

WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR EUROPE

WELTGESUNDHEITSORGANISATION
REGIONALBÜRO FÜR EUROPA



ORGANISATION MONDIALE DE LA SANTÉ
BUREAU RÉGIONAL DE L'EUROPE

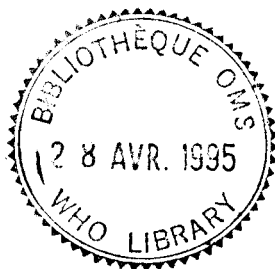
ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

EUR/ICP/PHC 120
6180F/6342F/6389F
ENGLISH ONLY

SELF-MEDICATION IN EUROPE

Report on a Study of the Role of Non-prescription Medicines

Edited by
Lowell S. Levin, Fritz Beske & John Fry



1988

EUR/HFA target 29

The issue of this document does not constitute formal publication. It should not be reviewed, abstracted or quoted without the agreement of the World Health Organization Regional Office for Europe. Authors alone are responsible for views expressed in signed articles.

Dieses Dokument erscheint nicht als formelle Veröffentlichung. Es darf nur mit Genehmigung des Regionalbüros für Europa der Weltgesundheitsorganisation besprochen, in Kurzfassung gebracht oder zitiert werden. Beiträge, die mit Namensunterschrift erscheinen, geben ausschließlich die Meinung der Autoren wieder.

Ce document ne constitue pas une publication. Il ne doit faire l'objet d'aucun compte rendu ou résumé ni d'aucune citation sans l'autorisation du Bureau régional de l'Europe de l'Organisation mondiale de la santé. Les opinions exprimées dans les articles signés n'engagent que leurs auteurs.

Настоящий документ не является официальной публикацией. Не разрешается рецензировать, аннотировать или цитировать этот документ без согласия Европейского регионального бюро Всемирной организации здравоохранения. Вся ответственность за взгляды, выраженные в подписанных авторами статьях, несет сами авторы.

TARGET 29

Providers of primary health care

By 1990, in all Member States, primary health care systems should be based on cooperation and teamwork between health care personnel, individuals, families and community groups.

Index:

SELF MEDICATION
DRUGS, NON-PRESCRIPTION
EUR
DENMARK
FRANCE
GERMANY, FEDERAL REPUBLIC OF
GREECE
PORTUGAL
SPAIN
SWEDEN
SWITZERLAND
UNITED KINGDOM

ACKNOWLEDGEMENTS

The editors want to express their gratitude to several people whose behind-the-scenes contributions made doing this study both productive and pleasant. Eddie Phillips of Yale University helped in constructing the survey instruments, assuring both content and clarity. Gopa Mitra of the Information Office of the Proprietary Association of Great Britain painstakingly undertook the organization of the mail survey data for analysis. In Copenhagen, June von Essen and Erlinda Petersen of the Health Education unit in the WHO Regional Office for Europe kept the whole effort on course. We are most appreciative of their patient devotion to this undertaking.

Of special importance was the extraordinary cooperation of the governments of the 31 Member States involved in providing core data for this study. We are also indebted to our many colleagues in the nine countries studied in depth for the data and insights that they shared with us. They gave us a deeper understanding of self-medication in their countries. This study was truly interdisciplinary, intersectoral and international.

ADVISORY GROUP

- Dr M.N.G. Dukes
Regional Officer for Pharmaceuticals, WHO Regional Office for Europe
- Dr Ilona Kickbusch
Regional Officer for Health Promotion, WHO Regional Office for Europe
- Dr K. Reese
Director-General, World Federation of Proprietary Medicine Manufacturers
- Mr W. Sedlag
Director, European Proprietary Association
- Dr M. Wagner
Regional Officer for Maternal and Child Health, WHO Regional Office for Europe
- Mr J. Wells
Executive Director, Proprietary Association of Great Britain

