Making National Drug Policies a Development Priority
A Strategy Paper and Six Country Stories

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Norway provides an interesting and significant example of a successful National Drug Policy. Characteristics such as a 'need clause' (which implies that a drug is assessed not only from a scientific and technical viewpoint but also in relation to medical need, and thus the social perspective of health priorities), a restrictive attitude to fixed combination drugs and the limiting of approval and registration of a drug to a five-year period have kept the number of pharmaceuticals at a reasonable level—just over 2,000—and protected consumers from useless or unnecessary drugs. This development towards an equitable National Drug Policy has occurred without any major conflicts between the health authorities, the professional organisations and the drug industry. The reason for this may be that the Norwegian drug policy has developed in stages through most of this century and has been part of a health policy and an overall social policy—which may be characterised as typically Scandinavian—where the emphasis on equity has been one of the main pillars. This emphasis goes right through the system as it now works and has been particularly evident in the field of drug distribution, where the less profitable pharmacies in marginal areas are sustained by more profitable ones located in more populated areas, a modern ‘Robin Hood approach’. The importance attached to the last link in the drug chain—patients and prescribers—is another example of this emphasis.

The story of Norway’s highly relevant experience in this field is told here by two Norwegians and a Swede who all have been closely involved in the development of drug policies, nationally and internationally. Marit Andrew is Assistant Director of the Department of Pharmaceutical Services at the Norwegian Board of Health in Oslo. Before taking up this position she spent ten years working with the government pharmaceutical wholesaler, the Norwegian Medical Depot, and another ten years at the Department of Pharmacotherapeutics at the University of Oslo. She has also been involved in the development of WHO’s Ethical Criteria for the Promotion of Medicinal Products. Bjørn Jøldal served as Director of the Department of Pharmaceutical Services on the Norwegian Board of Health from 1964 to 1997 in close cooperation with the Directors-General Karl Evang and Torbjørn Mork, who together were instrumental in forming the Norwegian drug policy. He was also very active in Nordic and European cooperation efforts in the field of medicinal drugs,
Marit Andrew, Bjørn Jøldal and Göran Tomson

and, above all, within WHO where together with Mork and Professor Per Knut M Lunde, now at the Department of Pharmacotherapeutics, he played an important role in the development of the Essential Drugs Concept and the Drug Action Programme. Since 1991, he has been the proprietor of Sandvika Apotek (Pharmacy). Göran Tomson, an Associate Professor at the Unit of International Health Care Research (IHCAR) at Karolinska Institutet in Stockholm, is a paediatrician who has worked in the broad fields of public health and health policy, international health systems research and global pharmaceutical issues. His doctoral dissertation was entitled Drug Utilization Studies in Sri Lanka. Towards an Understanding of Medicines in Society (1990). Göran Tomson coordinated the work on the study presented here.

Background

A country’s National Drug Policy (NDP), although it may have many similarities with the drug policies of other countries, is specific to the context in which it is formed. It emerges gradually and is shaped by a range of factors relating to geography and natural resources, history and culture, and the social, economic and political climate. What are these factors in the case of Norway?

Norway stretches further north than any other country in Europe, with a substantial part of its territory, including Svalbard, to the north of the arctic circle. With only 4 million people living in an area covering 326,000 square kilometres, it is the second most sparsely populated country in Europe after Iceland. Less than a quarter of the area is suitable for cultivation: 3 per cent for agriculture and 20 per cent for productive forest.

Although Norway is on the same latitude as southern Greenland, its climate is relatively mild because of the proximity of the Gulf Stream. Most of the country has an average temperature of 15°C or below in mid-summer and -5°C or below in mid-winter. In the past, the high mountains and heavy snowfalls made contact between different parts of the country difficult during winter. Today, the situation is different, with road, rail and air networks generally usable all year round. However, every now and then nature takes over, leaving trains stuck in the snow and roads temporarily closed.

The 20th century has seen a transition in Norway from a society based on the primary industries of farming, forestry, hunting and fishing, to one based mainly on secondary industries, including mining, construction and hydro-
electric power, and tertiary activities such as transport, trade, business and private and public services. Most of this development has taken place since the Second World War, when Norway was occupied, and has been the basis of strong economic growth and the development of the welfare state. During the last 20 years, oil and gas production in the North Sea has emerged as a principal industry, and Norway is today the major oil- and gas-exporting country in Europe.

The post-war period united the Norwegian people in an atmosphere of reconstruction and solidarity. In the first election after the war, the Social Democratic Party gained an overall majority. It remained in power for 20 consecutive years until 1965, when the Conservatives came to power for a period of six years. This was followed by another 10 years of Social Democratic government. Since 1981 there have been several changes of government. Although the Social Democrats have not always been able to form a majority government the party has maintained its leading position.

Being a small and remote country, Norway has by tradition been strongly internationally oriented, and has had a high international profile considering its size. For example, it could be mentioned that the first Secretary General of the United Nations, Trygve Lie, was a Norwegian.

Since the late 1980s, Norway, as other European countries, has been faced with reduced economic growth and dramatically increasing unemployment, from 2.3 per cent in 1988 to around 8 per cent in 1994. The economy is still, however, among the healthiest in Europe.

The notion of the welfare state implies among many things that the government strives to give every citizen an equal opportunity for self-realisation, through access to education, health care, housing, and adequately remunerated employment. The essential elements of the system are public insurance, covering costs incurred in the case of illness, accident or social problems; and social security, including, for example, public pension schemes, and well-developed medical and social services. One result of the equity policy is that the difference in wages between high- and low-income groups is among the smallest in Europe, while both direct and indirect taxes are fairly high. Norway is generally acknowledged to have one of the highest standards of living in the world.

The government’s health care policy for 1994-1997 is based on the principle of solidarity and equal access to high-quality services. It emphasises the im-
portance of every citizen having confidence in the health care system.¹ All the major political parties support the fundamental concepts behind the welfare state but there is a continuing debate about what is or is not realistic and how best to organise the system. This reflects the fact that the workforce has to pay for a growing number of retired and, more recently, unemployed people, increasing the per capita cost of welfare provision. Another factor is a delay in young people entering the active work-force, because they stay longer within the education system. This tendency is reinforced by reduced employment opportunities.

