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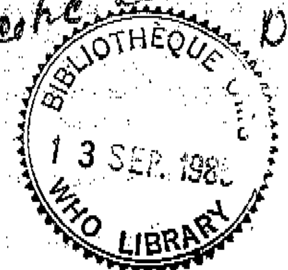

DRUG CONTROL AND DISTRIBUTION IN NORWAY[1]

A CASE STUDY

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[1] The Director-General acknowledges with appreciation the contribution of this case study by the Government of Norway.

DRUG CONTROL AND DISTRIBUTION IN NORWAY

Introduction

1. The basic aim of a drug policy is to ensure that effective and safe drugs of good quality are available to cover the health needs of the country. A national drug policy should be considered as an integral part of any comprehensive health care policy. The formulation of national drug policies varies even between similar countries because of conflicting interests and different political, economic, and social pressures. It is influenced by such factors as:

- the health situation of the country
- the medical care system
- the education and training of health personnel
- the social security and health insurance schemes
- drug research and development possibilities
- the domestic production of drugs
- the determination of the demand for drugs
- the system of drug distribution
- the possibilities for evaluation and control of drugs
- international policies on medicinal products.

2. The implementation of a national drug policy requires a national drug control system. Drug control in all its aspects is a basic element in a rational drug policy, and a well functioning drug regulatory agency is a major instrument in implementing control.

3. Some drug control functions are listed in Fig. 1.

Selection of drugs

4. Since 1928 quality, safety, efficacy, and cost requirements have formed the basis for drug evaluation and registration in Norway. Some 10 years later the concept of need was included. The present criteria for selection of drugs are summarized below:

- selection should be based on scientific documentation
- the efficacy/toxicity ratio must be weighed against the severity of the disease
- new drugs should represent better therapeutic alternatives than those already on the market
- drug combinations should be avoided unless the combination shows a clear advantage over that of each ingredient

- there should be a clear-cut medical need for any new product
- the number of drugs should be limited
- approval should be given for a limited period (5 years)
- the drug may be restricted to the use of hospitals or specialists

Additional criteria are price, local therapy traditions, etc.

The need clause

5. The assessment of needs forms the basis of most evaluations of programmes, products, or personnel. If there is no need to be met, there is usually no reason for determining the merit of a drug. This is obvious enough in a product or programme evaluation, but less true in other areas, e.g., aesthetic evaluation.

6. The term "need" may be defined in different ways and may differ from time to time and from one community to another. What is considered a dietary need in Norway would be regarded as somewhat of a luxury in many other parts of the world. The definition of need is a matter of considerable controversy, and even if we use a loose definition we shall almost certainly have to distinguish between needs and wants because we must rank for urgency.

7. According to the Norwegian regulations a pharmaceutical speciality must be medically justified and be considered to be needed. As the term "need" has not been defined more precisely, the registration board has had to establish its own practice. By using the need clause, the number of similar preparations and synonyms has been limited. By allowing some synonyms, price competition as well as the supply of drugs have been ascertained. Medical need has been used to avoid the registration of too many combinations.

8. A study of decisions taken by the Specialities Board during the years 1981-1983 shows that approximately 40% of applications are rejected. Need considerations are involved in more than 60% of the rejections. One striking effect of the assessment of need is the limited number of drugs on the market: about 1100 different drugs (1950 including different dosage forms and strengths of drugs) are registered in Norway compared with 10 times that number in some other European countries. The number of drugs is probably also influenced by the small size of the Norwegian drug market.

Fixed combinations

9. When rationally formulated, combination drugs may provide greater convenience, cost less and sometimes confer greater therapeutic efficacy. However, when formulated solely for commercial purposes without regard to therapeutic principles, combination products are at best fraudulent and at worse dangerous.

10. The Norwegian policy has been based on some essential requirements:

- each component should make a contribution to the claimed effect
- a component may be added to enhance the effectiveness or safety of the active ingredient to minimize the potential abuse of the ingredient

- the components should have approximately the same half-life and duration of action.

In addition, a patient population of reasonable size should benefit from the combination. The limitation of the number of fixed combinations has been made possible by using the need clause.

11. Reasons advanced for the limitation of the number of drugs are simplicity, safety, and economics. The physician has the possibility of working with an armamentarium he can keep in mind. In the distribution chain both the wholesalers and the pharmacies can keep a limited number of drugs in stock. No unneeded preparations clutter the shelves. The total drug bill is kept down to a reasonable level.