CONTENTS

	<u>Page</u>
Foreword	vii
Chapter 1 Lay self-care in health and the role of self-medication	1
Chapter 2 Findings of the questionnaire	11
Chapter 3 Results of the in-depth study of central Europe: France	23
Chapter 4 Results of the in-depth study of central Europe: Federal Republic of Germany	43
Chapter 5 Results of the in-depth study of central Europe: Switzerland	67
Chapter 6 Results of the in-depth study of central Europe: United Kingdom	87
Chapter 7 Results of the in-depth study of Scandinavia: Denmark	117
Chapter 8 Results of the in-depth study of Scandinavia: Sweden	167
Chapter 9 Results of the in-depth study of southern Europe: Greece, Portugal and Spain	201
Chapter 10 Issues and needs	211
Annex 1. Questionnaire	217
Annex 2. In-depth country study guide	228
Annex 3. Detailed results from the questionnaire	234

FOREWORD

The concept of primary health care, as set out in the Declaration of Alma-Ata, emphasizes the importance of citizen participation. The years since Alma-Ata have seen substantial advances in lay participation in health care, particularly in self-care and self-help. People are trying to care for their health and are seeking additional skills and resources to make their efforts more effective and satisfying.

A central aspect of lay self-care is the responsible selection and use of effective medication not requiring professional control. Home remedies, herbal recipes and non-prescription manufactured medicines make up a substantial pharmacopoeia for lay use. Although in combination these medicines constitute the bulk of medication taken, relatively little is known about their regulation, availability, acceptability and use in Europe. This study fills the gap in information on non-prescription medicines used in self-medication. Non-prescription preparations are especially important in self-medication for several reasons. First, the trend of European governments to reduce free access to prescription medication puts a competitive cost factor into a person's decision to purchase medicine. Second, governments are beginning to review and approve the transfer of certain active ingredients from the controlled to the non-prescription category. Finally, perhaps the most relevant trend is the growing interest of the public in gaining more personal control of health, including easier access to effective and safe medicines.

Public health policies must now take self-medication into account and seek to optimize the use of this important practice. Health professionals need to learn more about self-medication and non-prescription medicines. The public especially must have enough information for decisions about self-medication.

The WHO Regional Office for Europe continues to work to strengthen self-care and self-help. The release of this study and *Guidelines for the assessment of medicinal products for use in self-medication*^a is part of this effort. Both programmes and publications are examples of productive cooperation between the Regional Office, governments of Member States and nongovernmental organizations with related interests and expertise.

We in the Regional Office welcome readers' comments on the issues and options raised in this study.

J.E. Asvall
Regional Director
WHO Regional Office for Europe

^a *Guidelines for the assessment of medicinal products for use in self-medication*. Copenhagen, WHO Regional Office for Europe, 1986 (European Drug Guideline Series, No. 8).

LAY SELF-CARE IN HEALTH AND THE ROLE OF SELF-MEDICATION

Self-care

All health care systems contain four essential and inevitable levels of care: lay self-care, primary professional care, general specialist care, and super-specialist care (1). Within this structure, lay self-care is the broad base of the pyramid of health care and has always been its biggest part. In recent years, it has been rediscovered and evaluated for its actual and potential contribution. This new interest in self-care in the developed world reflects the changing patterns of disease, from acute and infectious to chronic conditions, and the necessity of lay participation in care. The cost of professional health care has drawn attention to the unnecessary use of professional resources and the potential for strengthening the lay role in health care as a supplement or substitute. People appear to find substantial satisfaction in gaining more personal control over their health through self-care. More information, medical technology designed for lay use, and effective non-prescription medication also support the growth of the lay role in health care.

Clearly, strengthening the scope and quality of lay self-care could greatly benefit individuals and society. Health professionals and health educators are increasing their efforts to promote safe and effective self-care practices (2). At the Alma-Ata Conference on Primary Health Care (3), the Director-General of WHO, Dr Halfdan Mahler (4), fully acknowledged the importance of self-care and self-help. A recent WHO scientific meeting helped to clarify the potential of lay self-care as a major resource in achieving health for all by the year 2000. Indeed, the WHO Regional Office for Europe is pursuing a programme designed to encourage wide and equitable public access to knowledge, skills and technology for self-care.