In common with many other industrialised countries, Norway has a ‘greying’ population, with a 2.5 percent annual increase in the number of people over 75 years of age. As approximately 50 per cent of all drugs are used by those who are over 65 years of age, this factor will have clear implications for drug use in the years to come.

The national health and social insurance scheme is financed through the tax system, shared by employers and the public.

Health and health care

The health care system is the largest ‘company’ in Norway, employing 10 per cent of the labour force.² The municipalities are responsible for organising primary health care for all inhabitants, including the provision of nursing homes. Hospitals are run by the counties and all hospital treatment is free. Until the early 1980s, curative medicine and hospital development overshadowed preventive medicine and care.³ However, the Municipal Health Act of 1982 reflected a change of priorities. This gave the municipalities both the responsibility and the power to provide health services for those living in their area.

Health concerns are also in a general way integrated in the legislation to a larger extent than in most other European countries.⁴

The development of a Norwegian drug policy

The development of a drug policy, as in any other country, is influenced by factors such as the health situation, the health care system, education and training of health personnel, social security and health insurance, research, national drug production, drug distribution, drug control and international drug policies.

For centuries, mountains, fjords, and vast, uninhabited forests divided the Norwegian people into small, separate communities which had to be largely
self-sufficient, as they were completely cut off from neighbouring communities for long periods of the year. In such close-knit small communities with a high degree of stability and homogeneity, the philosophy of mutual assistance—and what might be called social conscience—comes naturally. This community model of mutual help lays the basis for replication on a national scale.

More than 350 years ago, the first physicians to establish themselves in Norway were paid by the government, as it was assumed that most people were not in a position to pay for medical services out of their private resources. This first step towards a nationwide system of medical care was ‘socialised’ medicine in its purest form, but it was operating a couple of centuries before the term socialism was invented. Although problems and outlooks have changed considerably since that time, we believe that this tradition of solidarity and mutual assistance influenced the solutions that were arrived at later in the country’s history.

The basic aim of the Norwegian drug policy is to ensure that effective and safe drugs of good quality are accessible and that measures are taken to ensure their rational use in keeping with the health needs of the country.

Traditionally, Norwegian society has tried to control the quality and use of medicines in order to safeguard the public and to ensure proper medical treatment. Before the industrial era of ethical drug production, the major efforts towards control were in the education of medical personnel, the establishment of drug standards in official formularies, the control of the production and distribution chain, mainly pharmacies, and the introduction of prescription rules. The first Norwegian pharmacy was founded in 1595 in Bergen—400 years ago!—and the second, ‘The Swan Pharmacy’, in Oslo in 1628. The latter is today the oldest functioning enterprise in Oslo.

With the industrialisation and commercialisation of drug production and marketing, new control measures became necessary. The first of these came with the first Drugs and Poisons Act as early as 1914. In 1928, these regulations were extended by an act of parliament, according to which the marketing of each drug product had to be approved by a government authority. Drug advertising was regulated and restricted by the same act.

The importance of the individual

As important as the social, political and economic framework are the actions of people with vision and commitment. Especially in the post-war period, with the huge growth in the numbers of drugs and growing pressure
from the transnational pharmaceutical companies, Norway had strong directors of health services and far-sighted leaders of pharmaceutical services.

*Karl Evang*, who was Director of Health Services from 1938 until 1972, was the main architect of the Norwegian welfare state as we see it today, and also one of the pioneers whose ideas led to the establishment of the World Health Organization. He was a convinced Social Democrat, and had strong views about the need for government responsibility for the development of the health care system. He also had a very special interest in and insight into drug issues, and wrote a book about the use and misuse of medicines, with a public health perspective, as early as 1965. The need for a healthy pharmaceutical industry was also addressed.

*Torbjørn Mork*, his successor, continued along the same lines, both nationally and internationally, emphasising the need for a drug policy as an integral part of overall health policies. He was one of the key people behind the launching of WHO’S Action Programme on Essential Drugs (DAP), instituted in 1981.

The Director of Pharmaceutical Services in Norway for 26 years until 1991, *Bjørn Jøldal*, played the role of pharmaceutical policy architect and implementor and was, together with colleagues, responsible for gaining international acceptance for the WHO Drug Action Programme.

*Per Knut Lunde*, at the University of Oslo, Professor and Head of the Department of Pharmacotherapeutics, paved the way for the international acceptance of the Essential Drugs Concept (EDC) and was one of the individuals who drafted the first Essential Drugs List, published in 1977.

Like many other industrialised countries, Norway had until recently no single document setting out its drug policy. Elements relating to quality, safety, efficacy, need, control of prices, and promotion, are included in the drug act, while those relating to distribution are embodied in the pharmacy act. Pharmaceutical benefits are covered by the national insurance act.

However, in 1987, a government white paper entitled *Health services towards the year 2000* (No. 41, 1986-87) was brought before Parliament. A small but crucial part of the document deals with the pharmaceutical area. The main aim is to provide the best possible pharmaceutical service to society. The need for coordinating the development of pharmacy services and other health services is emphasised.
In accordance with the main aim, expressed in the document, the pharmacy services should contribute to:

- easy access to safe and effective medicines of high quality in all parts of the country, at reasonable prices which should be the same in all parts of the country;
- proper and medically sound use of medicines. Health personnel should have the necessary information on drugs, and pharmacies, together with other parts of the health care system, should join forces to promote the rational prescribing and use of drugs.

Essential elements in the Norwegian drug policy are: a drug regulatory control body; a strictly regulated distribution system; a reimbursement system; and a strategy for the rational prescribing and use of drugs.

National drug regulatory control

A well-functioning drug regulatory agency is vital for the implementation of a rational national drug policy. In 1930, a government agency with a quality control laboratory was established, and in 1948 a laboratory for drug standardisation was set up. In 1974, these services were merged and reorganised with the establishment of the Norwegian Medicines Control Authority, the main functions of which are described below.

Financing of drug regulation activities

Drug control activities have traditionally been financed directly or indirectly through registration fees, partly an application fee and partly an annual fee. In 1994, the application fee was NOK 35,000 (US$ 5,000) and the annual fee was 0.7 per cent of the wholesale turnover of the drug.