12. By including the need clause in the Norwegian legislation some 40 years ago, a social dimension was introduced into drug policy at a very early stage. Drugs were not only assessed from a scientific or technical point of view but also in the light of health priorities and the delivery of health care to the population as a whole.

13. The WHO approach on essential drugs corresponds very well with this way of thinking. The report on the selection of essential drugs is of importance not only to developing countries but also to developed countries. The Norwegian registration policy has for several decades demonstrated that it is possible to limit significantly the number of drugs on the market without detrimental effects on patients.

Advertising

14. In Norway all advertising, price lists, catalogues, etc. must be approved before use. This provision applies to advertising both to the public and to physicians. Advertising must be moderate and objective, not give a misleading or exaggerated impression of the product's medical value, and not be so formulated as to encourage unnecessary or non-medical use of the product. Any advertising of non-registered specialities or of drugs included in the Pharmacopoeia or approved formularies is prohibited.

15. Advertising of drugs to the public is permitted only for non-prescription drugs and on certain conditions. Drugs may not be advertised on radio or television or in cinemas, public premises, or streets or roads.

16. Advertisements to physicians, dentists, and veterinarians must contain only generally approved indications. Quotations, curves, etc. from medical literature should be adequately reproduced with a complete indication of the source. The advertising must state the composition of the product, the contraindications, and the most important side effects. If a generic name exists, it must be clearly indicated. There are also strict rules on the distribution of samples.

17. The pharmaceutical industry spends a substantial amount of its budget on marketing. During recent years it has put more stress on the use of manufacturers' representatives in its promotional efforts. It commonly arranges symposia and smaller product-oriented meetings in hospitals and pharmacies. Another trend is the extensive use of new technical equipment such as video cassettes.

Information

18. To counteract the promotional activities of the pharmaceutical industry, various initiatives have been taken to produce prescriber-oriented information from sources independent of the producers such as:

- drug information bulletins
- drug sheets for new drugs
- comprehensive therapy-oriented booklets for all major therapeutic classes and problems
- therapy-oriented drug formularies giving comparative criteria for selection by the prescriber
- national and local (clinical pharmacology and hospital pharmacy units) drug information centres
- drug information to the public (pamphlets, books).

19. In Norway a distinct academic institute, the Institute of Pharmacotherapy, was established at the University of Oslo as early as 1964. In addition to its academic staff the Institute has a network of some 10 therapy groups. Literature on relevant drugs and their use can be obtained through the Institute, and 4-6 pages of digested information are published as therapy letters in most issues of the Journal of the Norwegian Medical Association.

Pricing

20. Norwegian price control covers all categories of pharmaceutical preparations, both prescription and non-prescription drugs. Price control seems rather comprehensive compared with the situation in other European countries. According to the Norwegian legislation the price of a pharmaceutical speciality shall not be "in disproportion to its value". The cost of a drug should be set against its direct or indirect benefits compared with alternatives. Data on these matters are scarcely available in optimal form, most countries appearing to adopt an arbitrary approach. In Norway price consideration is an integral part of the registration procedure. Negotiations are conducted with the manufacturer to agree upon an acceptable price. Prices of new products are compared with the prices of similar products on the market and with the prices charged in other European countries, particularly in the country of manufacture.

21. It is less difficult to judge whether a price increase is reasonable. In many countries the authorities have concentrated on this kind of control. In recent years the Norwegian public health authorities and the pharmaceutical industry have developed models for price adjustments. In these formulas inflation, changes in exchange rates, etc. are taken into account.

22. Measures need to be taken to obtain a greater insight into the cost of developing, producing, and marketing drugs. A greater degree of openness on these issues could lead to more equitable policies.

Distribution system

23. In establishing a pharmaceutical service one of the basic requirements must be that patients have a safe and reasonable access to medicines, appliances, and other goods for medical use. This implies a sufficient number of pharmacies, an even geographical distribution, opening hours according to the patients' needs, an adequate stock of medicines, and enough qualified personnel. In most European countries the geographical distribution of pharmacies is controlled.

24. All the Scandinavian countries have a rather high population/pharmacy ratio. However, it is always dangerous to use averages. On the face of it, in countries with a low population/pharmacy ratio the public has more convenient access to a pharmacy. This may not necessarily be true. Where there is no control over the establishment of new pharmacies it may well be the case that the population per pharmacy in the highly populated areas is substantially lower than the figures indicate and that the pharmacies in less densely populated areas serve a much larger number of people spread over a wide geographical area. Within the 19 provinces of Norway the population per pharmacy varies from 20 000 in certain rural areas to 10 000 in the Oslo area.

