

## RESULTS OF THE IN-DEPTH STUDY OF SCANDINAVIA: SWEDEN

During the period of the study, a number of medicines were transferred from prescription-only to over-the-counter status.

In all cases, the interviewer met with very interested and positive attitudes. All interviews were carried out in an open-minded and friendly atmosphere. The individual interviews lasted from a few minutes to several hours. A record of each interview was kept either on tape or in writing. Two colleagues, who have been helpful far beyond what could reasonably be expected, must especially be mentioned: Mr Göran Alsterlind, ACO Läkemedel AB, and Mr Magnus Sjöblom, National Corporation of Swedish Pharmacies.

### Presentation of non-prescription medicines

The Medicines Act defines a medicine as a commodity intended to prevent, diagnose, relieve or cure disease or symptoms. Some medications such as natural medicines are partly exempt from the regulations specified in the Medicines Act.

Medicines are divided into pharmaceutical specialities and extemporaneous preparations. A pharmaceutical speciality is a standardized medication that is intended to be supplied to the consumer in the manufacturer's original packaging. An extemporaneous preparation is a medication produced in the pharmacy according to a physician's specific prescription. The sales of extemporaneous preparations have now fallen to less than 2% of the total turnover.

The number of pharmaceutical specialities has decreased as follows (registered each 1 January):

<u>Year</u>	<u>Brand names</u>
1976	1682
1979	1479
1980	1418
1981	1337

The National Corporation of Swedish Pharmacies was established by a decision made by Parliament in 1970. The Corporation is two thirds owned by the state and one third by a foundation under the auspices of the Swedish Academy of Pharmaceutical Sciences. Since 1971, the Corporation has had, with few exceptions, the exclusive right to conduct retail trade of medicines, including operating the pharmacies. By an agreement with the Government, it is responsible for maintaining a good supply of medicines, providing good services to the public and to the health care system, utilizing new developments in the field of medicine, and keeping medicine costs as low as possible.

The Association of the Swedish Pharmaceutical Industry (LIF) is the trade organization for Swedish pharmaceutical companies engaged in research and manufacture of medicines, while the Association of Representatives of Foreign Pharmaceutical Manufacturers in Sweden (RUF1) sells prepackaged imported pharmaceuticals and carries out clinical research. LIF and RUF1 cooperate closely in various areas and are both members of the European Proprietary Association (AESGP). Thus, the members of LIF and RUF1 are obliged to follow the code of marketing practices developed by AESGP. However, LIF and RUF1 already established a voluntary board themselves in 1969: the Board for Evaluation of Pharmaceutical Information (NBL).

The purpose of NBL is to ensure that LIF and RUF1 member companies comply with the industry's rules for pharmaceutical information. NBL consists of six members from the industry, a chair, a deputy chair, two medical consultants and a representative of the Swedish Medical Association. NBL deals with complaints from companies, physicians and the public. A physician regularly examines the printed information issued by the pharmaceutical industry. The voluntary NBL system reinforces the official regulations, as the Medicines Act says that withdrawal of licensing can take place if a medicine is subject to advertising containing incorrect, strongly exaggerated or misleading data on the medicine's effects or other properties. This rule has not been utilized in practice. Television commercials for medicines are generally not allowed, but non-prescription medicine can be advertised in public places such as railroad stations and in newspapers.

Promotion is based on the Marketing Act and supervised by the National Board of Consumer Policies (NBCP). All product claims for

conditions that may be suitable for self-medication must be substantiated, and no product claims may be made about diseases or symptoms that require a physician's diagnosis (as determined by the National Board of Health and Welfare). In practice, such claims are rarely examined because of the lack of resources and internal priorities of the NBCP.

The National Corporation of Swedish Pharmacies has a special policy on medicine information for the public. The policy implies that brand-name products are not allowed to be advertised within pharmacy premises. When specific preparations are mentioned in brochures written by the Corporation or individual pharmacies, the rule is that two brand names are mentioned if comparable preparations are available. The Corporation's product inventory policy specifies that the sales of non-restricted goods shall be influenced through ethical marketing. The Corporation has initiated education of personnel in active marketing. Further, brochures, posters and, to some extent, advertisements are used as marketing means for non-restricted goods, besides normal exposure in self-service departments.

In 1978, the Swedish Medicine Insurance Association was founded. All pharmaceutical companies operating in Sweden must join this association to indemnify people suffering from medicine-induced injuries. This plan deals especially with unforeseen damages, but known adverse effects can be compensated in cases that are unexpectedly severe. A patient insurance association operates concurrently with the Medicine Insurance Association.

Advertisements are not intended as an educational media for the public. They are used to catch attention and to communicate a short message about a medication. Consequently, advertisements are used intensively when new products are introduced or when prescription medicines become available over the counter. This was the case when paracetamol was transferred to over-the-counter status in 1974 and when hydrocortisone preparations became available for topical use without prescription in 1983. Consumer education is expected to take place in pharmacies, predominantly by written and oral information given by pharmacy personnel.

Package inserts are almost never used in Sweden. The question of a general insert requirement has been brought up in Parliament several times. However, manufacturers have not specially been interested in producing inserts, because it is expensive to introduce new packaging machinery. Exceptions are the bigger multinational companies such as Sandoz and Roche, which already have the necessary equipment. Instead, a coordinated system of written consumer information on prescription and non-prescription medicines has been

established. Information about prescription medicines is seen as a necessary link in the general self-care project of the National Corporation of Swedish Pharmacies.

The written medicine information that is available almost anywhere in the country includes self-care booklets, treatment instructions, instructions for users, and brochures on specific topics such as the introduction of new non-prescription medicines.

Further, the journal *Apoteket* [The pharmacy] gives advice on medicines. The written information is supplemented by oral information when medicines are dispensed in pharmacies.

## Self-care booklets

The initiative to work out a self-care booklet was taken in 1979 by a pharmacist who has been especially active in the field of medicine information: Jan-Erik Ögren. The idea has rapidly spread all over the country, and now most communities have these booklets. The booklets are worked out and developed cooperatively by pharmacies and the local health care system. The idea is that people will receive uniform information about how to treat milder illnesses. The contents vary slightly, but all booklets comment, in alphabetical order, on 25-30 milder symptoms such as acne, the common cold, fever and toothache. Under each symptom, there is a description of appearance, causes, advice on contacting the health care system, advice on self-care, and advice and recommendations on medicines. Self-care booklets recommend a number of selected medicines, usually two different products, for symptoms/diseases where medication is useful. The self-care booklets are handed out free of charge and have been received very positively by the public and health care personnel.

## Instructions to users

About 40% of all medicines dispensed are accompanied by information on use; for example, the medicine must not be taken in combination with a meal or it shall be swallowed whole. By the use of computers, a cipher code in the price list reminds pharmacy personnel of the information. The information is adapted to the individual when the medicine is dispensed.

Educational material addressed to pharmacy personnel has been produced by the National Corporation of Swedish Pharmacies.

## Distribution

Medicines are produced by about 125 foreign and 35 domestic manufacturers. Only two wholesalers operate at present: a subsidiary company of the National Corporation of Swedish Pharmacies, which controls a total of 80% of the distribution, and Kronans Droghandel AB, which is owned by a number of mainly foreign pharmaceutical companies. The population in the primary sector is served by about 760 pharmacies and 1500 other outlets for medicines. On average, one pharmacy serves 10 900 inhabitants. This is at the same level as the other Nordic countries, but it is a much higher density of pharmacies than is found in other developed countries. However, the number of inhabitants per pharmacy varies, so that in rural areas the ratio is much lower than in the cities. At present, less than 1% of the population lives more than 30 km from a pharmacy.

"Over-the-counter", as a concept, is not mentioned in Swedish medicine legislation. Traditionally, the concept has been used exclusively for non-prescription pharmaceutical specialities. Because of the increasing interest in self-medication, new product groups have been added to the inventory of over-the-counter products, the basic idea being that these products are to be controlled by public agencies (1).

All products intended to be marketed as pharmaceutical specialities are evaluated by the National Board of Health and Welfare for efficacy, safety and quality. For non-prescription medicines, it is further specified that the medicines:

- be of low toxicity;
- have no troublesome adverse effect;

be intended mainly for simple, short-lasting, well known symptoms or diseases;

and that treatment can be instituted without medical advice but aided by proper labelling.

There are about 750 non-prescription pharmaceutical specialities. However, almost one third of these products are injection and infusion preparations, medicines for diabetics, and circulation-increasing preparations: preparations that are not intended to be used in self-medication. In practice, they are not used in self-medication anyway, because of the lack of reimbursement for over-the-counter purchases.

Unrestricted medicines, homoeopathic products, some oral preparations and natural remedies are totally or partly exempt from the requirements for pharmaceutical specialities and may be sold outside pharmacies.

Unrestricted medicines include ointments for wounds and antiseptic preparations, mainly for external use. The products must adhere to marketing regulations issued by the National Board of Health and Welfare. Unrestricted medicines are sometimes reclassified as pharmaceuticals because of adverse effects (for example, benzoyl peroxide).

Homoeopathic products are exempted from the Medicines Act if they contain less than one part per million of an active ingredient. Mineral water and oral preparations are exempted if they contain what is allowed to be in food. Regulation of ingredients is carried out by the National Food Administration.

Natural products were exempted from the Medicines Act beginning in January 1978. The products must be of natural origin and the seller/importer must demonstrate that the product is harmless. The products must be labelled with the following statement: "This product has not passed the obligatory medicine inspection." About 450 products were listed as natural products in 1983.

## Prescription-only to over-the-counter status

Paracetamol is an analgesic that was introduced in Sweden in 1958 as a non-prescription medicine. Because of the suspicion of renal failure in phenacetin abusers, the National Board of Health and Welfare reclassified both phenacetin and its main metabolite, paracetamol, as a prescription medicine. In 1974, paracetamol became a non-prescription medicine again, but was subject to certain restrictions in package size and strength, and the package must carry specified labels. In 1977, following discussions in the medical press on paracetamol and hepatic toxicity, the National Board of Health and Welfare reduced the permitted package size from 25 to 20 tablets.