Selection of drugs

At the time of the thalidomide disaster in the early 1960s, only very few countries, among them Norway and Sweden—where the relevant legislation dates from 1928 and 1935 respectively—had gained experience with systems to assess the efficacy of new drugs.

Since the Drugs Act of 1928, quality, safety, efficacy and cost have been the main criteria for drug evaluation and registration in Norway. Some 10 years later the concept of need was introduced as a further criterion. Emphasis on particular criteria has varied over the years. In the 1950s the focus was on quality, in the 1960s on safety and in the 1970s on efficacy. During the 1980s the economic aspects of drug provision have received increased attention, as has rational drug use.
Since the 1940s the criteria for the selection of drugs have been as listed below. However, in 1994, as a result of Norway joining the European Economic Area (EEA)—previously a trade agreement between EEC and EFTA countries, today in practice EU, Norway and Iceland—the need clause had to be sacrificed. This will lead to an estimated increase in the number of products on the Norwegian market by 50-100 per cent. (See pages 46-48 for further comments on the EEA-agreement.)

- 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;
- fixed drug combinations should be avoided unless the combination shows a clear advantage over that of each active ingredient used separately;
- there should be a clear-cut medical need for any new product (the need clause);
- the number of drugs should be limited;
- approval should be given for a limited period (five years);
- a drug may be restricted to use in hospitals or by specialists.

There are three criteria in the Norwegian drug selection process which may deserve special comment:

- the need clause;
- the restrictive attitude to fixed combination drugs;
- the limited period of approval/registration.

These have all been important in keeping the number of drugs at a reasonable level, and have been specific to Norway and have not been adopted by most other industrialised countries. Reasons advanced for the limitation of the number of drugs are simplicity, safety, and economics.

It has been estimated that a general practitioner can have pharmacological knowledge of about 50 drugs and be familiar with another 150. In the distribution chain both the wholesalers and the pharmacies can keep a limited number of drugs in stock. With approximately 2,000 products on the market, medical needs are met, while confusion, waste and logistic problems are minimised. This, in turn, contributes to keeping costs down.

As a safety valve, it is possible to apply for a licence to import non-registered drugs.
The need clause

Until 1994, the Norwegian regulations required that a pharmaceutical product, in addition to being medically justified, should also be needed.

Through the inclusion of the need clause in the Norwegian legislation some 50 years ago, a social dimension was introduced into drug policy at a very early stage. Drugs were assessed not only from a scientific or technical point of view but also in the light of health priorities and with the aim of protecting the individual from exposure to unnecessary drugs.

The draft parliamentary documents do little to explain the rationale for the inclusion of a need clause. In retrospect, it is also interesting to note that this important principle of medicine with a social dimension was so readily accepted by the medical profession, in contrast to other country cases, where attempts to rationalise drug markets have met with major resistance.8-9

In the registration process the control authorities have routinely consulted leading medical experts in order to select the most valuable drugs within each therapeutic group. By actively involving opinion leaders in different fields in the drug selection procedure, the regulators gained the support of these crucial actors and stakeholders for the policy.

The number of drugs on the market has in fact been surprisingly constant during the last 20 years. In 1974, there were 1,903 products, in 1977, 1,889, in 1985, 2,080, and in 1992, 2,244 products. The acceptance of a modest number of drugs has also mainly persisted until today. The number of registered drugs thus seems to have met the real needs of the population.

As the term ‘need’ has not been defined precisely, the Registration Board has had to establish its own practice. The need clause has been used to limit the number of similar products and of combination drugs. However, a small number of similar or synonym products has been allowed to ensure price competition as well as the continuing supply of drugs.

A study of decisions taken by the Registration Board during the years 1981 - 1983 shows that approximately 40 per cent of applications were rejected.” Need considerations were involved in more than 60 per cent of these. During the course of 1992, 32 per cent of the applications were rejected and 42 per cent of these were on the grounds of absence of need.12
**Fixed combinations**  
Combination drugs, when formulated for commercial purposes without regard to therapeutic gains, as is commonly the case, are at best fraudulent and at worst dangerous.\(^1\)

The Norwegian policy has been based on some essential requirements:

- each component should make a documented contribution to the claimed effect;
- a component may be added to enhance the effectiveness or safety of the active ingredient, or to minimise potential abuse of the active ingredient;
- the components should have approximately the same duration of action.

In addition, a patient population of reasonable size should benefit from the combination. During the last decade, combination drugs have constituted approximately 10 per cent of the Norwegian market. This contrasts sharply with, for example, Spain where they make up approximately 40 per cent of the market.\(^1\)

In Norway, different stakeholders have taken different views on the issue of fixed combination drugs. The medical profession has been supportive of the policy, the industry has been negative but has strategically kept a low profile whereas the general public has been little involved.

**Limited period of registration**  
Drug safety and efficacy cannot be established definitively. Many problems, such as dependence-producing liabilities, appear only after widespread and/or prolonged use. Regular re-evaluation, periodic or continual, is therefore essential. This needs to be based on experience with the drug in common use, and on information derived from monitoring both efficacy and adverse reactions.

In Norway, it has been common practice that the registration period for a drug expires after five years. The drug company must then make a re-application, which may require submission of up-dated safety and efficacy data. The Registration Board has an opportunity to determine whether the drug is still appropriate for marketing or whether indications should be changed. At times, the mere request for efficacy data has resulted in voluntary withdrawal by the manufacturer. In addition, unscheduled revision may be carried out at any time, usually when there is evidence of undue side effects. The principle of having a limited period of registration has now also been adopted by the European Union (EU).
Over the last 20 years, several withdrawals have been initiated by the regulatory agency, most often because of poorly documented clinical effects or harmful effects. Examples of drugs that have been withdrawn are throat lozenges, barbiturates, phenylbutazone, hydroxyquinoline and triazolam.

Hospitals and doctors are routinely granted import licences for non-registered drugs. These are most often required for special purposes such as the treatment of patients with unusual illnesses ('orphan drugs'), and trials of new medication prior to registration. Annually, approximately 20,000 applications for non-registered drugs are granted. This 'loophole' may have contributed to the general acceptance among medical personnel of the strict registration policy.