What is lay self-care in health? It is a comprehensive undertaking that includes health promotion, disease prevention, diagnosis, the treatment of minor illnesses and injuries, the management of chronic disease, and rehabilitation. It involves a variety of methods. A British study (5) found that nearly one third of the study population used medicines and means other than those traditionally recommended by physicians, including herbal preparations, ear trumpets, copper bracelets and self-cauterization. In a United States study of self-care practices (6), nearly 20% of the total symptoms experienced by those interviewed were treated with such homely procedures as resting, rubbing, gargling or bandaging.

Investment in research on the amount and quality of lay self-care has been modest compared with investment in research on professional care. Studies in the United Kingdom and, to a somewhat lesser extent, the United States are the main source of data on lay health care. Since this study was begun, however, research in Europe on self-care and on self-medication in particular has steadily increased. Unfortunately, data from such new work were not available for inclusion here. The data seem to be rather consistent with the findings of previous research in Europe and the United States. Although differences in study populations and the definition of self-care make conclusions tenuous, these findings are consistent with the view that lay people provide 65-95% of all health care for themselves and their families. A study in the United Kingdom found that health professionals treated less than one third of all illnesses (7). Another study in Britain (8) documented the extent of illness not treated by professionals in England and Wales, concluding that for virtually every category of disease the medical practitioner saw only the tip of the iceberg. In a study of British women aged between 20 years and 44 years (9), only one in every 37 symptom episodes was brought forward, solely on the individual's initiative, for medical consultation. The authors of this study noted clear differences between symptoms cared for by the individual (headache or changes in energy) and those brought to the general practitioner (bladder, skin and genital symptoms).

Without doubt, self-medication is a major, if not the most important, form of self-care and the most frequently studied aspect of self-care. Evidence from several studies in Great Britain and the United States shows that non-prescription medicines are the most common response to symptoms. A British study (5) also found that non-prescription medicines outnumbered prescription medicines by two to one. Other British research (10) confirms that self-medication is the most frequently reported response to symptoms, surpassing doing nothing, seeing a physician, and all other treatment methods. Two thirds of the respondents in another study in Great Britain (11) reporting having taken non-prescription medicine during a four-week

study period, in contrast to 25% having taken prescription medicine during the same period. In the United States, a longitudinal study established that prescription medicines were used in about 30% of illnesses and non-prescription medicines in 70%. A 1984 study of eight developed countries (12) reported that at any one time one third of the population was taking non-prescription medicines and another third was taking prescription medicines. The most recent national research in the United States found that non-prescription medicines were used to treat 35% of health problems reported by the study population over a two-week period. Prescription medicines already in the home were used for 11% of the problems reported, and physicians or dentists were called or visited for 9%.

These and other data sources seem to show that in Britain and the United States non-prescription, or over-the-counter, medication is the norm. This is particularly interesting because the form in which health services are available appears to have little or no effect on the level of public demand for non-prescription medicines. The most common explanation for this has to do with convenience. As one author put it, people want to avoid going through "... the time-consuming machinery of obtaining (free) professional medical advice" (13). Clearly, public confidence in the utility of these products must also be assumed. In Britain, only 4% of one study population said the non-prescription medicines did not help (10).

The effectiveness and safety of self-care practices are difficult to measure precisely. Research on the subject has been very modest and sometimes biased by the values of the study sponsor. For example, in 1982, the United States Government concluded from a national survey that self-care represented "rampant empiricism" (14). On the other hand, two non-representative studies of the patients of two general practitioners, one in Great Britain (15) and one in Denmark (16), looked at what patients did about symptoms before contacting their physicians and concluded that, in 90% of the cases, the self-care practices were judged either helpful or harmless.

Self-care can also be evaluated for its effects on the use of professional health services. Some health planners believe that more and better self-care might lead to less or more appropriate use of professional resources. One study (17) supports this view by showing a decrease of 17% in total visits to a prepaid group health organization in the United States and a 35% reduction in visits for minor illness. Reduction in medical consultation is, of course, a short-term effect.