At the request of the manufacturers, the National Board of Health and Welfare decided to transfer one-dose pipettes of nose drops containing oxymetazoline 0.1-0.5 mg/ml from prescription-only to over-the-counter status. A maximum package size of 50 pipettes was allowed for the 0.25 mg/ml and 0.5 mg/ml strengths. The main reason for the decision was the abuse of oral medicines that reduce the swelling of the mucous membrane. The decision comprised two points: the indications of oral mucous membrane preparations

were to be restricted to allergic and vasomotoric rhinitis, and one-dose packages of these nose drops would be available with the above-mentioned restrictions.

The experiences with this oxymetazoline case were very positive, and therefore the National Board of Health and Welfare decided, after deliberations and hearings, to transfer a number of medicines to over-the-counter status in the autumn of 1983. The medicines were cough preparations containing dextromethorphan, and creams, ointments and liniments containing hydrocortisone. However, the transfer of milder hydrocortisone ointments has led to some discussion on concomitant risks. Restrictions specified a maximum content of 1% hydrocortisone and a maximum package size of 20 g or 20 ml. Nineteen different hydrocortisone products were transferred.

"Pharmacy outlets" dispense medicines ordered in advance, prescription and non-prescription. "Type II pharmacy outlets" have a further inventory of 10-12 non-prescription medicines, while "type III pharmacy outlets" have about 70. "Pharmacy branches" have a more diverse over-the-counter product inventory (2).

The self-service policy of the National Corporation of Swedish Pharmacies operates with four different recommendation and display levels that determine the inventory of products offered in the self-service departments of some pharmacies.

There are no regulations restricting the sale of medicines to minors. Non-prescription medicines restricted to sale in pharmacies can be dispensed by pharmacists and pharmacy technicians.

There are no differences in the official policies governing domestic and foreign pharmaceutical specialities; all products must adhere to the same regulations.

The market share for imported medicines (prescription and non-prescription) has increased about 50% during the past 15 years. Foreign companies produce about 60% of the total inventory of medicines.

Corresponding figures are not available for non-prescription medicines. However, domestic manufacturers have larger market shares in this field. It was estimated by one interviewee that about 85% of the total over-the-counter turnover comprised Swedish products. This estimate is supported by the market shares in different therapeutic groups, where Swedish companies sold most of the products in these typical over-the-counter groups (percentage sold by Swedish companies in 1982 in brackets): analgesics (74%), cough and cold remedies (69%), antacids (66%).

The rules for distributing and marketing generic over-the-counter products are the same as for pharmaceutical specialities. A few generic non-prescription medicines are available but are rarely sold. Examples are acetylsalicylic acid, ascorbic acid and senna pods. Natural medicines and food additives may be sold outside pharmacies.

## Pharmacy sales, pricing and economics

The number of pharmacy purchases is about 60 million per year. Twenty million people buy prescription medicines, 36 million non-prescription medicines and other goods, while the rest buy prescription and non-prescription goods.

The number of prescriptions for primary care tripled from 1973 to 1983. In 1983, the number was 40 million prescriptions. Sales amounted to SKr 3785 million, yielding a mean price of SKr 94.50 per prescription. The total turnover of medicines increased from SKr 1676 million in 1973 to SKr 5277 million in 1983. More than 95% of sales take place in the Corporation's pharmacies. The turnover of medicines in 1982 equalled 8.0% of the total health care expenditure. Almost two thirds of medicine expenditure are paid by the social health insurance system. Different reimbursement principles exist: prescription medicines can be completely free or price-reduced. Since everyone has to pay an annual deductible (or co-payment) based on all health services utilized, and all health care expenses after this deductible are fully reimbursed, some medicines are free of charge for this reason.

The public's annual expenditure on all products for self-medication can only be estimated, as sales statistics are available only through the National Corporation of Swedish Pharmacies (Table 37).

In 1983, sales increased to SKr 6010 million, and the distribution in different groups was the same as for 1982 (3-6).

About one half of the parapharmaceuticals sold in pharmacies are closely related to pharmaceuticals (skin disinfectant, acne preparations, dermatological preparations, gargles and eye lotions).

Total sales in pharmacies have been increasing for decades, and this applies to prescription and non-prescription medicines. However, the number of prescriptions has stagnated during the past 10 years. The proportion of non-prescription medicines decreased until the late 1970s but has been stable since 1978 (3).

Pharmacy sales of parapharmaceuticals have increased in both value and volume (Table 38) (3).

Table 37. Distribution of pharmacy sales

	Million SKr	1982 (%)	1979 (%)	1975 (%)
Prescription medicines in primary care	3370	63	66.5	66
Non-prescription medicines	424	8	8	10.5
Parapharmaceuticals	360	7	7	5.5
Free consumer articles and special food	212	4	2.5	2
Hospital sales	861	16	16	16
Services	105	2	-	-
<b>Total</b>	<b>5332</b>	<b>100</b>	<b>100</b>	<b>100</b>

Source: *Statistiska sammanställningar 1982, 1983 (3).*

Table 38. Sales of parapharmaceuticals through pharmacies

	1979	1980	1981	1982	1983
Sales (million SKr)	235	275	320	360	430
Number of packages	27	28.5	29	29.5	32.5

Source: *Statistiska sammanställningar 1982, 1983 (3).*

Sales of health food and natural remedies increased 700% from 1972 to 1982. Sales of vitamins through everyday shops are also increasing.

A total of 4.0 million packages of vitamins was sold by pharmacies in 1976, and the same was true in 1983 (7). During this period, sales fluctuated, with a minimum of 3.7 million packages in 1977 and a maximum of 4.2 million in 1980. The everyday shops have increased their sales of vitamins during the same period, and their market share is about one fourth that of the pharmacies (8).

Information on the sales of over-the-counter preparations in different therapeutic groups was obtained from the National Corporation of Swedish Pharmacies. Measured by the number of purchases, pharmacy sales of non-prescription cough remedies, throat lozenges and vitamins have decreased. The turnover of other non-prescription products has remained about the same. However, the total number of packages sold remains at a stable level of 3.9 packages per capita per year.

In a study, carried out one week in 1978, on sales from four Jämtland pharmacies (9), 2719 non-prescription medicines were bought in 2113 transactions. The medicines sold most belonged to the following therapeutic groups (percentages of total number in brackets): analgesics (45%); vitamins, tonics, nutritional preparations and minerals (16%); remedies for respiratory diseases (14%); gastrointestinal remedies (12%); nose, mouth and throat remedies (7%); dermatological agents (3%). The analgesic group was dominated by acetylsalicylic acid preparations, the respiratory group by expectorants.

Information on purchases of over-the-counter analgesics is available from the National Board of Health and Welfare (10), the National Corporation of Swedish Pharmacies (4) and the pharmaceutical industry (11). It appears that total sales have remained at a stable level. The composition of sales has altered, as sales of effervescent tablets have increased. In addition, paracetamol received an increased market share after its introduction on the over-the-counter market in 1974.

It must be remembered that over-the-counter products refer to those that are actually bought without prescription. However, many non-prescription medicines are prescribed in Sweden because of special prescription rules; only one third of non-prescription medicines are in practice purchased over the counter. There may be price differences between prescription and non-prescription medicines, as all prescription medicines are covered by the reimbursement system.

The medicine prices of the National Corporation of Swedish Pharmacies have to be uniform throughout the country, according to an agreement with the state. Prices have to be maintained at a level that covers the Corporation's expenses and returns profit on their investment.

The Corporation's purchase prices for pharmaceutical specialities are determined in negotiations between the Corporation and the manufacturers. Medicine prices are comparable to those in other countries, the distribution costs being the lowest in Europe.

The Corporation's pricing policy for parapharmaceuticals implies "reasonable prices" in comparison with other outlets, but these products must pay their own way. Hence, the pharmacies' inventory of parapharmaceuticals cannot be subsidized by medicine sales. There is no agreement controlling prices for other outlets, but recommended prices exist in some cases. The specialized shops generally have a higher price level for health food and health care products than everyday shops.

The same companies usually produce non-prescription and prescription medicines. This is mainly because the documentation restrictions for pharmaceutical specialities are the same for all products, although in practice the requirements differ for different indications. The companies are generally organized pharmacologically so that they can concentrate on a few therapeutic groups. Their increasing emphasis on export marketing has contributed to the trend of concentrating on a specialized product inventory.

ACO Läkemedel AB, a company that originated in pharmacy production, is especially oriented towards the domestic market and over-the-counter products. ACO focuses on basic medicines and does not develop novel ones, but it stresses low-technology preparations in many different dispensing forms, packages, tests, etc. Competitive prices are another important component of ACO's marketing policy. ACO has a market share of 30% of over-the-counter products.

Some minor agents for foreign companies that sell only over-the-counter products exist, but these are of minor importance.

Three over-the-counter preparations, all produced by Swedish companies, were among the ten top-selling products in Sweden in 1982. With the transfer of preparations from prescription-only to over-the-counter status, an increase in market share is expected by Swedish manufacturers. Manufacturers of parapharmaceuticals are predominantly domestic. LIF and RUFİ cooperate closely in different areas.

According to the interviewees, non-prescription medicines will be emphasized much more in the future. One interviewee expected the borderline between medicine and other health care products to diminish in the future.

## Public interest in and acceptance of non-prescription medicines

### *Trends influencing self-medication*

The Swedish self-care debate has differed from the debate in most other countries, as it has been a debate among health professionals

and politicians (both Parliament and county councils). Patient associations have not been involved, and lay people in general have only been involved by being represented by politicians. The public have been spectators to the discussion. Self-care has been introduced and implemented "from the top down", in contrast to the mode of operation of lay health organizations. This corresponds to the positive attitudes towards self-care among health professionals. The Swedish Medical Association and the Swedish Pharmacists' Association have been very positive towards self-care. Pharmacists have discussed self-medication at a large number of meetings, such as the 1976 Pharmacy Day (12) and the 1977 Pharmaceutical Congress (13). Self-care and self-medication have been discussed in detail in the two pharmaceutical journals *Svensk farmaceutisk tidskrift* and *Farmaceutisk revy*. In addition, the Swedish pharmaceutical industry, and especially representatives of ACO, has been very supportive of self-medication.