According to the Norwegian legislation, the price of a pharmaceutical product shall not be 'in disproportion to its therapeutic value'. The cost of a drug should be commensurate with its direct or indirect benefits, as compared to those of alternative products. Data on these matters is, however, difficult to obtain in an objective form and most countries appear to adopt an arbitrary approach.

In Norway, price consideration has, up to 1994, been an integral part of the registration procedure, both for prescription and non-prescription drugs. Negotiations have been conducted with the manufacturer until an acceptable price has been agreed upon. The prices of new products are compared with those of similar products on the market and with prices in other European countries, particularly in the country of manufacturing origin. The system has been more comprehensive than that operating in most other European countries. Prices in Norway, as in Sweden, are substantially lower than those in Switzerland and Germany, for example. Although since 1994, as a result of the EEA agreement—price negotiations can no longer be directly linked to the registration procedure, government approval of price is still required before marketing of prescription-only drugs can be marketed.

It is less difficult to judge if a price increase during the registration period is reasonable. In many countries the authorities have concentrated on this kind of control. In the early 1980s, the Norwegian public health authorities and the pharmaceutical industry developed and agreed on models for price adjustments which take into account factors such as inflation and changes in exchange rates. As would be expected, the pharmaceutical industry has at times opposed the registration and pricing policy. During the early 1980s,
after unsuccessful price negotiations with the National Board of Health, drug manufacturers turned directly to the Ministry and achieved a 15 per cent hike in prices—a substantial increase. Since this 'accident' there has been close cooperation between the Ministry and the National Board of Health in these matters. Since 1994 price issues have become the responsibility of the Norwegian Medicines Control Authority. This institution will be strengthened in 1995 through the establishment of a pharmacoeconomic section.

Advertising and promotion

In general, Norwegian regulations regarding promotion activities correspond closely with WHO'S Ethical Criteria for the Promotion of Medicinal Products. On certain points they have been more strict, for example in not allowing advertising on radio or television or in cinemas, public premises, streets or roads. There are also strict rules on the distribution of samples, and advertising of non-registered drugs is prohibited. During the last few years comprehensive guidelines have been developed on ethical conduct in terms of contact between the industry, physicians and pharmacists.

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. Advertising to the public is limited to selected non-prescription drugs. All advertising which is not strictly based on approved data sheets has been approved by the Norwegian Medicines Control Authority prior to use. Pre-approval of advertising to the public has been given high priority. In an international study of advertisements in medical journals, those in Norwegian publications emerged as being of a relatively high quality. The greatest challenge, however, is represented not by written ads but by hidden promotional activities, such as ‘marketing’ clinical trials and meetings, even though these too are covered by the regulations.

Marketing regulations are formally enforced by the Norwegian Medicines Control Authority. Breaking the rules may result in a demand for the distribution of a written corrective statement—5-10 cases a year—or a one-year ban on advertising—1-2 cases a year.

Violations of marketing regulations are also dealt with within the industry itself. A secretariat, staffed by one individual employed by the industry, screens ads in the most common professional journals, identifying 50-70 cases of misconduct a year. Of these, the more complicated cases (approximately 10 per year) are brought before an independent council. Most cases
are, in fact, raised by the secretariat itself or by the competing companies, and only a very small number by doctors and pharmacists. Violations resulting in such reactions may, for example, be promotional claims, indicating a medical effect that is not documented, or hidden advertisements for prescription drugs directed at the general public. The council may impose a fine.

The pharmaceutical industry operating in Norway, while mainly adhering to the rules, also tries out the limits. Marketing activities follow both written and unwritten laws; the pharmaceutical industry, as other actors, adapts its behaviour according to the prevailing ethical codes of conduct and its knowledge of acceptable limits. In Norway, the industry may risk more by stretching the rules than from complying, as the probability of negative publicity is high.

As part of the EEA agreement, the regulations governing advertising and promotion have been slightly amended and now allow, for example, advertising on radio and in public places (but not on TV). Also, more responsibility for monitoring promotional practices has been transferred to the industry itself. Reactions to violations will, however, still be prompt.

It is a declared policy in Norway that all citizens shall have reasonable and reliable access to medicines, medical and health equipment or appliances and related goods for medical use. This requires a sufficient number of pharmacies, an even geographical distribution, opening hours that are in accordance with the needs of the public, an adequate stock of medicines and qualified personnel. No drugs may be sold outside the pharmacy system.

With 4 million inhabitants, Norway has 322 privately owned pharmacies, 68 of which are branch pharmacies. Linked to the pharmacies there are also 1,200 pharmacy sales outlets with a restricted assortment of over-the-counter (OTC) drugs. In addition, there are 26 hospital pharmacies owned by the counties or the state. The population per pharmacy varies from 20,000 in certain rural areas to 10,000 in the Oslo area.

In Norway, distances represent the real challenge. That is why location as much as the number of pharmacies is an important issue. The Norwegian Board of Health decides where pharmacies shall be located, in accordance with a national plan which is regularly revised. Pharmacies are established primarily on the basis of the needs of the public, and not on the basis of business opportunities. The decision to open or close a pharmacy is guided by
such considerations as population per pharmacy, distance between pharmacies, and transport facilities. The local health authorities are responsible for identifying in which locations new pharmacies may be needed.

Because of this policy, a significant number of pharmacies in Norway has insufficient business to be profitable. In these cases, private enterprise would fail without some form of state intervention. To keep these pharmacies going, the government has set up a system of tax benefits and subsidies to ensure equity, which aims at levelling out inequalities of income stemming from more or less economically favourable locations: the Robin Hood principle. The system is of fundamental importance for the operation of Norwegian pharmacies. Parliament imposes the pharmacies tax each year while the Norwegian Board of Health monitors the economic performance of the individual pharmacy. The tax is progressive and is calculated on the basis of the annual turnover of the pharmacy. The greater part of the revenue is used to subsidise pharmacies whose profit patterns are not satisfactory. Subsidies are not granted automatically, but only after scrutiny of the accounts, especially with respect to wholesale expenses, the cost of wages, and depreciation. If costs are within acceptable limits, pharmacy proprietors in less densely populated areas may rely upon making a reasonable living.