25. The Directorate of Health decides whether pharmacies shall be established or closed. They are established when it is desirable or necessary from the point of view of the public. The Board of Health or the local authorities are responsible for raising the question of establishing a new pharmacy when there is a need for it. The decision to open a pharmacy is based on such considerations as population per pharmacy, distance between pharmacies, and transport facilities. There are more than a few pharmacies in Norway that do not have enough business to make them profitable. Nevertheless, they must be maintained for the doctors and people of small isolated communities who would otherwise be put to no end of delay and trouble to get medicines. Here private enterprise would fail if social control was not exercised. To keep these pharmacies going the Government has set up a tax system that evens out the inequalities of income stemming from either better or less favourable locations.

26. The system of tax and subsidies is of fundamental importance for the operation of Norwegian pharmacies. The Parliament imposes the tax each year. The tax is progressive and is calculated on the basis of the annual turnover of the individual pharmacy. The greater part of the tax is used to subsidize pharmacists whose profit patterns are not satisfactory. The subsidies are not granted automatically, but only after consideration of the accounts, especially with respect to wholesale costs, the cost of wages, and depreciation. If the costs are within acceptable limits, all pharmacists may rely on making a reasonable livelihood.

27. The wholesale distribution of pharmaceutical products in Norway is carried on by a state monopoly, Norsk Medicinal Depot (NMD). The main premises of the NMD are in Oslo; branch depots have been established in three other regions of the country. Although pharmacies may vary widely in size and many are situated at a great distance from the nearest branch depot, the prices charged are the same, irrespective of the quantity ordered or the delivery distance. All orders are processed with the aid of computers, and the computing unit provides drug statistics for administrative, scientific, and other purposes.

28. Part of the net income of the NMD is used for supporting the Institute of Pharmacotherapy, which provides the medical profession with information on drugs. It is also used to support clinical pharmacological research. The NMD also pays transport costs from the pharmacies to the patients.

29. Towards the end of 1984 there were 263 pharmacies in Norway, with a few branch pharmacies linked to larger pharmacies. The sale of medicines is generally restricted to pharmacies only, but to meet the needs of the public in some areas, mainly areas where the population is insufficient to support a pharmacy, sales from other nominated outlets are permitted. These 1300 outlets are subject to control by a pharmacy, and only prescription medicines are distributed from them. All the Scandinavian countries operate this system of distribution. The policy of restricting to pharmacies the right to sell medicines reflects recognition of the important protective role played by pharmacists in health care. The public accepts this pattern of medicine distribution.

30. In addition to dispensing prescriptions, the pharmacist sells medical products, dressings and surgical appliances, and other health and hygienic preparations. More than 90% of sales consist of pharmaceuticals; the other products account for less than 10%. The items that may be sold in a pharmacy are restricted; such things as photographic goods, optical goods, or hearing aids are not available from Norwegian pharmacies.

31. The Norwegian pharmaceutical service is characterized by its exclusively professional nature and the very strict government control over both professional and economic matters.

Drug utilization

32. When the NMD was established a unique opportunity arose for obtaining data on the overall sales of pharmaceutical specialities and raw materials. Since the start of the NMD's operations an integrated on-line computerized system for drug purchasing, sales, invoicing, and stocktaking has been gradually developed. The NMD has also paid attention to the medical advantages of having convenient drug sales and utilization statistics.

33. A drug classification system has been developed. This system - the ATC Classification System - is based on the same main principles as the International Marketing System anatomical classification system, extended to include chemical groups and substances.

34. As part of an international collaborative effort the NMD has also contributed to developing a convenient methodology for establishing comparable drug statistics within and among countries. For this purpose a "defined daily dose" is used as a unit of comparison. A complete list of daily doses for all drugs given for systemic use in Norway has been available since 1975. Such daily doses have now been defined for most of the drugs registered in the Nordic countries. With the data for drug sales in terms of defined daily doses per unit time and population, it is possible to estimate roughly the number of patients being treated with a drug or group of drugs within the country or region. Another advantage of using this unit of measurement rather than a monetary unit is that the unit is independent of price and currency variations with time and among countries.

35. Drug utilization data may be used for the following purposes:

- to describe patterns of drug use
- to look at the development of therapeutic profiles with time
- to make rough estimates of the number of patients exposed to various drugs

- to measure the effects of educational, information, and regulatory efforts, price policies, etc.