Public interest in health has been demonstrated by the number of articles and books appearing in the media. Many publishers have their own self-care books, occasionally translated and adapted from books published in the United States.

*Patient-FASS*, a comprehensive medication catalogue intended for the public, is a best-seller. It was first published in 1983 and sold 300 000 copies during the first six months. The book is published by LINFO AB, a company owned by LIF and RUFU, the pharmaceutical industry's trade organizations in Sweden. The introductory section contains 12 chapters on general questions about medicines, such as dispensing forms, adverse effects, medicine insurance and health insurance. The major part of the book contains, in alphabetical order, descriptions of all pharmaceutical specialities on the Swedish market. For each product, the following is described: prescription/non-prescription, manufacturer, dispensing form(s), contents, background and indications for use, dosage, adverse effects, cautions, pregnancy and breastfeeding precautions, storage, and available sizes of package. The prices are not included.

*Patient-FASS* was evaluated by a telephone survey of the public (consumers), pharmacists, physicians and nurses. The consumers surveyed used the book especially for information on specific medicines. If they did not read all the information about a medicine, they at least read about the adverse effects and indications. The introductory chapters were of more limited interest. Most people had a positive attitude towards the book. The most negative attitudes were held by the physicians surveyed, of whom 5% found the book bad or very bad (14).

*Apoteket* [The pharmacy] is a magazine intended for pharmacy customers and has been published since 1980. *Apoteket* is published four times a year, and 400 000 copies are distributed free of charge. The magazine covers a broad range of topics concerning self-care and medicines and is very popular among the public. The articles are usually written by people employed by the National Corporation of Swedish Pharmacies. The magazine also contains a column with questions from customers, and a few advertisements.

During recent decades, Swedish society seems to have developed towards specialization, centralization, institutionalization and "bureaucratization" at a faster rate than most other developed countries. In the health care sector, specialized treatment and high technology have been focused on in large-scale hospitals. The primary health care sector almost vanished during this development. A policy of restriction and control of people's lifestyles has a long tradition, as exemplified in the strict controls placed on alcohol purchase. Since the early 1960s, improvements in lifestyle and nutrition and the promotion of nonsmoking and exercise have been stressed through health education programmes worked out by different national boards. An example from the mid-1970s is the large posters in the cities announcing that "the National Board of Health and Welfare recommends that you eat 5-8 slices of bread daily".

Reactions to societal developments have sparked criticism in different ways (15,16): criticism of the inadequate results of the specialized, high-technology health care system; criticism of the professionalization of health care; criticism of the lack of interest in the individual; criticism of the dehumanization of patients; increased public interest in alternative health care; and criticism of the way resources are spent in the health care sector.

The term *egenvaerd* [self-care] was used for the first time in Sweden in a health care policy programme produced for the county councils in 1974. Gösta Tibblin, a professor of general practice medicine, gave a lecture in 1976 that included a broad definition of self-care, and this lecture has been widely discussed and debated (17).

In 1976, for the first time in 44 years, Sweden had a non-social-democratic government. The new Minister of Social Affairs, Ingegerd Troedsson, advocated the idea of self-care, especially "taking more responsibility for one's health". Ingegerd Troedsson mentioned different ways of promoting self-care: health education on lifestyle factors such as the use of tobacco and alcohol, and poor nutrition; self-treatment of milder diseases; postponement of physician consultations for illnesses such as the common cold and influenza; and increased activities in schools and in society to teach people about their bodies. Concurrently,

self-care was seen as a way of reducing expenses in the health care sector (18).

The self-care concept was extensively discussed in the following years, especially by politicians and health professionals. The debate was covered by both the professional journals and the mass media.

The resistance to the concept of self-care can be summarized as follows:

- focusing on the right and responsibility of the individual patient is just a way of eliminating public, collective responsibility, leaving weak people to fend for themselves;
- self-care is merely a way of justifying austerity in the social and health care sectors with an ideological rationalization;
- self-care focusing on self-medication increases total medicine use in society.

However, this resistance gradually faded out in the late 1970s, and now it seems as if the concept of self-care is generally accepted at an overall level.

HS 90, a new health care policy programme presented in 1984, does not focus on self-care especially. The programme stresses efforts to reduce inequalities in health and health care between different population groups, the role of preventive efforts and the role of primary, decentralized health care (19).

In the period since 1945, the field of medicine has been characterized by development of high-technology medicines. Only a few companies, such as ACO, have focused on non-prescription medicines. Hence, the tendency has been that a continually increasing share of the product inventory remains prescription-only.

Do-it-yourself health technology is available both in pharmacies and in other shops, as it is not defined as medicine. In Sweden, there has been no sales boom on the home care market, in contrast to the United States. Blood-measuring cuffs are not normally sold for patient use. In the field of diagnostics, there have been increased sales of pregnancy testing kits. They are sold through many everyday outlets.

Following the increase in alternative health care practices, various types of technology have been marketed. Shoes with stimulating knots for use in zone therapy and devices for magnet therapy are examples of this type of technology.

Pharmacies have the major share of the lay health technology market. This is partly because of tradition and partly because of the reimbursement system for free-of-charge consumer articles. These articles are disposable or for short-term use. Articles for extended use are distributed by the supply centres at the hospitals. Free consumer articles comprise aids for people who have had colostomies or ileostomies, people suffering from urinary and intestinal incontinence, and technical aids for diabetics. The National Board of Health and Welfare is responsible for the product inventory, but in practice the Institute for the Handicapped works out the lists of free articles. As of 1984, this was about 700 articles.

During the last decade, the number of diabetics has been stable at 42 000, the number of people who have had colostomies or ileostomies has increased from 11 000 to 13 000, and the number of people with treated incontinence has doubled to 70 000. In the field of diabetes, the turnover of test material for blood sugar measurement and blood testing devices has increased. Different syringes and insulin pumps have also been marketed. Products for people who have had colostomies have improved radically but have concomitantly become more expensive (2).

There is no evidence that epidemiological and demographic trends have increased the interest in self-medication practices. However, the change in age structure has led to a growing elderly population, and hence an increase in the use of non-prescription medicines such as laxatives.

The shift in morbidity and mortality patterns from infectious to chronic diseases has been one of the elements in the discussions on self-care. What has been especially stressed is the possibility of prevention by changes in lifestyle in areas such as diet, exercise and smoking (20). Self-medication practices have apparently not been emphasized in this context.

Mutual aid organizations directed towards specific diseases and handicaps have several thousand members. The National Rheumatism Association has 40 000 members, while the Association for the Deaf and Blind comprises 130 members. These organizations function mainly as pressure groups to obtain benefits for the members' specific needs, and politicians are often the chairs of these associations. Mutual aid organizations have not been involved in the discussions on self-care and self-medication. Discussions on medication have concentrated on the desire to obtain medication and other treatment free of charge. Some associations operate partly as mutual aid groups, such as Amningshjälpen (Breast-feeding Aid) and Viktoria (the association for women who have been operated for breast cancer). References to mutual aid organizations can be found in health care handbooks (21,22).

During the past 15 years, the holistic health movement has gained increasing acceptance. It holds a critical attitude to allopathic medicine. Specialized, high-technology medical care is not able to prevent and cure widespread illness and disease. There is also a lack of controlled clinical trials that provide evidence of treatment efficacy. The main hypothesis of the holistic health movement is that all diseases can be prevented or treated by optimization of environmental factors and the right food. Diet, health food and natural remedies are in focus in the therapeutic arsenal of this health movement (23,24). Originally, this health movement began as a lay movement, but in recent years the physicians involved in it have been declared as gurus and apostles by their physician colleagues. There is a special journal for naturopathy, the *Svensk tidskrift för biologisk medicin* [Swedish journal of natural medicine].

There are very few consumer-initiated demands in the field of non-prescription medicines. The initiatives in the fields of self-care and self-medication have been taken mainly by health professionals, politicians and the pharmaceutical industry.

Consumer organizations have shown interest in safety questions, but this is expressed as demands for more restrictions on medicines. The Organization for Helping Medicine Abusers is involved in preventing abuse of medicines. People connected with Health Action International have been seeking restrictions on clioquinol preparations and attempting to secure indemnification for people impacted by subacute myelo-optic neuropathy (25).

The monitoring of consumer issues on health care remedies such as slimming preparations is dealt with by the National Board of Consumer Policies, which is a public organization. The activities of the Board regarding medicines can be characterized as supplementary to the activities of the National Board of Health and Welfare and the National Corporation of Swedish Pharmacies.

Women's health groups are literally nonexistent in Sweden, in contrast to the Federal Republic of Germany, the United Kingdom and the United States.

#### *Influences on the choice of non-prescription medicines*

According to the interviewees, the public has the necessary knowledge to handle medication in a way that does not lead to any harm. People have a basic knowledge of indications, dispensing and utilization. When it comes to knowledge about differences among products and pharmacological questions about how the medicines work, knowledge is poor. For cough medicines, it has been found that 10-15% of the users have this knowledge.

A number of studies dealing with information needs and levels have been carried out as ways of evaluating means for experiments on medicine information.

The public's perception of the appropriateness of different types of non-prescription medicine seems to depend especially on the availability of products, symptoms (including experience) and cultural traditions. The use of different types of medication has been analysed in several Swedish studies (26-29).

People's attitudes towards different types of medicine were the main topic of a 1980 survey of 240 adults (30). People find that prescription preparations are stronger and more effective than the non-prescription preparations sold in pharmacies. Some believe that prescription medicines are more reliable than non-prescription medicines. Non-prescription preparations are generally thought to be safer and do not lead to abuse or misuse to the same extent as prescription medicines. In comparison with health food products, prescription and non-prescription medicines are both regarded as more effective, and yet more dangerous with respect to adverse effects.

Another study showed a similar picture (26). Out of 1000 respondents, 72% agreed that prescription medicines give better/faster results than non-prescription medicines; 65% agreed that non-prescription medicines sold in pharmacies are more effective than preparations sold outside pharmacies; 55% agreed that natural remedies from health food/everyday shops are helpful for milder conditions. On the other hand, 73% of the respondents disagreed with a statement saying that non-prescription preparations sold in pharmacies have more adverse effects than preparations sold in everyday shops.