Wholesale distribution: the Norwegian Medicinal Depot

The wholesale distribution of pharmaceutical products in Norway has up to mid-1995 been carried out by a government wholesaler, the Norwegian Medicinal Depot (NMD). Its main premises are in Oslo, and branch depots have been established in three other regions of the country. Although pharmacies vary widely in size and many are situated at a great distance from the nearest branch depot, the prices charged to them have been the same, irrespective of quantities ordered and of delivery distance. All orders are processed with the aid of computers, and the computing unit provides statistics for administrative, scientific, and other purposes.

The NMD was established by law in 1953 as a consequence of the difficult supply situation that prevailed during the Second World War and the tense international political situation in the late 1940s, and was operative from 1957. In addition to being a central organisation for import and wholesale of drugs, the NMD has played an important role in implementing the Norwegian drug policy.

Part of the net income of the NMD has been used for funding the Department of Pharmacotherapeutics at the University of Oslo, which provides the medical profession and also the pharmacies with independent informa-
tion on drugs. It has also been used to support clinical pharmacological and pharmaceutical research.

Until 1994 the NMD had a formal monopoly status. With the implementation of the EEA agreement, the monopoly was abolished, but the NMD will continue as a government-owned wholesaler. New wholesalers will be operative during 1995. However, legal obligations as to delivery to all parts of the country and ability to provide all registered drugs have been introduced.

General medical care is provided either by local public health officers or by private general practitioners. People are free to go to the doctor of their choice, but in the more isolated regions, especially in the north and west, there may be only one doctor who can easily be reached for treatment. Hospital treatment including drug treatment is free of charge, while in outpatient care a cost-sharing system operates. The patient pays a nominal fee per consultation, and the physician claims the remainder of the fee from the government, through the national insurance scheme. The consultation fee does not include drug costs.

The basis of the Norwegian drug cost reimbursement programme is that it applies to patients with prolonged or chronic diseases and sexually transmitted diseases. The diseases for which treatment costs may be reimbursed are specified in the regulations. They should be in a chronic stage and the physician must be convinced that long-term medication is necessary. The formulary now includes 40 chronic diagnoses. The prescribing of certain categories of drugs within the reimbursement system is limited to specialists only and the amount which can be dispensed from a pharmacy is limited to a 3-month supply. For non-chronic ailments, such as acute infections and acute pain, patients pay the full costs. The same applies to non-prescription drugs and contraceptives. Also most hypnotics and sedatives are not reimbursed.

From 1960 up until the end of 1980, medications for all persons suffering from the listed prolonged or chronic ailments, irrespective of age, were completely covered by the health insurance. Then in 1981, concerns about increasing costs led to a change in the regulations and the introduction of cost-sharing. Up until 1988, the patient share was a fixed amount per prescription. In 1989, it was changed to a percentage of the total prescription cost (30 per cent in 1994), up to a maximum amount per year (approximately 150 USD in 1994). The remaining costs are covered by the insurance. Retired people pay a smaller amount per prescription, but the maximum payment
per year is the same as for other patients. There is no charge for children under 7 years of age. An important point is that the annual maximum payment also includes certain other patient shares, e.g. those for consultations.

Due to escalating reimbursement costs, prescribing of low-cost synonyms has been encouraged for many years. In 1991, it became compulsory within the reimbursement scheme to prescribe the cheapest synonym products unless there are compelling medical reasons for doing otherwise. The effect of this cost-saving initiative was limited, mostly due to reluctance among physicians, and by 1992 low-price synonyms accounted for only 50 per cent of the market segment in question (calculated in defined daily doses). In 1993, a maximum reimbursement amount per product where synonyms are available (price of cheapest synonym product + 5 per cent—reference price) was introduced. The additional amount must be paid by the patient, and doctors are required to inform patients about consequences if they prescribe a drug which imposes extra costs. This immediately led to manufacturers dropping prices voluntarily. Presently, only a handful of drugs are priced higher than the maximum amount that will be reimbursed. The price drop was on average approximately 15 per cent, corresponding to an annual saving of 65 million Norwegian crowns (USD 9 million).

The savings should be judged in relation to a total reimbursement budget for drugs of approximately USD 450 million. Most of the reimbursement budget is, in fact, generated by drugs where patents have not expired, and thus synonyms are not available. Therefore, in Norway the potential for cost-saving through prescribing of cheap synonyms is limited.

The increase in reimbursement costs is dependent on several factors: price increases, the growth in the number of elderly people and the introduction of new and more costly drugs. The latter accounts for most of the increase in reimbursement costs.

In Norway, two-thirds of the total national drug bill (including OTC-drugs) are paid by the government, either through hospitals where drugs are free, or through prescription reimbursement. Thus, the government, as the main customer, is in a strong position to negotiate terms on the basis of cost-effectiveness. In order to strengthen this position, it was proposed that a more systematic ‘health economics’ evaluation as basis for granting reimbursement should be introduced. A government-funded pharmaco-economic unit to support such evaluations will be established at the Norwegian Medicines Control Authority during 1995.
With the increasing tendency in most countries to focus attention on health budgets, the pharmaceutical industry has found it advantageous to present cost-effectiveness data for marketing purposes. Such data are obviously important for health authorities, who correspondingly need competence to evaluate them and also make independent assessments of health economic aspects of drug use.

Even a high-quality drug, effectively distributed and affordable by both the government and the individual patient, will not have a positive health impact unless it is appropriately selected (prescribed or self-medicated) and consumed in a rational way. Alongside concern about the proliferation of drugs, the irrational use of drugs became an important issue in the mid-1960s.

More than in many other countries, producer-independent drug information has been used consciously in Norway as an instrument for achieving more rational drug use.

To understand the determinants of use it is necessary to draw on insights from pharmacology, epidemiology and the social sciences, and from political science. Drug use, as part of the process of medical care, requires the people who give and take drugs to make various types of decisions. At all points, they are affected by their varied cultural values, social networks and existing legislations and regulations. The importance of the last link in the drug chain—that of utilisation—was recognised early on in Norway.

