legislation which seeks to encompass far more than the limited functions of the Committee on the Safety of Drugs.

The Medicines Act

The Medicines Act 1968 was based mainly on the White Paper "Forthcoming Legislation on the Safety, Quality and Description of Drugs and Medicines" of 1967. In brief, the Secretary of State for Social Services and the Minister of Agriculture were to act as a licensing authority to issue licences governing the marketing, importation, and manufacture of medicines for human and veterinary use.

Medicines Commission

The Act also established a Medicines Commission (which is not the Licensing Authority as is sometimes erroneously thought) to be an advisory body to the Ministers on the broad aspects of policy regarding medicines and to direct the preparation of the *Pharmacopoeia* by the British Pharmacopoeia Commission, hitherto the responsibility of the General Medical Council. The Medicines Commission is required also to advise the Ministers on the numbers and functions of expert committees to be established under the Act, particularly for the purposes of preparing the *Pharmacopoeia* and for giving advice on the safety, quality, and efficacy of medicinal products. With the exception of the British Pharmacopoeia Commission such committees are not subject to direction by the Medicines Commission. The latter, however, will act as an appeal tribunal should an appeal be made against any adverse advice given by a Safety Committee to the Licensing Authority, and its recommendations on appeal will doubtless establish precedents to which the expert committee will probably take heed subsequently. Thus the Act envisages the Commission not as the ordinary direct source of advice on licence applications but as a body with wide advisory functions in relation to general policy, and as an appeals court in licensing disputes about considerations of safety, efficacy, and quality.

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The members of the Commission were appointed by the Ministers after consultation with interested organizations and, apart from the Chairman, they consist of four medical men, two veterinarians, an expert on animal nutrition, two pharmacists, a chemist, two members of the pharmaceutical industry, and a stipendiary magistrate, who is the present chairman of the Poisons Board.

The Sainsbury Report†, which dealt primarily with issues of drug economics, was published after the White Paper on which the Act was based. Nevertheless, a major addition to the Act resulted from the Report in that powers were given to the Medicines Commission, which were not included in the White Paper, to initiate the production, in addition to the *Pharmacopoeia*, of other compendia and information about medicines.

Licences

The requirements of the Act involve the licensing of manufacturers, wholesalers, and the persons responsible for the composition of the medicine or the importers of it. Questions of price and comparative efficacy (unrelated to safety) are ruled out by the Act as considerations for refusing a licence. Licences of Right refer to products already on the market before the commencement of the licensing system, and these do not have to be appraised for safety or quality. Licensing control operates at the manufacturing and wholesale level but not at the retail level, and the details are unlikely to interest most doctors.

Committee on the Safety of Medicines

Apart from the slight change in name and some variation in personnel the procedures to be followed by the statutory Committee on the Safety of Medicines in relation to the licensing of new medicines are similar to those previously undertaken by the voluntary Committee on the Safety of Drugs, and it will advise the Licensing Authority on matters of safety, efficacy, and quality. If the Licensing Authority proposes to give an adverse decision the applicant for the licence has the right to be given reasons for the decision and to appeal to the Medicines Commission. There are other elaborate safeguards, which did not exist under the old voluntary system, to ensure that medicines will not be withheld from the market except on proper grounds.

Relationships of the Medicines Commission and other bodies.

The Safety Committee may with the approval of the Ministers appoint subcommittees either alone or jointly with other expert committees. As the responsibilities of the new

Safety Committee will be greater than those of the old one, its subcommittees may be more numerous. They have not yet all been determined, and some of those indicated in the Figure are conjectural.

Veterinary Products Committee

The only other expert committee, besides the Pharmacopoeia Commission, which has so far been appointed on the advice of the Medicines Commission has been the Veterinary Products Committee, which is the counterpart of the Committee on the Safety of Medicines and will advise on the corresponding aspects relative to veterinary medicines. The two safety committees will need to maintain close links particularly in relation to antibiotics, in respect of which the Medicines Commission has made a strong recommendation for the establishment of a joint subcommittee.

Advertising and Promotion

The Act replaces the provisions of the Pharmacy and Medicines Act of 1941 in relation to advertising and promotion, whether directed to practitioners or to the public. The Act requires that any promotional material must be consistent with the terms of the product licence, and this must be preceded or accompanied by a data sheet setting out the essential facts in an objective and standardized way. It is envisaged that the Committee on the Safety of Medicines will approve the design of data sheets and the particulars to be included. This will give the Committee considerable powers to ensure that indications, contraindications, and possible adverse effects are plainly and concisely brought to the prescriber's notice.

General Sales List

A considerable part of the Act dealing with retail sale and supply consists in rewriting and consolidating previous legislation, but there has been an important change of emphasis and method regarding its control. The old law permitted any medicine to be sold at any shop unless it contained a substance in Part I of the Poisons List or Part II of the Therapeutic Substances Act of 1956. The new Act provides that all medicines except those appearing in a General Sales List shall be sold only from registered pharmacies. Other requirements relating to the sale and supply of medicines under poisons and therapeutic substances legislation will be replaced by orders and regulations under the Medicines Act. The separation of medicines from the poisons legislation, the establishment of the General Sales List, and the question of a committee to deal with these matters will be put to the Commission later.