The evaluation of self-care requires more sophisticated methodology, representative samples, clear definitions of the independent variables, and clear and valid measures of outcome.

Measurement of the outcome of self-care practices must take into account benefits that users perceive as valuable and perhaps unique - such as enhancing self-confidence, gaining control over the situation or self-fulfilling healing effects (10) - and consider the merits of self-care compared with those of professional care for the same complaint, in terms of effectiveness, safety and cost. This would place self-care within the comprehensive and legitimate framework of health services and allow the analysis of the absolute, relative and interactive values of each component of the system. For example, similar non-prescription and prescription medicines might be compared in their application in a given situation not only for their ultimate benefit (cure or symptom relief) but also for costs, side effects, and accessibility and acceptability for the client.

In the long term, an evaluation of self-care should also take into account the more durable benefits that result from bringing together lay and professional health care resources in a complementary, mutually reinforcing, social system of health care (18). Self-care is not limited to sensible attitudes towards good health and a bag of skills for the treatment of minor illnesses and caring for a chronic disease. It also involves the collaboration of health professionals and lay people, in which cooperation and mutual respect can contribute to a satisfactory outcome (19).

Self-medication

Self-medication, the self-administration of materials perceived as benefiting health, is as old as human life. It has existed in all known cultures and has been part of each stage of social and economic development, and there is little reason to doubt that it will continue. Typically, these materials are mostly taken to relieve symptoms, to relieve pain or discomfort. Some are taken to cure a few reasonably well defined diseases. Some, such as topical steroids, are taken as antiseptics. Others are considered helpful in preventing disease. For example, calcium is taken to prevent osteoporosis, and vitamins are often believed to promote health in the general sense. Ordinarily, medicines categorized as self-administered are those materials available to people on their own initiative, based on their own perception of need and appropriateness, and not requiring the prescribing authority of physicians or other health professionals. This definition excludes prescription medicines stored in the home and used later by someone other than the person for whom the prescription was written.

As noted earlier, non-prescription medication is widely used; it is a major component of lay health care and consequently health care as a whole. While self-medication is often discussed in the scholarly literature, this is most useful in its yield of hypotheses.

Most studies are small, with their own definitions of self-medication and limited study populations. International studies of self-medication are rare, and those dealing with policies on non-prescription medication are not available. A number of groups, however, have interests and responsibilities that now demand more information on the role of self-medication in health care and health care policy. Manufacturers of non-prescription medicines are concerned about matters of production, available active ingredients, distribution, advertising and sales, and the safety and efficacy of their products. Government regulatory agencies have a particular interest in safety and efficacy, but also in matters of appropriateness and equity of public access to non-prescription medication. Sources of funds for medical care, both public and private, want more information about self-medication policies, their rationale, and evidence of how they might help to solve the problem of the escalating costs of medical services by reducing the excessive use of expensive prescription medicines.

Health professionals who influence the level and quality of self-medication include pharmacists, nurses and physicians. As advisers to consumers about appropriate and safe non-prescription medication, they want to know what research is available on the interaction of non-prescription with prescription medicines. What special educational resources for self-medication are available for groups such as the elderly and parents of young children? Where can they be found? Social scientists seek answers to their questions as well. These concern patterns of use of non-prescription medicines, cultural and social variations in self-medication preferences, how public policy on self-medication is formulated, and how policies on and practices of self-medication are changing.

WHO is working for health for all. Achieving this goal will necessarily include encouraging effective and appropriate self-care and self-medication in the wider definition of public access to health services. In this effort, public and professional education about responsible self-medication is important. The content of such educational efforts and their appropriate audiences must now be defined.

Of course, most central of all is the interest of the public in full disclosure of the benefits, potential and limitations of self-medication. People want knowledge, skills in decision-making, skills in using non-prescription products effectively and safely, convenient and equitable access, and fair prices.