An important prerequisite to appropriate selection and use of drugs is the availability of comprehensive and reliable information. To balance the promotional activities of the pharmaceutical industry, various local and central initiatives have therefore been taken. Prescriber-oriented information are provided through independent sources such as:

- drug information bulletins and medical and pharmaceutical journals;
- data sheets for new drugs;
- booklets on therapies and treatments for the major illnesses and ailments;
- therapy-oriented drug formularies giving comparative criteria for selection by the prescriber;
- national and local institutions, such as university departments of clinical pharmacology and hospital pharmacy units, providing information on drugs and poisons.
The need for producer-independent information was promoted by a strong joint team of pharmacologists and pharmacists, and resulted in the establishment of a very unusual institution, a Department of Pharmacotherapeutics, at the University of Oslo in 1964. Funds were provided by the Norwegian Medicinal Depot out of its income from drug sales. The first professor of the department (Knut Naess) was a pharmacologist with a strong personality, who was held in high esteem by colleagues, including influential clinicians. A network of clinicians/therapy groups was established, involving the medical community and opinion leaders. A special column in the Norwegian medical journal, entitled ‘Drug therapy in practice’, gave the department a unique channel through which to convey clear messages and recommendations, based on thorough scientific considerations, to the medical community. The column may at times have been controversial, but it was seldom dull. As producer-independent drug and therapy information has become more readily available, the department has not needed to supply as much traditional information on the most common drugs and has been able to concentrate on communicating problem-oriented therapy issues, and also to carry out its own research into the use of drugs. It is difficult to assess the impact that the Department of Pharmacotherapeutics has had on drug use in Norway, but many of its activities, involving opinion-leading clinicians in discussions, as well as its provision of printed information materials have certainly contributed to a generally increased awareness among clinicians and probably also to the relatively low drug use in Norway.

Since the 1960s, drug and therapeutic committees, with clinicians and clinical pharmacologists, pharmacists and nurses working together, became common. More than 60 of these, based at hospitals around the country, have been involved in discussing principles and recommendations for drug use, along the same lines as the WHO’s essential drugs concept. In fact, in many ways drug and therapeutics committees in countries such as Norway and Sweden could be said to have paved the way for the WHO initiative. They have led to the publication of a number of limited drug lists and guidelines and, more occasionally, of handbooks. However, government demands for increased effectiveness in hospitals, and a preoccupation with budgetary concerns, have left committees with less time for in-depth work and have resulted in waning enthusiasm. The terms of reference for the committees and their authority vis-à-vis prescribers have also often been unclear. Since 1985, the Department of Pharmacotherapeutics has arranged bi-annual meetings for the committees. Experiments have been going on since the mid-1980s with drug and therapeutic committees in general practice.

In 1994, a pilot project with regional drug information centres were
Norway’s National Drug Policy

launched. The centres will collaborate closely with drug and therapeutics committees, clinical pharmacologists and clinicians and provide services to the primary health care system as well as to hospitals and other health institutions.

As new and sometimes extremely expensive drug therapies are introduced (e.g. new serotonin antagonist antiemetics, antidepressants and migraine drugs, hematopoietic growth therapies, erythropoietin, plasminogen activators (TPA), cancer drugs (such as taxol), and also because more drugs will become available as a result of the EEA agreement, drug and therapeutic committees are now arousing new interest and will be important actors on the future drug scene. Developing therapy guidelines, weighing benefits and costs of alternative options and also monitoring adherence to recommendations are clearly becoming more important than just providing limited lists of drugs.

The Norwegian Drug and Therapeutics Formulary, published regularly since 1984 (later than in many other countries) is a joint venture between the Norwegian Medicinal Depot, the Norwegian Medical Association, the Norwegian Pharmacy Proprietors Association and the Norwegian Medicines Control Authority. The Department of Pharmacotherapeutics is strongly involved in the editorial work. It provides independent comparative information on drug therapy and is provided free to all prescribers and pharmacies. Treatment recommendations are given for all common conditions, and all necessary prescribing information about registered drugs is included. Although the formulary is increasingly being used by prescribers, the manufacturers’ catalogue, with products arranged alphabetically, still remains a major source of prescribing information for physicians. This remains a challenge!

Producer-independent drug information leaflets covering the most widely used prescription drugs are distributed through pharmacies as part of the dispensing. They are far more user-friendly than traditional package inserts. Since 1984, a Drug and Therapeutic Formulary for the general public has been published. Since package inserts will be compulsory as a result of the EEA agreement, these will in most cases replace the information leaflets.

With the establishment of the Norwegian Medicinal Depot a unique opportunity for obtaining data on sales of drugs and raw materials was created. Then, in the early 1970s, two important methodological tools for the study of drug utilisation were developed in Norway. A common drug classification
system, known as the Anatomical Therapeutic Chemical (ATC) classification system, was developed and has since been adopted by WHO for international use; and a new and more precise unit of measurement for drug consumption—the defined daily dose (DDD)—was established and is now used internationally in comparative drug utilisation studies. The NMD played a crucial role in this work. In 1982, a WHO Collaborating Centre for Drug Statistics Methodology was established at the NMD. The centre is responsible for maintenance and further development of the ATC and DDD systems and serves all interested countries.

Norway was one of the first countries in the world to publish regular drug sales data, showing general trends as well as regional differences. This service, which began in 1977, has brought a transparency into the system which enables monitoring of various interventions in the sale, prescribing and use of drugs. For the first few years the industry was represented on the editorial committee. The general approach and level of detail of published figures have reflected medical rather than commercial interests, and protests from the industry have been negligible. The publication is now regarded as a matter of routine, and there is no longer need for an editorial board.

Drug use in Norway is lower per inhabitant than in other Nordic countries and in most European countries. Norwegian health care indicators are rated among the best in the world, with a low infant mortality rate and high life expectancy, indicating that moderation in drug use is not jeopardising health.