A representative study on attitudes towards natural medicines in Stockholm county in 1977 revealed that about two thirds of the respondents expected natural medicines to be increasingly used in the future. Most people found these preparations useful, and less than 1% found them harmful. Most people start to take natural medicines as a result of recommendations from family members, friends, colleagues or health food shops. One out of eight users reported dissatisfaction with allopathic medicines as the initial reason for taking natural medicines. The discontent was related especially to a perceived lack of effect, and only to a lesser extent was discontent based on perceived adverse effects (27).

The pharmaceutical industry and the National Corporation of Swedish Pharmacies have carried out a number of studies concerning consumer attitudes toward medicines and health care products bought in pharmacies and other outlets. According to a 1980 survey (30), pharmacy preparations are generally evaluated positively. People

seem to have confidence in them because they are analysed and controlled. When it comes to health food products, these are especially valued when they are of natural origin.

When health food shops were compared with department stores, two thirds of those surveyed found that the product inventory was about the same. To some extent, people find that the specialized shops are more expensive but have a variety of products to choose from and give better service (30). Prescription medicines are found to be the cheapest group of products. Attitudes towards health food products bought in health food shops and other stores are similar.

In 1977, 400 customers in health food shops were questioned about natural medicines (27). Thirty per cent of the respondents found the social atmosphere and information in health food shops so valuable that they would not consider buying natural medicines elsewhere. Sixty-eight per cent of the respondents would consider buying from other outlets, with price being the decisive factor.

Only vitamins, minerals, natural medicines and non-restricted parapharmaceuticals can be sold in places other than pharmacies. The number of mineral purchases during the past decade has decreased from 0.3 million to 0.1 million packages per year. Concurrently, pharmacy sales of parapharmaceuticals have increased 20% (measured in packages). However, it is difficult to know how the overall sales for all outlets were distributed, whether sales increased overall or whether the market share for non-pharmacy outlets decreased. For natural medicines, sales increased for all outlets.

People's attitudes towards different pharmaceutical outlets were studied in 1980 (26). The pharmacy is ranked as the first choice for non-prescription medicines for all health complaints. However, everyday shops and health food shops rank quite high for some health complaints. The mean number of outlets desired increased to an average of 1.7 for cold and influenza medicines. It was found that young people wanted a wider variety of outlets than elderly people.

In a 1980 study (30), 65% of the respondents wanted to buy their medicines in pharmacies, one third preferred to buy them in everyday shops, while 6% chose health food shops. The motive in choosing pharmacies was primarily a matter of confidence, skilled personnel and pharmacy quality control. The health food shops were preferred because of the inventory of natural remedies and the everyday shops because of their convenience of access. Convenience of access (too great a distance to the pharmacy) was mentioned as a reason for choosing everyday shops as the preferred outlet for non-prescription medicines (26,30).

This question is also related to access to the health care system. The waiting time before an individual can see a doctor for minor health problems such as athlete's foot (*tinea pedis*) or haemorrhoids will usually cause people to visit a pharmacy and purchase an over-the-counter remedy. Saving of resources is also part of the philosophy behind transferring medicines from prescription-only to over-the-counter status.

In most cases, consumers have no choice with respect to the price of prescription and non-prescription medicines. However, according to the interviewees, the reimbursement system can be important. If an over-the-counter product is relatively expensive, such as effervescent vitamin C tablets, some people prefer to consult a doctor to get a prescription to subsidize the product. The same may be true for over-the-counter preparations that can only be bought in small packages. However, many people value time more highly than money, and this will lead to over-the-counter purchases in most cases.

In a study in 1978 in four Jämtland pharmacies, 49% of the respondents wanted more information about medicines they had purchased. Six per cent specified that they wanted oral information from pharmacy personnel, while 2% mentioned physicians as the preferred primary source (9).

A study carried out by the National Corporation of Swedish Pharmacies in 1980 (31) showed that one out of 20 customers asks pharmacological questions in pharmacies. A difference was found between conventional pharmacies and self-service pharmacies, showing that customers in pharmacies with self-service departments ask more specific questions. General questions about technical aspects (price, packages, dosage forms) were asked by one in five customers in conventional pharmacies but only by one in eleven in self-service pharmacies. More specialized questions about differences among medicines and when and how to use them were asked by one in ten customers in conventional pharmacies and one in seven in self-service pharmacies.

A 1980 study (30) showed that pharmacy personnel ranked third in public confidence as an information resource after physicians and nurses. Twenty-nine per cent of the respondents were very confident of pharmacy personnel as an information resource; 41% were quite confident and 23% were confident to some extent; 1% did not have confidence in pharmacy personnel. Another study (26) showed that people who have a lot of confidence in primary information from pharmacists are women, elderly people and people with good access to a pharmacy.

Two thirds of the people who had bought *Patient-FASS* stated that they would prefer to get information from pharmacy personnel on non-prescription medicines, 23% preferred written information, and 5% preferred information from physicians (14).

## Consumers' use of non-prescription products

### *Patterns of use*

According to a study of natural medicines (27), people who use these remedies are more often ill than a comparable population of non-users. However, this applies to those who use allopathic medicines. Women use more natural medicines than men. This pattern is also seen in the use of allopathic medicines. These findings are supported by the fact that people mainly use natural medicines in conjunction with allopathic treatment rather than as a substitute (27,32).

Elderly people (over 65 years) seem to use about twice as much medicine as young people. Because non-prescription medicines are primarily intended to treat non-chronic illnesses, the differences in use among age groups are generally less pronounced for these medicines. However, for laxatives and remedies for haemorrhoids, the increase in use with advancing age is enormous. The data in Table 39 are taken from the national surveys on living conditions carried out in 1968 and 1974 (33).

Table 39. Laxative use during a particular two-week period

Age	Percentage of respondents	
	1968	1974
15-29 years	1.1	1.4
30-55 years	3.4	2.8
56-76 years	10.1	10.1

Source: Virtanen (33).

It is well known that mistakes in the use of medicine are frequent among the elderly. This phenomenon is primarily explained by the use of multiple medicines, and it is sometimes compounded by reduced memory capacity and increased confusion. Elderly people do not expect and do not ask for information in pharmacies as frequently as young people. At the same time, they are more content with the information that is given. The National Corporation of Swedish Pharmacies has produced illustrated information material directed especially towards the elderly: *Raad om medicinering* [How to medicate]. A working group is dealing with the need for further information material for the elderly.

In 1978, a study of non-prescription medicine purchases showed that 46% of the respondents were going to use the medication themselves; 20% bought the medication for a family member, 23% for the whole family, and 10% for somebody else (26).

In 1974, a survey revealed that women determined about two thirds of family pharmacy purchases: analgesics, 67%; vitamins, 69%; toothpaste, shampoo, etc., 63%; skin remedies, 76% (34). Natural medicine purchases are influenced by the family to some extent. In one study, 44% of the respondents reported that they bought natural medicines because of personal recommendations, family tradition or the good reputation of the medicine. Fifty-nine per cent of the consumers of natural medicine discussed its use with their family (27).

#### *When are non-prescription medicines used*

When and how different types of non-prescription medicine are used in relation to the self-care cycle depends on both the nature of the symptoms and the nature of the medicines. For example, vitamins and minerals are used to prevent deficiency diseases. Herbal medicines are used both as an initial response to symptom onset and concurrently with or supplementary to allopathic medicines (27).

The sales statistics of the National Corporation of Swedish Pharmacies reveal that around half of the purchases are for aches and fever, 15% for gastrointestinal problems, 12% for prevention (vitamins), 9% for coughs, and 6% for skin problems.

In one 1980 study, a questionnaire was mailed to a random population sample (26); 1042 people aged 15-69 years responded to the survey, which asked about their responses to seven common illnesses/symptoms the last time they had suffered from them in the previous six months. The answers thus gave a retrospective measurement of incidence rates. Non-prescription medicines were used to a much greater extent than prescription medicines. Home remedies were used most frequently by people with colds, and herbal

medicines most often for hair problems. Another postal questionnaire was conducted in 1982 (28); 1540 questionnaires from a random sample of 1900 households were returned. The respondents were asked the following questions regarding 13 different illnesses/symptoms: "What did you do the last time somebody in your household suffered from ...?" The use of non-prescription medicine was the most common response in all cases. From the detailed answers, it appears that people were not always aware of which medicines are prescription and which are non-prescription. This seems especially to be true for analgesics. It also appears that analgesics (acetylsalicylic acid preparations and paracetamol) are used for several symptoms: headache and pain, the common cold, fever, sore throat and even for cough.

In 1980, a comprehensive three-step study was carried out (29,30). Step one consisted of questioning a national sample of the population aged 16-69 years, totalling 483 men and 512 women. People were asked what they would normally do in response to 13 common symptoms/illnesses. The responses comprise information on the use of non-prescription medicines, health food and home remedies. Almost 75% of the respondents take non-prescription medicine for headache. Symptoms such as fever and cough are second with approximately 40%. Natural medicine was used most extensively for hair problems (6%), stomach problems (5%) and colds (4%). Prescription medicines were mostly used for the following (percentages of respondents in brackets): skin problems (23%), colds (20%), stomach problems (19%), and aches and pains (18%).

Indications for the use of natural medicines were reported in a survey carried out in Stockholm county. The most common reasons for taking 171 preparations were as follows (percentages of indications in brackets): preventive, strengthening (24%), constipation (8%), nervousness (8%), gastrointestinal problems (8%), respiration, infections (7%), anaemia (4%), urinary tract problems (4%), skin problems (4%), and others (19%).

Non-prescription medicines are used especially for common, physical ailments: ache, fever, cough, sore throat and different stomach problems. In addition, there is widespread use of vitamins. Many common episodes of illness involving extensive use of non-prescription medicines also include prescription medicines, though to a varying extent (26). Some episodes of illness, such as psychiatric problems, are usually medicated with prescription-only products.

As a part of a family study, 593 family members kept a health diary for 28 days (35). Health problems were registered in 30% of the 15 680 report days. Out of all illness episodes, no action was taken for one half of the cases. Self-selected medicines were taken twice as often as prescription medicines (36).