- to define areas for further investigations of the efficacy and safety of drug therapy

- to indicate overuse, underuse, misuse, and abuse of drugs

- to estimate drug needs in terms of morbidity patterns, thus aiding in the planning of drug selection, supply, and distribution.

Drug utilization data should be part of the material that drug policy discussions are based on.

36. A detailed monitoring system for drugs covered by the Single Convention on Narcotic Drugs makes it possible to follow the prescribing pattern down to each single drug, doctor, and patient. This system has proved useful in the control of such drugs. The number of prescriptions for narcotic drugs issued in outpatient facilities decreased substantially in the period 1970-1980.

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Comments and conclusions

37. How can we promote the rational use of drugs? The problem is complex and heterogeneous. From a global perspective the level of sophistication in the developed countries may appear irrelevant to the needs of the less developed countries, where the major problem may still be a desparate lack of proper facilities, including professional manpower at most levels, money, and even the most important drugs. To what extent can we assist and give advice to others on the basis of our own experiences? To what extent are our criteria for the evaluation of drugs generally valid?

38. The Norwegian criteria for registration of drugs have been much discussed, especially the medical need requirement. By including the need clause in the Norwegian legislation some 40 years ago, a social dimension was introduced into drug policies at a very early stage. Drugs are assessed not only from a scientific or technical point of view but also in the light of the health care of the population as a whole.

39. The WHO approach on essential drugs corresponds very well with the Norwegian approach to drug registration. The report on the selection of essential drugs is of importance not only to developing countries but also to developed countries. The Norwegian registration policy demonstrates that it is possible to limit the number of drugs on the market significantly without detriment to the patients.

40. In examining the solutions in various countries, one must give consideration to the historical development of health care, geographical conditions, and other factors which may have considerable influence. While Norway has one of the largest territories of European countries, it is one of the most sparsely populated, with only four million people. The southern part of Norway reaches as far south as the northern tip of Scotland. The northernmost tip is found at 71°12N, that is about 1000 km further north than Anchorage, Alaska. About one-third of the territory, with one-twelfth of the population, lies north of the Arctic Circle. Providing a good pharmaceutical service to the whole population under such conditions may

require special arrangements, e.g. as regards the remuneration of pharmacists. The system of tax and subsidies is of fundamental importance for the operation of Norwegian pharmacies, enabling all pharmacists to gain a reasonable livelihood. One obvious advantage is that the Norwegian pharmacist can devote most of his time to professional matters, and conflict with commercial interests is to a great extent avoided. The Norwegian pharmaceutical service is self-financing; any increase in services must be paid for by price increases or by cost reductions in other parts of the system.

41. The Norwegian pharmaceutical service is characterized by its exclusively professional nature and the very strict government control of both professional and economic matters.

42. The establishment of the Norsk Medicinal Depot - a state monopoly for the import and wholesale distribution of drugs - has been an important tool not only for the distribution of drugs but also for the support of drug information and research and the improvement of drug utilization.

43. In small countries only limited resources are available and extensive programmes for the continuous evaluation of all kinds of drug therapy problems are beyond reach. This situation calls for international cooperation. Within the Nordic area the control authorities have for many years maintained close cooperation on the evaluation, standardization, and post-marketing control of drugs, including statistics on medicines. In recent years this cooperation has been further developed to include the harmonizing of requirements for clinical trials, application forms, labelling, etc.

44. Drug problems are international by nature. Norway contributes to several activities within the drug field such as the WHO drug action programme, including the development of drug policies, essential drugs programmes, and the training of health personnel. It supports the international control of dependence-producing drugs and, at the regional level, supports and participates in drug utilization studies, studies of drug regulation, etc. Through bilateral assistance to and cooperation with other countries such as Botswana, it has gained experience and developed new approaches to drug problems that could serve as useful models for future work.

FIG. 1. Drug control functions to be executed by official bodies

Selection	Standardization	Post-marketing control	Information
Approval of clinical trials	Legislation and guidelines	Pharmaceutical/ technical control	Reference works and and information bulletins
Approval of new drugs	Drug standards (Pharmacopoeia)	Monitoring of efficacy and adverse reactions	Brochures on specific groups of drugs or related to particular drug problems
Granting of restricted licences		Price control	
		Control of labelling and publicity	Specific information to health personnel or patients
Production licences	Standards for GMP	Inspection of producers and distributors	
		Drug utilization studies	

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