Overall sales data showing intra- and international differences may generate hypotheses, open up new areas for research and provide important information on trends and developments. ‘The Norwegian Prescription Survey’ has been running since 1990, and provides broad prescribing information, linked to patient age, sex and diagnosis and also prescriber characteristics for a rotating sample of prescribers and a registration period of one week for each prescriber. Feedback on prescribing habits is provided to participating doctors, giving them a basis from which to assess and improve the quality of their prescribing. The data are available for research purposes, and have to a limited extent been edited for general publication. The further development of the system to provide long-term drug profiles on an individual level (prescriber and patient), for example based on computerised pharmacy records, represents a challenge, but it also raises professional and ethical concerns about confidentiality. Pharmacy-based projects involving feedback to prescribers have shown that discussions can have an effect on prescribing habits.
After some years of sales data being published, a book entitled *Drug Utilisation in Norway in the 1970s—increases, inequalities, innovations* was published.\(^3\) The use of 15 selected drug categories was analysed in depth. Among the conclusions were that some groups were overused (laxatives, iron, vitamin B 12), some were partly underused (heparin) and others were misused (minor tranquilisers, hypnotics, analgesics). Medically sound explanations could not be found for the majority of the regional differences observed.

It is our belief that general transparency around data on drug use, and regular comments on usage trends in professional as well as general-interest publications, have contributed to increased awareness and accountability among prescribers, the public and health authorities. That the public is sensitised to the issues is of value to all actors on the drug scene.\(^2\),\(^3\) Contrary to experiences in other countries, such as Germany, the industry has not opposed the relative openness around sales data,\(^5\) possibly because it has assessed the attitudes of the other major medical actors to be strongly supportive. It may also have reached the conclusion that such openness does not pose a threat to its interests. Today, there is full agreement on the usefulness of publicly available drug utilisation data.

Transparency alone, however, does not bring about change. It is more important that there is regular debate among health personnel, especially doctors and pharmacists, as well as a high level of accountability. Doctors need to scrutinise their prescribing patterns—individually and together with close colleagues—and modify their practice according to the lessons learnt. Generally, there is a need for better understanding of decision-making in the context of general practice where the majority of prescribing takes place.

Drug use is determined by many factors. The increased use of drugs, partly brought about by aggressive promotion—especially in the Third World—has had an obvious cultural impact.\(^4\) On a global scale, it has increased dependency on allopathy and therefore on doctors and pharmacists as social groups.

Governments are responsible for carrying out regulatory functions to ensure that all drugs on the market are of acceptable quality, safety and efficacy. A most basic question is whether drug regulation achieves its declared aim, that is protection of the public from ineffective, unsafe, or inadequately tested drugs. One way to assess the degree to which a regulatory agency is serving the purposes set for it is to count the drugs on the market.
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Norway, through application of the need concept, has kept the number of drugs marketed at a low level for the past 25 years, with around 2,200 products (brands, dosage forms and strengths included). This compares with non-Nordic European countries where numbers range between 7,000 and 25,000.\textsuperscript{35}

However, medical views on the range of drugs required to meet health needs can differ from country to country. Looking at the acceptance and rejection of drug applications should throw some light on the registration process. Applications for irrational drug combinations have commonly been rejected in Norway. The need clause has kept the number of drugs per therapeutic group very low; in 1980 there were for example just seven non-steroidal anti-inflammatory drugs, compared to 50 in Italy,\textsuperscript{36} and only five benzodiazepines: probably the lowest number on the market in any industrial country.

\textit{International harmonisation}

In small countries, only limited resources are available, and extensive programmes for the continuous evaluation of all kinds of drug therapy problems are not possible. This situation calls for international cooperation. Within the Nordic area the control authorities of different countries have cooperated closely for many years on the evaluation, standardisation, and post-marketing control of drugs, including providing statistics on medicines, and more recently on the harmonising of requirements for clinical trials, application forms and labelling. In this way it has been possible to make better use of limited resources. As long as the main objectives of a National Drug Policy can be maintained, international harmonisation must be looked upon as positive.

Also on a broader international scale, regulatory agencies have been working to harmonise procedures and to increase acceptance of data and standards generated in other countries.\textsuperscript{37,38} This cooperation has had some important consequences:

- the criteria for quality, safety and efficacy of drugs have been progressively harmonised, as have many aspects of registration procedures;
- duplication of analytical and toxicological tests and clinical trials can be avoided;
- tests on manufacturing batches carried out in the producing country are accepted by other countries; and
- general requirements concerning labelling and package inserts have been harmonised.
As part of the development of a free market for medicinal products within the EU, a complete new registration procedure will be implemented from 1995. The European Medicines Evaluation Agency is operative from 1995. These developments within the Community will obviously have consequences for Third World countries too and regular contacts have been established with USA, Japan and European countries outside the EU.

In November 1994, the Norwegian people voted against Norway joining the EU. Most of the changes relevant to the pharmaceutical area are, however, part of the EEA agreement. This otherwise important decision will, therefore, not have a significant impact on the development of the pharmaceutical sector.

The ongoing and forthcoming changes in the Norwegian NDP, partly as a result of Norway joining the European Economic Area and harmonisation with the EU, give some cause for concern. Obviously, some of the changes are results of negotiations on a give-and-take basis, including other areas than health, and are in reality a setback. The Norwegian Medicinal Depot's monopoly on import, export and wholesale of drugs formally came to an end in January 1994. At the same time the need clause was abolished, which is likely to result in an increase in the number of products from 2,200 to around 3,000–4,000 within a few years. A larger number of synonyms will make the daily life of doctors, pharmacists and patients more difficult. A larger number of names on the market will cause confusion. The duration of patents may indirectly be prolonged, if the protection period of 15 years from first date of actual marketing in an EU country is introduced. This will delay the introduction of cheaper synonyms and contribute to increased drug costs. Intensified marketing of drugs by the industry is expected as a result of increased competition. A more liberal promotion of OTC drugs to the public, through radio, journals and the mass media, will be allowed. Television commercials are, however, not allowed.

Many of these changes represent a challenge to the government’s goal of a rational use of drugs. It must be emphasised, though, that as a result of international developments on the drug scene, with new and expensive drugs, often markedly increasing drug costs, increasing expectations among the public and limited government resources for health care, many of the changes have been necessary independently of the EEA/EU harmonisation.
Measures to meet these new challenges include:

- strengthening of the drug regulatory agency, especially as regards producer-independent drug information (in total 15 new posts have been created during the last three years);
- the creation of Regional Drug Information Centres;
- an increase in producer-independent drug information available to physicians and the public through the above measures;
- strengthened price control in relation to reimbursement and the establishment of a government pharmacoconomics unit.