It seems as if people seek professional care if treatment with non-prescription medicines does not work or if persistent symptoms are viewed as being too severe for self-treatment. For example, the National Corporation of Swedish Pharmacies and the pharmacies recommend that the use of non-prescription medicines for athlete's foot (*tinea pedis*) and constipation not exceed three to four weeks.

*Effects of self-medication*

The general opinion of people working in the health care sector is that health care costs are reduced by transferring medicines from prescription-only to over-the-counter status. In a 1980 study questioning physicians about common symptoms, 75% of the physicians surveyed (general practitioners and district medical doctors) believed that their patients could be treated more often by self-care (36). Another dimension of the question, namely the information aspect, was elucidated as part of the evaluation of the introduction of self-care booklets in Vänersborg municipality (37). Before the distribution of the booklet, the proportion of "unnecessary" telephone inquiries to the Public Medical Care Information Service was 20%. After distribution of the self-care information, the percentage of "unnecessary" calls decreased to 11% of total telephone inquiries.

The storage and reuse of non-prescription medicines by consumers has not been subject to specific analysis. One study revealed some information on medicines stored in homes (30). The respondents had supplies of the following medicines at home:

<u>Medicines</u>	<u>Percentage of respondents that had medicines at home</u>
Over-the-counter analgesics	73
Cough medicine	53
Skin remedies	47
Vitamins	45
Antacids	36
Nose drops	34
Lozenges	30
Iron preparations	23
Laxatives	22

Storage of medicines is considered a central topic for the written and oral information, given to consumers by pharmacies, on the technical aspects of medicine use. For example, information on storage includes the following:

- keep medicines well out of the reach of children;

- do not use medicine prescribed for another person and do not give prescription medicine away;
- store prescription medicine only if a physician has told you to do so;
- return unused and old medicine to the pharmacy, where it will be destroyed.

According to the respondents, it has become increasingly common for families to have medicine cabinets that lock.

According to the respondents, abuse of non-prescription medicines is rather limited. However, abuse of analgesics containing codeine does take place to a limited extent. The pharmacies' policy is to discuss the problem with these people, but they cannot force them to change their behaviour. The overall sales of analgesics are quite extensive, but it is expected that 25-30% of medicines in this therapeutic group will be scrapped. Excessive chronic use of laxatives has also been reported.

Adverse reactions to non-prescription medicines are seldom reported to the board on adverse reactions to medicines. The reasons could be (1) there are no adverse effects, (2) physicians underreport adverse effects, or (3) the reporting system does not function for non-prescription medicines.

Some preparations have been transferred from over-the-counter to prescription-only status because of the risk of intoxication. In January 1980, a number of pharmaceutical specialities containing theophylline were transferred because of the risk of intoxication. In March 1982, some anabolic steroid injection preparations were transferred owing to the risk of abuse by people engaged in body-building. In January 1983, cinchocaine eye ointment was transferred. By mistake, it had not been mentioned on the prescription-only list. Chlorhexidine disinfection spirits were also transferred in January 1983 because of the risk of use as an alcoholic beverage. Inhalation anaesthetics were transferred in July 1983 because of the risk of hepatic intoxication and the risk of abuse by inhaling.

Interactions of non-prescription medicines with food or other medicines have not been a matter of special concern among physicians. However, pharmacists have discussed the problems to some extent. Interaction with iron preparations is well known (iron preparations and antacids containing aluminium, calcium or magnesium; iron preparations and tetracycline). Also, the risk of acetylsalicylic acid in combination with warfarin is well known, although this risk affects relatively few people.

## Health professionals and self-medication

In general, pharmacists regard themselves as the key persons to advise consumers on medicines. Especially for non-prescription medicines, pharmacists hold a central position, as they are often the only health professionals involved. This view was expressed by interviewees (pharmacists) and is reflected in a huge number of articles in the pharmaceutical press. Initiatives in the field taken by individual pharmacists or groups of pharmacists comprise self-care booklets (38-40), medicine lists (41), education and information of specific groups such as the elderly; films and videos on the use of medicine, and education on medicines in public schools. Most of these initiatives have been supported by the National Corporation of Swedish Pharmacies.

The National Corporation of Swedish Pharmacies is required to develop information in the field of medicines. Since the early 1970s, the Corporation has worked to develop proper information on medicines for the public. Initially, the efforts focused on different topics for brochures and pamphlets for the public, but in the 1980s a comprehensive policy on self-care ("health-care-directed self-care") was prepared as a basis for initiatives in this area. This policy is in line with the ideas on self-care presented by Gösta Tibblin (17,42,43). The development and evaluation of self-care booklets and the education of pharmacy and other health care personnel are the basis of these activities. The self-care initiatives have been evaluated very positively by the public and by pharmacy and other health care personnel.

During recent years, most pharmacies have established some kind of self-service department. The basic reason is that consumers get a better idea of the product inventory and receive information adjusted to individual needs. For instance, it is expected that information on mere technical details can be obtained as written information, leaving the more complicated questions/information to oral communication between pharmacy personnel and customers. The information and the product inventory displayed in self-service departments are based on the recommendations in the self-care booklets. The inventory is based on a four-group recommendation on non-prescription medicines implemented by the National Corporation of Swedish Pharmacies. The groups are based on the amount of supervision by pharmacy personnel that is necessary. Group one includes parapharmaceuticals, while group four includes products to be sold only if the consumer insists. The continuing education programme is designed to ensure the proper education of personnel.

The Association of Swedish Pharmacists (the pharmacists' trade union) focuses on the informational and educational role of the

practising pharmacist in securing the safe use of medicines (44). There is general agreement with the policies of the National Corporation of Swedish Pharmacies, but some disagreement exists. The union stresses that self-service departments should be staffed. The questions of self-medication and information on non-prescription medicines has a central position in the Association's policy and action programme "Yrket i Fokus" ["The profession in focus"] launched in 1983; 2000 out of 3800 organized pharmacists joined study circles on the programme in 1983.

The union has declared its support for the new prescription rules, stating that pharmacy personnel have to give information individually adapted to the patient (45). The union has also expressed dissatisfaction with the lack of interest in medication in the report on the health care system in the 1990s (HS 90) (19), as well as dissatisfaction with the diminishing role intended for pharmacists as recommended by a report on medicine information for the elderly (46).

The subject of home remedies, herbal preparations and non-prescription medicines plays a negligible role in the curricula of health professional schools and universities. In the education of physicians, dentists and nurses, the focus is on pharmacokinetics and high-potency products, that is, the effects and problems associated with these medicines. Thus, "harmless" products are not dealt with. In recent decades, the use of herbal preparations has been considered to be caused by quackery and people's misguided belief in inefficient remedies. The practical education of physicians and nurses in hospitals supports the tendency to neglect non-prescription medicines. Knowledge about self-medication and non-prescription medicines is very limited among all health professionals, except for pharmacists, whose knowledge has increased considerably during recent years. Different aspects of self-medication/non-prescription medicines have been studied in student projects in social pharmacy.

Personnel in health food shops are required to go through a course dealing with biology, nutrition, health food and natural medicines.

Physicians' attitudes towards self-care and self-medication are generally positive, with the preparation and introduction of self-care booklets being a contributing factor. The self-care booklets have formed the basis for joint education of health care and pharmacy personnel. In practice, cooperation among health care personnel has led to an increase in joint referrals of patients. The attitudes towards alternative treatment are generally negative, except for a few physicians who lead the alternative health movement (24).

The Swedish Medical Association has a positive attitude towards self-medication, including the transfer of some medicines from prescription-only to over-the-counter status. The Association believes that a necessary precondition for proper self-medication is oral and written information supplied by pharmacy personnel (47).

The Union of Health Care Workers (Nurses) has a rather critical attitude towards the self-care concept. The focus on self-care has been seen as a means of effecting reductions in the health care sector. Only the health education aspect is viewed positively (18).

According to the interviewees, physicians recommend that their patients take non-prescription medicines to some extent. Especially in municipalities where the self-care booklets have been fully introduced, physicians usually recommend that people go to the pharmacy. In many places, there are guidelines that recommend in which situations physicians should refer people to the pharmacy and vice versa.

The experience gained from transferring nose drops containing oxymetazoline (0.1-0.5 mg/ml) from prescription-only to over-the-counter status implies that physicians now ask people who call for a prescription to go direct to the pharmacy.

It has to be remembered that the health care system in Sweden, including the pharmacies, is a public system and people are employed on salary.

## References

1. Lönngrén, T. Legislative environment. In: *Proceedings of the 19th Annual Meeting of the European Proprietary Association (AESGP)*, Stockholm, 8-10 June 1983. Paris, European Proprietary Association, 1983.
2. *Apoteksbolaget mot år 2000* [Apoteksbolaget towards the year 2000]. Stockholm, Socialdepartementet, 1984.
3. *Statistiska sammanställningar 1982, 1983* [Statistical information 1982, 1983]. Stockholm, National Corporation of Swedish Pharmacies, 1983.
4. *Arsredovisning 1983* [Annual report 1983]. Stockholm, National Corporation of Swedish Pharmacies, 1984.
5. Nohrlander, A. Swedish pharmacies and OTC distribution. In: *Proceedings of the 19th Annual Meeting of AESGP*, Stockholm, 8-10 June 1983. Paris, European Proprietary Association, 1983.