This study was undertaken to provide some information for the European Region as a whole and for each of its Member States. The first needs were an overview of the situation in the Region, an assessment of the availability of data, the nature of the management

of data on non-prescription medication in each country, and the general level of research activity on patterns and preferences in the use of non-prescription medication. These could set the stage for establishing both strategies for data collection and a research agenda for epidemiological, sociological, pharmacological and economic studies. We are, almost literally, at a data frontier in this crucial area of health practice.

Purpose of the study

This publication is a report of an initial study of self-medication policies and practices in Europe. The study was co-sponsored by the WHO Regional Office for Europe and the European Proprietary Association (AESGP), acting on behalf of the World Federation of Proprietary Medicines Manufacturers. Work on the project began in 1982; data were collected in 1983-1984. The objective of the study was to develop a general understanding of the role of non-prescription medication in the health care of citizens of this Region. It is a first step in a longer process of collecting information useful to governments and regional health advisory agencies, particularly the Regional Office for Europe. Data from the European Member States were sought on non-prescription medication from the standpoints of the governmental level(s) of legislative initiatives, the licensing of medicinal products, supplies for manufacture, labelling regulation, distribution systems, advertising, codes of practice, payment policies, sponsored research on the use of non-prescription medication, the role of special interest groups in self-medication, and general policies governing non-prescription medication. In addition, more detailed data on the same topics were sought from nine countries, to learn more about the relationship of policies of self-medication to practices and problems and to activities for improving the contribution of self-medication to national goals for health.

Few data were available to compare the availability, promotion and regulation of self-medication among European countries. Reliable published reports were rare and usually limited to one country or cluster of countries such as Scandinavia. Basic information was obviously needed.

Agreeing on this need, the Regional Office and AESGP sponsored this study to benefit European governments and the pharmaceutical industry they regulate.

Methods

An advisory group was formed, with six representatives of the Regional Office and AESGP, to direct the study and to review and

revise the various instruments of data collection. The advisory group also selected nine European countries for in-depth study and three consultants who would collect data in the nine countries. Professor Fritz Beske, University of Kiel, undertook in-depth studies of France, Federal Republic of Germany, Switzerland and the United Kingdom. Professor Ebba Holme Hansen, University of Copenhagen, collected data on Denmark and Sweden. A review of the situation regarding non-prescription medicines in Greece, Portugal and Spain was contributed by Professor Nicholas Choulis, University of Athens.

Professor Lowell S. Levin, Yale University, was appointed study director to supervise instrument development and data collection. Dr John Fry, a general practitioner in the United Kingdom, and Professor Beske joined Professor Levin to prepare this report.

Data collection

The group agreed to establish a baseline of data on policy in the 33 countries then comprising the European Region of WHO. A questionnaire, prepared in English and translated into French, sought brief replies to 23 questions, to be supplemented with detailed documentation as available and appropriate. In addition to the short answers, respondents were invited to comment further. The advisory group revised the questions but did not formally test them. Several revised forms were reviewed before the first mailing in March 1983. Non-respondents received a second copy of the questionnaire about six months later. All questionnaires were addressed to ministers of health, with the understanding that parts, if not all, of the questions could be passed on to others in the ministry or a collateral agency for reply. Thirty-one countries returned the questionnaires; two did not respond. Annex 1 comprises the questionnaire and a list of the countries involved.

The second source of data was a structured set of questions to be used by the three consultants assigned to collect more data. The criteria used to select the countries included geographic spread, variation in design of the health care system, and level of economic development. After official approval was received, in-depth studies were undertaken in the nine countries of the Region. A list of these countries and the study guide used make up Annex 2.

Forty-six questions were considered to be relevant to this study, although information on all of these was not necessarily available in all nine countries. Furthermore, much of the data would be anecdotal material, case histories and opinions, to gain an appreciation of the extent and quality of data available on the use of non-prescription medicine, the nature of current and proposed research on the subject, and the general level of governmental and

nongovernmental interest. Clearly, much of this information could be gleaned only through interviews with people involved in, or with special interest in, the role of self-medication in health care. This relatively qualitative approach was expected to be an important supplement to the information derived from the questionnaire sent to all Member States.