The Department of Pharmacotherapeutics, a main resource centre for drug information, is now funded directly by the Ministry of Health and Social Affairs, and the gathering of statistics on drug regulation previously paid for by the Norwegian Medicinal Depot has been transferred to the Norwegian Board of Health. There is in fact a general unease about the effect of the EU not only on the future of drug regulation in Europe but on health issues in a wider perspective. The cornerstone of EU regulations is the original philosophy of a free market, rather than concern for public health. The Norwegian drug regulatory system evolved as a means of serving and protecting consumers. Norway has a very different starting position from that of many other European countries, and mechanisms are needed to ensure that basic aims are maintained. This includes preserving the good elements of the Nordic registration model and drug policy.

The challenge involves preserving as far as possible the principles of the Essential Drugs Concept in the face of strong pressure for free trade at the expense of the well-being of consumers. Some maintain that the risks are overstated but emphasise that governments, professionals, the industry and other actors involved, need to be aware of the dangers.

Whereas for several decades the Norwegian market was governed by a National Drug Policy which operated on a basis of cooperation rather than confrontation, the process of discussing accommodation to EU requirements has meant that conflicting opinions are now being expressed.

Thus, in the debate previous to the referendum on Norwegian membership of the EU, representatives of the industry were claiming retrospectively that the Norwegian NDP has been contrary to its interests, while regulators warned about the risks of deregulation, and researchers questioned whether a drug supply controlled by the free market could be in line with major public health goals.
Previously, the general policy situation paved the way for a relatively harmonious development of an equitable National Drug Policy. Consultation rather than confrontation has characterised the process. Tools such as the need clause, the five-year rule and a critical attitude to fixed drug combinations have kept the number of registered drugs at a strictly low level, corresponding to about 2,000 drug products. This restricted list, one of the shortest in the world, makes it possible for doctors, pharmacists and patients to get to know the drugs they are exposed to in their various capacities.

For a quarter of a century there have been few, if any, major conflicts between the health authorities, the professional organisations and the drug industry in relation to pharmaceutical issues. Naturally, the industry has been critical of the registration and pricing policy, but, by and large, it has kept a fairly low profile, adapting to the political environment.

One central question to ask is in which way and to what extent tight drug regulation has served public interests. As with social regulation in general, there are conflicting interests. Some have argued that excessive regulation delays the marketing of useful new drugs, thus hindering the research process and impeding the future introduction of new products. The responsible actors have, however, no reason to believe that the restrictive drug policy has deprived Norwegians of necessary drugs.

_tEquity_ has been important in the drug distribution system, with the Robin Hood principle safeguarding the sustainability of less profitable pharmacies in supplying drugs and pharmaceutical services in remote rural areas; likewise, social security and reimbursement schemes have enabled access to necessary drugs independent of income.

For three decades Norway has emphasised the importance of the last link in the drug chain—patients and prescribers. Using part of the profit from drug sales to inform patients, doctors and pharmacists about drugs has helped sensitise society to the issue of the rational use of drugs, including when _not_ to take drugs as solutions to everyday problems.

Consultation with opinion-leading clinicians in the drug regulatory process proved effective in overcoming potential opposition to a policy restricting the number of registered drugs and thereby the sacrosanct right of doctors to prescribe as they wish. A majority became convinced of the benefits of a rational drug policy, in fact supporting the right of all people to be informed about appropriate drugs. The crucial role of visionary leadership in policymaking and implementation has also been demonstrated.
The present process of working towards harmonisation with the EU, together with the general development in the pharmaceutical field, represents an intervention into a situation where balance between the actors involved had previously been established. New positions will be taken up. The industry is most in favour of the ongoing and expected changes in the pharmaceutical area, whereas health care workers as well as the public are expressing concerns. A democratic society has the responsibility to share information so that the public can make informed choices. This becomes all the more important when a national policy is at risk of being subsumed in a pan-European one, and the media’s role in providing the public with information has therefore to be strengthened. The challenge is to maintain a well-functioning National Drug Policy with a public health perspective that has served as a model internationally. The vision of a society in which medicines are seen as something more than a commodity must be allowed to survive.

Norway
Key Facts

I. General
Size: 324,000 km² (mainland)
Population: 4,300,000 inhabitants; 20 per cent under 15 years, 14 per cent over 67 years.
Population density: 13 per km²
Proportion of population living in urban areas: 72 per cent
Capital: Oslo
Languages: Norwegian, Lapp
Religion: Christian protestant
GNP per capita (1991): 23,000 USD
Literacy: close to 100 per cent in relevant age groups

II. Health
Health care expenditure (1991): NOK 55 billion
Health care expenditure, as percentage of GNP: 8 per cent
Life expectancy: women 80 years, men 73 years
Infant mortality rate (1990): 7.0 deaths under 1 year of age per 1000 live births, 2.0 under 24 hrs after birth
Doctors (in active employment): 9,443
Population per doctor: 455
Pharmacists: 2,033 (1136 cand.pharm., university level)
Pharmacies (not including hospital pharmacies): 322
Population per pharmacist: 2,116
Population per pharmacy: 14,000

III. Drugs

Total costs: NOK 5.5 billion (consumer price) (USD 0.8 billion)
Patient share of total drug costs: 34 per cent
Total drug costs (incl. patient share) as percentage of health care expenditure (1991): 9.6 per cent

Number of drugs on the market (brands, strengths, dosage forms): 2,200
Chemical entities: 750

Combination drugs (examples):
- **antibiotics**: 5 out of 80 registered brands: trimethoprim+sulfonamide (3), combination of sulfonamides (1), imipenem+cilastin (1)
- **cardiovascular**: 9 out of 96 registered brands: diuretic+potassium (3), tiazide+amiloride (6)
- **minor analgesics**: 9 out of 22 registered brands: acetylsalisylic acid+codeine (2), paracetamol+codeine (4), fenazon+coffein or codeine (3)
- **hypnotics and sedatives**: 0 out of 15 registered brands

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