Implementation

When the Royal Assent was given to the Medicines Act Ministers concluded that it would be impracticable to bring the whole Act into effect at the same time and that it would be desirable to start with the parts of greatest importance and urgency, leaving the remaining provisions till later.

Implementation of the Act fell naturally into two stages. Some parts of the programme of stage 1 have been started already: the Medicines Commission has been established; the B.P. has been taken over and a new British Pharmacopoeia Commission appointed; the Safety of Medicines Committee has been convened and a corresponding Veterinary Products Committee; a good deal of preparatory work has been done on regulations which will have to be made in connexion with licensing and the separation of medicines from the poisons law. To secure a smooth transition on the "first appointed day" arrangements are being made to deal with advance

†Report of the Committee of Enquiry into the Relationship of the Pharmaceutical Industry with the National Health Service, 1965-1967 (Chairman, Lord Sainsbury), Cmnd. 3410. London, H.M.S.O., 1967.

applications for licences. It seems unlikely that these dates can be achieved before the early part of 1971.

The second stage of the Act for implementation will involve a review of Licences of Right, a possible control of medical and veterinary devices—ligatures, dressings, implants, and so forth—and the possible initiation by the Medicines Commission of publications other than the *British Pharmacopoeia*.

Mr. Kenneth Robinson, the Minister of Health who introduced the Act, seemed determined to preserve the spirit of co-operation which characterized the previous Safety of Drugs

Committee. There is indeed no reason why communications between doctors and the medical staff of the new Safety Committee and its subcommittees should not be as flexible and informal as they have been under the voluntary system, or why applications from firms should be handled less expeditiously. Any legislation must provide for offences, legal proceedings, and penalties, but with co-operation and mutual confidence such proceedings should be most exceptional, and as the new arrangements develop doctors should find them beneficial and helpful and in no way hampering to their clinical freedom.

Chronic Disease and Disability in the Community: A Prevalence Study

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Summary: A two-stage prevalence survey of disability (defined as the inability to perform unaided defined activities essential to daily life) used questionnaires on a random sample of the population living in north Lambeth. The central estimates of the prevalence of disability in those aged 35-74 are 7.2% for men and 9.7% for women. Among the disabled population locomotor impairments were more common in women; internal impairments were more common in men. For men and women together chronic respiratory disease, mainly bronchitis, was shown to be the single most common condition associated with disability.

Though for women there may be an association between low social class and disability and between marital break-up and disability, these associations, though statistically significant, are weak. The data are therefore considered to be more widely relevant for the planning of health and welfare services.

Introduction

There are many difficulties in estimating the prevalence of chronic disease in a population. As Katz *et al.* (1969) point out, it is a group of many diagnoses, and multiple pathology results in different combinations of diseases, different patterns of complications, and combinations of diseases in different stages of severity. Lack of knowledge of the natural history of many chronic diseases makes definition and measurement difficult. Most chronic diseases, however, result in some disability and dependence, so it is possible to estimate the burden of chronic disease in a community by measuring the prevalence of disability. At the same time attempts may be made to screen the population for the presence of certain definable diseases associated with disability.

Little information on the prevalence of disability is available. For this reason and because of the increasing importance of chronic non-communicable disease in middle and old age as a cause of morbidity, it was decided to estimate the prevalence of disability in the catchment area of St. Thomas's Hospital to facilitate planning of health and welfare services.

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Definition and Measurement of Disability

We define disability in functional terms as limitation of performance of one or more activities essential to daily living, such that the person is dependent on others, and severity of disability is proportional to dependence. Essential activities are (1) mobility: walking, negotiating stairs, transfer in and out of bed or chair, and travel; (2) self-care: feeding, dressing, and toilet care; (3) domestic duties: shopping, preparation and cooking of food, household cleaning, clothes-washing, and/or (4) occupation: the ability to hold unmodified employment in open industry appropriate to the individual's age, sex, and skill.

For the anatomical, pathological, and psychological disorders which may cause or be associated with disability we use the term impairments. These may be classified into four categories: those affecting locomotion or any motor activity; those of sensory origin; those referable to internal medicine—for example, cardiac and respiratory disorders—and those of primarily psychological origin together with unclassifiable organic disorder.

There are three main methods by which such disability can be identified and measured: by clinical assessment of performance, by standard tests of performance conducted by a trained observer, and by detailed questioning of the person by a trained interviewer about his level of daily performance. Comparison of the three methods suggests that the interview is the most reliable, and it has obvious administrative and practical advantages for a large-scale survey conducted in the respondents' homes. We therefore developed and validated an interview schedule, details of which will be published separately.

Method

The study was based on a two-stage sampling design. In July 1966 a private census of a 20% random sample of dwellings in the six northern wards of Lambeth was undertaken and each enumerated person born before 1 January 1951—that is, aged 15½ and over—was asked to complete a short self-administered questionnaire. This contained 15 questions, of which 10 related to disability and impairment, each requiring a "yes" or "no" answer. Four questions asked whether the respondent could perform four essential activities of daily living without help, and a fifth whether there were limitations in any daily activities. Five questions inquired for selected physical impairments which might seriously affect locomotor activity and be associated with disability. The remaining five questions concerned personal and occupational data.