6. Florén, I. et al. *Apotekens sortimentspolitik* [The pharmacy's product inventory policy]. Thesis in social pharmacy, Uppsala University, 1980.
7. Wessling, A. *Handköpsstatistik som underlag för och uppföljning av patientinformation* [Over-the-counter sales statistics as the basis for and evaluation of patient information]. Paper presented at the 14th Nordic Pharmacy Conference, Helsinki 28-31 May 1984 (unpublished).
8. Olsson, K. Health care products outside pharmacies. In: *Proceedings of the 19th Annual Meeting of AESGP*, Stockholm, 8-10 June 1983. Paris, European Proprietary Association, 1983.
9. Boëthius, G. et al. Valet av receptfria läkemedel [The choice of non-prescription medicine]. *Svensk farmaceutisk tidskrift*, 83: 12-16 (1979).
10. *Information fraan Socialstyrelsens Läkemedelsavdelning* [Information from the Pharmaceutical Department of the National Board of Health and Welfare]. Stockholm, National Board of Health and Welfare, 1980, Vol. 5 (Suppl.3), pp. 8-9.
11. Asberg, L. OTC marketing: industry experience. In: *Proceedings of the 19th Annual Meeting of AESGP*, Stockholm, 8-10 June 1983. Paris, European Proprietary Association, 1983.
12. Eklund, L.H. Självmedicinering - inledande synpunkter [Self-medication - initial opinions]. *Svensk farmaceutisk tidskrift*, 80: 330-371 (1976).
13. Troedsson, I. Egenvaard - ge individen bättre möjligheter att ta ansvar för sin egen hälsa [Self-care - give individuals better opportunities to take responsibility for their own health]. *Svensk farmaceutisk tidskrift*, 81: 573-629 (1977).
14. Institute for Medical Marketing Research. *En vane- och attitydundersökning: Patient-FASS* [A habit and attitude study: Patient-FASS]. Stockholm, LINFO AB, 1983.
15. Borgenhammar, E. *Hälsans pris. En hälsokontroll av sjukvaarden* [The price of health. A health check-up of the health care system]. Stockholm, Studieförbundet Näringsliv och Samhälle, 1982.
16. Serner, U. *Ansvar för min sjukdom, politikerna, jag själv, vaardpersonalen* [The responsibility for my illness, the politicians, myself, health care personnel]. Stockholm, Liber Förlag, 1980.

17. Tibblin, G. Vad är egenvaarden värd? [How much is self-care worth?]. *Hässle information*, 8: 11-18 (1976).
18. Brodin, G. *Egenvaardsdebatten i Sverige - förnyelse eller social nedrustning?* [The self-care debate in Sweden - renewal or social austerity?]. Uppsala, Institute of Sociology, 1982.
19. Hälsö- och sjukvaard inför 90-taket - HS 90 [Health care and illness treatment towards the 1990s - HS 90]. *Farmaceutisk revy*, 83(12): 39-44 (1984).
20. Jersild, P.C. Vad är egenvaard? [What is self-care?] In: *Apoteket, tidning för apotekens kunder* [The pharmacy, the magazine for pharmacy customers]. Stockholm, National Corporation of Swedish Pharmacies, 1980, p. 21.
21. Tibblin, G. *Din nyckel til sjukvaarden* [Your key to the health care system]. Stockholm, Wahlström & Widstrand, 1983.
22. *Prismas handbok för patienter* [Prisma's handbook for patients]. Stockholm, Bokförlaget Prisma, 1981.
23. Lindahl, O. & Lindwall, L. *Vetenskap och beprövad erfarenhet* [Science and experience]. Stockholm, Natur og Kultur, 1978.
24. Lindahl, O. Hälsörörelsen och läkarna [The health movement and the physicians]. *Läkartidningen*, 76: 3369-3371 (1979).
25. Hansson, O. *De samvetslösa läkemedelsbolagen. Om SMON skandalen* [The unscrupulous pharmaceutical industry. The SMON scandal]. Zindermans, 1977.
26. Jönsson, B. *Egenvaard i Sverige* [Self-care in Sweden]. Stockholm, AB Marketing, 1980 (ABM 4518).
27. Jacobson, N.-O. *Naturläkemedel och okonventionella behandlingsmetoder* [Natural medicine and unconventional treatment methods]. Stockholm, Huddinge Hospital, 1979.
28. Unpublished market research. Stockholm, National Corporation of Swedish Pharmacies, 1982.
29. *Project egenvaard - fraageställningar i personlig omnibus* [Project self-care - comprehensive interview survey]. Lund, GfK-Sverige marknadsforskning AB, 1980 (unpublished).
30. *Egenvaard steg IIB - undersökning avseende inställning till behandlingspreparat* [Self-care step IIB - a study of attitudes towards treatment preparations]. Lund, GfK-Sverige marknadsforskning AB, 1980 (unpublished).

31. Sjöblom, M. Apoteksbolaget (personal communication).
32. Haglund, B. Alternativ vaard [Alternative health care]. In: *Offensivt hälso arbete* [Offensive health work]. Stockholm, SPRI, 1982, pp. 143-160.
33. Virtanen, P. *Vaardkonsumtion och välfärd (2). Om den vuxna befolkningens användning av läkemedel 1968 och 1974* [Health care consumption and welfare (2). On the utilization of medicine by the adult population in 1968 and 1974]. Stockholm, Institute for Social Research, 1979.
34. Karlsson, G. Hur sker inköpet och hur används läkemedlen? [How are medicines purchased and how are they used?]. *Svensk farmaceutisk tidskrift*, 84: 187-192 (1980).
35. Dahlqvist, G. et al. Hur är det med egenvaarden [How is self-care doing]. In: Eriksson, C.-G. & Tibblin, G., ed. *Aktiv egenvaard - en gammal nyhet* [Active self-care - an old news item]. Uppsala, Uppsala University, 1984, pp. 67-69 (Allmänmedicinsk rapport nr. 1).
36. Tibblin, G. The role of self-care in medical treatment. *Journal of social and administrative pharmacy*, Suppl. 1, pp. 15-18 (1984).
37. Karlsson, G. Written co-ordinated patient information on non-prescribed and prescribed drugs. *Journal of social and administrative pharmacy*, 2(Suppl. 1): 148-157 (1984).
38. Karlsson, G. Uppföljning av ett egenvaardshäfte [Evaluation of a self-care booklet]. *Svensk farmaceutisk tidskrift*, 86: 30-31 (1982).
39. Ögren, J.-E. Apoteket - sjukvaardens förlängda arm [The pharmacy - the extended arm of the health care system]. *Farmaceutisk revy*, 82(2): 26-33 (1983).
40. Ögren, J.E. Egenvaard - en ny och viktig uppgift för apoteket [Self-care - a new and important task for the pharmacy]. *Farmaceutisk revy*, 79(6-7): 20-23 (1980).
41. Burman, R. et al. En "läkemedelsbok" för öppenvaardspatienter? [A "medicines book" for primary care patients?]. *Läkartidningen*, 74: 2522-2523 (1977).
42. Sjöblom, M. Projektet "Sjukvaardsled egenvaard" [The project "Health-care-directed self-care"]. Stockholm, National Corporation of Swedish Pharmacies, 1982 (unpublished).

43. Eriksson, C.-G. & Tibblin, G., ed. *Aktiv egenvaard - en gammal nyhet* [Active self-care an old news item]. Uppsala, Uppsala University, 1984 (Almänmedicinsk rapport nr. 1).
44. Säkerhet framför allt [Safety first]. *Farmaceutisk revy*, 81(67): 8-10 (1982).
45. Apotekens skyldighet informera fastslas [The pharmacy's duty to inform is established]. *Farmaceutisk revy*, 83(8): 7 (1984).
46. Läkemedelsinformation till äldre [Medicine information for the elderly]. *Farmaceutisk revy*, 83(6-7): 39 (1984).
47. Forbundsprogram positivt till egenvaard. De enskilda bör stimuleras att ta ansvar [Union statement positive towards self-care. Individuals should be encouraged to take responsibility]. *Läkartidningen*, 76: 4209-4211 (1979).

## Interviewees for the study report on Scandinavia: Sweden

Mr G. Alsterlind

Pharmacist, ACO Läkemedel AB; member, AESGP President's Committee

Ms I.-L. Andersson

Information pharmacist, Information Department, National Corporation of Swedish Pharmacies

Professor E. Borgenhammar

Nordic School of Public Health

Mr G. Brodin

Researcher, Health and Illness Care Project, Institute of Sociology

Mr I. Ehrlen

Director, National Corporation of Swedish Pharmacies

Dr L.-E. Fryklöf

Editor, Swedish Academy of Pharmaceutical Sciences

Miss A. Granzell

Information pharmacist, Information Department, National Corporation of Swedish Pharmacies

Mrs B. Hammarström

Vice-Chair, Association of Swedish Pharmacists

- Mrs A.-G. Hedstrand  
LINFO AB [Drug Information Inc.]
- Mrs M.-L. Hildén  
Information pharmacist, Information Department, National  
Corporation of Swedish Pharmacies
- Dr Anne Jung  
Practising physician, Hälsingborg Lazaretto
- Professor B. Jönsson  
Linköping University
- Mr G. Karlsson  
Chief pharmacist, Tranen Pharmacy
- Mr J. Lilja  
Assistant professor, Department of Social Pharmacy, Uppsala  
University
- Mr H. Mandahl  
Chief manager, Medicine Department, National Board of Health  
and Welfare
- Mr P. Manell  
Section manager, Medicine Department, National Board of Health  
and Welfare
- Mrs I. Nordenstam  
Information Department, National Corporation of Swedish  
Pharmacies
- Mr M. Sjöblom  
Project manager, Self-care project, Information Department,  
National Corporation of Swedish Pharmacies
- Professor K. Strandberg  
National Board of Health and Welfare
- Professor G. Tibblin  
Department of General Practice, Uppsala University
- Mr C. Wallén  
Chief pharmacist, Timra Pharmacy
- Mr L. Aasberg  
Sterling Winthrop AB

Mr J.-E. Ögren

Chief pharmacist, Skellefteaa Hospital Pharmacy



## RESULTS OF THE IN-DEPTH STUDY OF SOUTHERN EUROPE: GREECE, PORTUGAL AND SPAIN

### Introduction

Several states in Europe are undergoing rapid development of government infrastructures related to the role of medication in health care. At the time this study was undertaken, there was not a sufficient data base to obtain a full picture of the status of non-prescription medicines in these countries. This summary on Greece, Portugal and Spain is a useful indication of anticipated progress.

### Greece

The situation in Greece is apparently unique, as consumers can obtain nearly any type of medicine without prescription. This means that there is no difference between prescription and non-prescription medicines. Non-prescription medicines are generally prescribed by a physician: only a few products are labelled as over the counter, and these are subject to the same regulations as prescription medicines. The content of advertising has to be approved by the National Pharmaceutical Agency.

Non-prescription medicines are sold only in pharmacies, except in remote areas where medicine is provided by the physician free of charge to the patient. The Government pays the cost of prescription and non-prescription medicines.

All non-prescription medicines are manufactured domestically. Manufacturers are interested in the growth of the over-the-counter market. No studies have been reported on the patterns of use of non-prescription medicines, but women and rural and elderly people are thought to practise self-medication most often. There are virtually no studies on self-medication.

The pharmacist is considered an important source of information for over-the-counter products. Pharmacists encourage the use of non-prescription medicines; physicians oppose self-medication. Physicians do not differentiate between prescription and non-prescription categories of medicine, since all medicines are available to the public without prescription.

There is some scepticism about the introduction of non-prescription medicines into the Greek health care system at a level comparable to other developed European countries. A legitimate question is whether people who are used to social health insurance reimbursement of all prescription medicines will accept a system in which they will not be reimbursed for non-prescription medicines.

The advantages of introducing non-prescription medicines have been emphasized to the Greek Government. For the successful introduction of non-prescription medicines, however, appropriate mechanisms would have to be developed to satisfy both the consumers and the Government.

## Portugal

The concept of non-prescription medicines is relatively new in Portugal. In the introduction to the law enacted on 8 January 1983, it is stated that unrestricted use of these medicines by the population would enable health workers to make better use of their time.

The law also states that these medicines do not need, as do prescription medicines, prior authorization for advertising. The *a posteriori* control of the Directorate-General of Health replaces the prior authorization required for advertising by the professional code of the manufacturers. Further, unrestricted medicines are no longer subsidized by the Medical-Social Services Department of the Ministry of Social Affairs. This means that the total costs for purchasing non-prescription medicines must be borne by the buyer.

The law limits the indications for these medicines to the relief, treatment or simple prevention of symptomatic manifestations or mild health problems capable of being effectively treated with this type of medicine. The sale of unrestricted medicines is limited exclusively to pharmacies, although a prescription is not required. The package must clearly specify the fundamental therapeutic indications and recommendations for consumer use. The package insert should be directed to the consumer and should contain suitable information for using the medicine correctly, along with such advice as, "If symptoms persist, contact your physician."

It is difficult to inform consumers through providing package inserts because it is customary to ask for only three or four tablets. This means that consumers have no package and accordingly no insert. In such a case, consumers must completely rely on the advice of the pharmacist, and they are dependent on the advice given by the pharmacist in a way that they can understand and remember. It is believed that the majority of consumers read the information on the inserts when an entire package is purchased.

Since the introduction of non-prescription medicines is rather new, there are no statistical data on their sales and no studies on interests and trends in self-medication. Experts believe that their share amounts to 3% of all medicines sold.

Approximately 70% of non-prescription medicines are domestically produced. The Government is interested in increasing domestic production and in reducing the quantity of medicines imported. There are no price differences for non-prescription medicines since they are sold exclusively in pharmacies.

The regulations governing the quality of non-prescription medicines are the same as for prescription medicines. Non-prescription medicines must therefore meet the same standards as prescription medicines.

Convenience is thought to be the main reason for buying non-prescription medicines. People with minor health problems want to avoid visiting a doctor. The cost of a physician consultation is Esc 50 plus Esc 25 per item prescribed. There is also the cost of the time needed to see the social health insurance doctor (many hours). Some people may simply decide to purchase a convenient and inexpensive over-the-counter product, despite the financial disincentive in buying non-prescription medicines, as they are not reimbursed by the social health insurance system.

Nevertheless, it is hoped that over-the-counter purchases will reduce the cost to the Government of supplying medication through social health insurance, even if over-the-counter products are prescribed by a physician. A major source of savings is anticipated from the expected reduction in the number of visits to physicians as a result of the over-the-counter alternative. Physicians, however, disapprove of self-medication because they contend that they have total responsibility for the diagnosis and treatment of their patients.

These realities may brighten the future of the over-the-counter market in Portugal, as indicated by the increased number of applications by companies for inclusion of some of their products in the over-the-counter list.

## Spain

In Spain today, the use of non-prescription medicines is necessary and desirable because these medicines help to improve general health care services, and they have a high margin of safety.

Although non-prescription medicines have existed in Spain for a long time, specific legislation on them was enacted only very recently. The Ministry of Health created a diverse commission in May 1979 to develop legislation on this kind of product.

The functions of this commission included establishing a definition of non-prescription medicines, defining allowable active ingredients, designating a registration system, determining transfers from prescription-only to over-the-counter status, setting regulations on packaging, updating lists of non-prescription medicines, and establishing a policy for the liberalization of prices.

The commission was composed of members of the National Centre of Pharmacology, the Department of Pharmacy and Drugs and Executives of the Proprietary Association of Spain. The commission worked from May 1979 to the middle of 1981. Its work was made official by the publication of six legislative proposals covering different areas from November 1981 to September 1982.

Royal Decree 2730/1981 provides a detailed definition of non-prescription medicines, in which they are described as unrestricted pharmaceutical specialities that can be used without a prescription for the relief or treatment of minor symptoms or ailments not requiring professional medical attention. They are also used to prevent such ailments.

This royal decree also:

- restricts the active ingredients permitted in non-prescription medicines and specifies directions for their dosage and use;
- restricts the use of non-prescription medicines for infections;
- limits the sale of non-prescription medicines to pharmacies;
- regulates the packaging required for non-prescription medicines;
- regulates the registration system and the number of applications it will accept per year;
- excludes non-prescription medicines from the social health insurance reimbursement system.

In November 1981, the Ministry of Health published a list of non-prescription medicines in existence at that time and the rules for identifying them. In March 1982, the Ministry of Health published another ministerial order updating the list. The total number of non-prescription medicines listed was 380.

According to the Ministerial Order of 17 September 1982, over-the-counter products must have a definite composition. They must have proved their efficacy and safety for the indications for which they are intended, and their quality and quantity must also be identified.

Non-prescription medicines can only contain the active ingredients that appear in the lists published in the ministerial order; 34 therapeutic groups are listed (the main ones are analgesics and antacids) with a total of 255 active ingredients. Combinations of active ingredients are accepted, but the need for them must be justified.

The registration documentation is studied and approved by the same panel that studies and approves prescription medicines: the National Centre of Pharmacobiology of the Ministry of Health. Non-prescription medicines are produced to meet the same standards of safety, quality and efficacy as other pharmaceutical products. Their active ingredients must have been widely used in clinical therapy, and the dosage must be correct for the treatment of minor ailments.

Non-prescription medicines are consumer products, and advertising is therefore permitted for this kind of pharmaceutical product. Media advertising must be submitted to the Ministry of Health for approval before release by the granting of a preliminary health product advertising permit. With the aim of improving health education, the Proprietary Association of Spain recommended several years ago that a warning should be included in all advertisements of this type of product: "Keep medicines out of the reach of children."

Package inserts for non-prescription medicines contain the same categories of information as those for prescription medicines, although the inserts for non-prescription medicines must be written in language that is more readily understood by the user. The package, insert and label may constitute a single element provided that it includes all the required information.

Public expenditure on non-prescription medicines is believed to be 5% of the total pharmaceutical market, with steady increases in recent years. Non-prescription medicines are available only through pharmacies. Therefore, the role of the pharmacist is considered crucial in ensuring the necessary distribution, information and education.

To summarize non-prescription medicines in Spain:

- they may be single-ingredient or combination products;
- they are intended for the treatment of minor symptoms or ailments;
- they must include directions for dosage and use as intended for the final user;
- they can be sold only in pharmacies;
- they are not reimbursed by the social health insurance system.

## Interviewees for the study report on Greece

Professor N.H. Choulis

Dean, School of Pharmacy, University of Athens; President,  
Greek Pharmaceutical Society

Mr S. Demos

President, Pharmaceutical Manufacturers Association

Ms A. Giotaki

Director, National Pharmaceutical Agency

Dr G. Kavadias

President, National Pharmaceutical Agency

Mr S. Kazazis

Vice-President, National Pharmaceutical Agency

Professor P. Kostamis

Professor of General Medicine, School of Medicine, University  
of Athens

Mr V. Koukouvinos

President, Pharmaceutical Association

Professor A. Koutselinis

Professor of Toxicology, School of Medicine, University of  
Athens

Mr P. Marinopoulos

President, Proprietary Association of Greece

Professor D. Varones

Professor of Pharmacology, School of Medicine, University of  
Athens

Officials at the Pharmaceutical Directorate, Ministry of Health

Officials at the Directorate of National Health Insurance, National Organization for Social Security

Random sampling of practising physicians

Random sampling of practising pharmacists

Random sampling of pharmaceutical manufacturers

## Interviewees for the study report on Portugal

Dr A. Albuquerque  
President, Pharmaceutical Society of Portugal

Mr D'Almeida  
President, Manufacturers Association

Dr Andresen Leitao  
Professor of Therapeutics, Member of Medicines Approval Committee

Dr Aranjo  
Director of Medicines, Ministry of Health

Mr Conelha  
Minister of Health

Dr J. Coreiro  
President, Pharmaceutical Association of Portugal

Mr Forsenca  
Proprietary Association of Portugal

Mr Gonzalves  
President, Association of Wholesalers

Mr Guerra  
Proprietary Association of Portugal

Mr Leal  
Proprietary Association of Portugal

Dr A. Macedo  
President, Proprietary Association of Portugal

- Dr Martins  
President, Portuguese Medical Association
- Professor Mirabeau  
Dean of Medicine, University of Lisbon
- Professor Pereira  
Dean of Pharmacy, University of Lisbon
- Dr Quintino  
Director of Health, Ministry of Health
- Dr De Silva  
Vice-President, Pharmaceutical Society of Portugal
- Dr J. Silveira  
Secretary, Pharmaceutical Association of Portugal
- A number of local pharmacists and pharmacy shops

## Interviewees for the study report on Spain

- Mr J. Baiao Custodio  
Director, Marketing, ORFI-FARMA, Barcelona
- Dr F. Ferrandiz  
Former Director, Spanish Board of Health
- Dr C. Ferre Cabrero  
Director, Spanish Red Cross
- Dr A. Garcia de Pablo  
President, Spanish Consumer Association (ACUDE)
- Dr E. Marco Canizares  
President, Spanish Pharmaceutical Association
- Dr J. Mendez Espino  
President, National Consumer Institute, Ministry of Health
- Mr J.-A. Perrez-Espania  
President, Proprietary Association of Spain
- Dr R. Rivera  
President, Spanish Medical Association
- Dr J. Rodrigez  
Head, Pharmaceutical Registration, Ministry of Health

Professor J. Salva Miguel

Professor of Pharmacology, University of Barcelona

Dr P. Sanchez

Professor, Head of Pharmacology, Faculty of Medicine,  
Autonomous University of Madrid

Dr J. Sanchez Sobrino

Assistant Director, Board of Health, Ministry of Health and  
Consumer Affairs



## ISSUES AND NEEDS

This was an exploratory study. What was learned is the product of reconnaissance and review: an identification of gaps in our knowledge, clarification of partially revealed issues, priorities for further study, and hints for necessary action on non-prescription medicines in Europe.

Data on self-medication in Europe are scant and fragmentary. With a few notable exceptions, European countries have not undertaken systematic data collection on the manufacture, distribution and use of non-prescription medicines, much less the broader picture of self-medication as a whole. Relatively few scholarly studies have been reported on public patterns of preference or use. However, there appears to be a growing awareness of self-medication with special emphasis on the relationship of self-medication to the costs of professional medical services, and the regulation of non-prescription products to enhance safety and effectiveness.

This awareness may be heightened as Europe's population continues to age. As a result, non-prescription medicines in Europe appear to be a popular and credible health care resource.

### Government involvement

In all the responding European countries, there is widespread use of non-prescription medicines, with commensurate government interest in ensuring the safety and quality of those products through both statutory and voluntary measures, in cooperation with manufacturers and distributors. Many of the national control procedures are similar in principle but differ in specific strategies of application. An example is the strictness with which the distinction between prescription and non-prescription medicines is enforced in practice. For some countries surveyed, public access to prescription

medicines is hardly different than public access to non-prescription medicines, even though the laws may indeed clearly differentiate between the two classes of medicine. This raises substantial questions of public safety and severely clouds the picture of the true role of self-medication in those countries. Using data on the consumption of non-prescription medicines as an indicator of self-medication levels is meaningless under such circumstances.

While the above situations are dramatic, they are relatively few in number. More commonly, differences among countries are reflected in the categories of medicine available without prescription. For example, while the majority of countries allow over-the-counter access to preparations for eye and skin complaints, several prohibit direct public access to these broad categories of medicine. But perhaps the most interesting variation among countries is the range of active ingredients available for inclusion in non-prescription medicines.

## Public intervention and health education

Legislation on non-prescription medicines includes attention to public intervention essential to the safe and appropriate use of non-prescription medication. Regulations specify the type of information (uses, contraindications, persistence of symptoms, etc.) and the location of that information (labelling, package insert). However, few available studies measure the actual utility of the information provided. How clear is the information and is it read by the prospective user?

Advertising in the mass media is allowed in many European countries but prohibited in others. Where it is allowed, it is controlled, supervised and reviewed through various mechanisms. Advertising material is probably the chief means through which the public obtains its knowledge of non-prescription medicines.

While health education is arousing government and popular interest throughout Europe, the focus on healthy lifestyles seems to exclude emphasis on personal health care management: the empowerment of lay people in self-diagnosis, self-care and self-medication.

The WHO Regional Office for Europe is aware of this shortcoming and has been operating a programme to enhance self-care and self-help. It is recognized that health and health care involve both lay and professional responsibility. Indeed, the vast majority of Europeans self-treat most of the symptoms of minor illness and injury. It is important to strengthen the integrity of these commonplace lay medical activities by ensuring optimal levels of knowledge about the benefits and limitations of self-administered

medicines. To achieve this will require careful development of educational materials, both product-related and related to building self-care competence generally. With the increasing growth of consumer movements, there are signs that education in self-medication will become an area of particular public interest. However, the health professions in Europe do not appear to give commensurate priority to lay education in self-medication. Physicians, for example, have not fully utilized their opportunities to educate patients in the appropriateness and importance of self-care in health, particularly the selection and use of non-prescription medicines, as well as herbal and home remedies for minor symptoms.

## Professional education

It is clear from the responses and reports collected for this study that professional health education for physicians, nurses and pharmacists lacks emphasis on self-care and, in particular, self-medication. These subjects appear to receive scant attention in health curricula and are hardly ever mentioned in continuing education. Since most non-prescription medicines are bought in pharmacies, pharmacists seem to be in a particularly advantageous position to give advice. Point-of-purchase education has an immediate and specific impact. On the other hand, consumer education in this context is not a sales pitch. Indeed, it requires evoking pertinent information on symptoms from the consumer and inquiring about what has already been done, the existence of other medicines that the consumer may be taking for present or other health problems, and even perhaps the consumer's allergies to specific ingredients that may be present in a given medicine. In addition, pharmacists can define the appropriateness of a given medicine and orally interpret or emphasize aspects of medication use together with advice on persistence of symptoms or side effects.

To prepare pharmacists for their educational role, the training of pharmacists in several European countries has already undergone substantial change. But clearly, more must be done to strengthen pharmacists' educational role as members of the primary health care team. Given that pharmacists may be increasingly prepared to work towards improving the competence of the public in self-medication, the nine in-depth country studies failed to reveal instances of comparable commitment among their physician colleagues. Indeed, there is a distinct possibility that physicians are ambivalent about self-care generally and self-medication in particular. While pharmacists appear eager to widen the scope of their responsibilities, physicians seem to question the advisability of adding a new dimension to their practice, especially one that might erode their control over making decisions about medication. This conclusion is, of course, speculative, but it is to be noted that

almost all the studies and proposals to extend public competence in self-medication have been undertaken or put forward by the pharmacy establishment. Quite obviously, real gains in strengthening public involvement in responsible self-medication can come about only through cooperation among all those involved in primary health care, namely a motivated public and informed and forthcoming physicians and pharmacists.

## Need for research

The results of this study support the view that European governments have generally undertaken to legislate and regulate the manufacture, advertising and distribution of non-prescription medicines. It is clear, however, that the emerging recognition of the role of self-medication has been highly variable among the countries reporting. This has led to an uneven picture of which active ingredients are allowed for use without prescription, how these products are made available, and what professional and public education is associated with their use. As public demand for self-medication increases, as the safety and efficacy of low-dose active ingredients are proven, and as governments take cost saving into account, it is now timely to consider self-medication policies coordinated on a European basis. From such an effort, we can expect three central outcomes:

- common terminology for non-prescription products, such as categories and distribution outlets;
- criteria for determining appropriate legislation;
- an agenda for research on public preferences, uses, benefits and limitation of self-medication.

The in-depth studies showed extreme differences in the amount of social research on self-medication available from universities and government sources. To an important degree, decisions about regulation must be informed by the reality of public use and/or misuse and lay expectations for an active role in the health system. With data on these and other aspects of public self-medication behaviour, there is a greater likelihood that countries can adopt legislation that fits their special circumstances. Self-medication appears to be a dynamic complex of behaviour and attitudes that requires frequent monitoring as a basis for regulatory development. This fact argues for long-term and continuous studies of lay self-medication practices and their consequences. Schools of pharmacy, medicine, nursing and the social sciences should be encouraged to give self-medication a secure place on their research agendas.

This study has identified some of the major gaps in our understanding of the lay self-medication phenomenon. There are reasonably good data on distribution by type of outlet, but little is known or published about factors leading up to purchase. What symptoms precipitate the decision to buy a non-prescription product? At what stage of symptom is the purchase made and how long is the product used in the case of persistent symptoms? What advice is sought and accepted about product choice? How are non-prescription medicines used: singly or in combination with other non-prescription and/or prescription medicines? What is the pattern of household use of a given product? Are instructions for use easily understood and followed? What are the special requirements (product, access, instructions) for non-prescription medicines for children and the elderly?

Research on these questions can in some aspects be facilitated by using field-tested questionnaires already developed by several countries. These questionnaires collect data on diverse aspects of self-medication behaviour. They may actually represent only the tip of the iceberg, with many other useful research projects undertaken but not published. Direct inquiries to universities may yield a valuable pool of methods available for more universal application.

## Conclusion

There is little doubt that people are at a frontier in considering the role of self-medication in health. Until very recently, self-medication was not part of our consciousness when discussing and planning health service development. Health services were usually perceived as synonymous with professional services. The new appreciation for the role of self-care has opened an opportunity to redefine health care as a continuum of activities and responsibilities involving both lay and professional resources. However, it will not simply be a matter of applying established technology, concepts or even values to this expanded venue of activity. In considering self-medication, for example, we have to construct a new evaluation method that incorporates both professional and lay criteria for benefits and limitations. Investigation of self-medication will necessarily require methods that are unobtrusive, acceptable to the lay public and sensitive to psychological, social and cultural aspects of behaviour. This is a private and personal domain of behaviour and will mean seeking partnerships in research, demonstration and even policy formulation among medical and social scientists, as well as representatives of the ultimate beneficiaries: the public.

A major early step in this process will be to create a wider understanding about self-medication among health professionals and

government health officials. Their healthy scepticism and established practices cannot and should not be met with pleas and polemics about the real and potential benefits of responsible self-medication. What must be tapped is the scientific inclinations of health researchers and policy-makers to demand evidence of benefits and limitations. Operating in the public interest, health professionals must have access to data of high quality and demonstrable evidence of safety and efficacy, as well as social and economic benefits.

What is already known about self-medication must at the same time be introduced into the training of health professionals at all levels, but particularly at the level of primary health care. This will be easier said than done given the lack of drama of such a commonplace practice as self-medication. However, it is precisely the universality of lay health practice, its ubiquity, that should be emphasized as the rationale for its importance. The next major advance in health care may well be the strengthening of the partnership in health care, the mobilizing of an active, self-confident, competent laity in daily decision-making about health care. Certainly as important as understanding the pharmacology of non-prescription medicines and their appropriate use is an understanding of lay empowerment in health care as a benefit to the patient, health professional and the health care system as a whole.

This study has established the fact of self-medication in Europe. It is a virtually pervasive phenomenon, well established in practice and law. A framework for development and an agenda for needed research also exist. What is now required is the political will to move to the next stage of action.