The consultants were responsible for both arranging interviews and gathering relevant study reports and miscellaneous documentation. While too extensive to be included in this summary report, all the data are available for review at the Regional Office for Europe in Copenhagen.

Results

The questionnaire was designed to elicit a comprehensive overview mainly of governmental policies and practices affecting the availability and use of non-prescription medicine. Care was taken to supply respondents with clarifying comments and definitions as appropriate. A covering letter explained the intent and approach of the study. Despite these efforts to ensure valid and reliable responses, some countries were unable to respond fully to some questions. Reasons for missing or partial responses were not provided, but certain questions simply seemed inapplicable to the development of policy in some countries. A substantial amount of additional data, supplied to supplement some answers, was also included in the study analysis. Such extra data, of course, varied widely. Findings from the questionnaire are discussed in the next chapter and are summarized in Annex 3.

Chapters 3-9 contain the findings from the in-depth studies. The nine countries are divided into three groups: central Europe (France, Federal Republic of Germany, Switzerland and the United Kingdom), Scandinavia (Denmark and Sweden) and southern Europe (Greece, Portugal and Spain). As expected, the extent and quality of information available varied widely among the countries. The consultants, however, were able to explain and interpret the causes of gaps in data. Indeed, a major objective of this part of the study was to define the present status of interest, policy, programmes and available research. Although the general availability of data in the countries is reasonably well known, many areas required more time for investigation than was possible for the study. For this reason, the consultants could not pursue some potentially fruitful leads to information sources. In some countries, for example, more time with nongovernmental research agencies and consumer groups would have enriched the understanding of social trends such as public attitudes and preferences in self-medication.

References

1. Fry, J., ed. *Primary care*. London, Heinemann Medical Books, 1980.
2. Silten, R.M. & Levin, L.S. Self-care education. In: Lazes, P.M., ed. *The handbook of health education*. Germantown, MD, Aspen Systems Corporation, 1979, pp. 201-223.
3. *WHO Chronicle*, 32, 409 (1978).
4. Mahler, H. The meaning of health for all by the year 2000. *World health forum*, 2(1): 5-22 (1981).
5. Wadsworth, M.E.S. et al. *Health and sickness: the choice of treatment*. London, Tavistock, 1971.
6. Alpert, J.J. et al. A month of illness and health care among low income families. *Public health reports*, 82: 708 (1967).
7. Horder, J. & Horder, E. Illness in general practice. *Practitioner*, 173: 177-185 (1965).
8. Last, J.M. The iceberg: completing the clinical picture in general practice. *Lancet*, ii: 28-31 (1963).
9. Banks, M.H. et al. Factors influencing demand for primary medical care in women aged 20-44 years: a preliminary report. *International journal of epidemiology*, 4(3): 189-195 (1976).
10. Dunnell, K. & Cartwright, A. *Medicine takers, prescribers, and hoarders*. London, Routledge & Kegan Paul, 1972.
11. Jefferys, M. et al. Consumption of medicines on a working class housing estate. *British journal of preventive and social medicine*, 14: 107-114 (1960).
12. *Health care practices and perceptions*. Washington, DC, Harry Heller Research Corporation, 1984 (HHR No. 7292).
13. Rea, J.N. et al. Skin disease in Lambeth. *British journal of preventive and social medicine*, 30: 107-114 (1976).
14. National Analysts, Inc. *A study of health practice and opinions*. Springfield, VA, National Technical Information Services, US Department of Commerce, 1972.

15. Elliott-Binns, C.P. An analysis of lay medicine. *Journal of the Royal College of General Practitioners*, 23: 255-264 (1983).
16. Pedersen, P.A. Varighed fra sygdoms begyndelse til henvendelse til praktiserende læge [Period between onset of disease and consultation with a general practitioner]. *Ugeskrift for læger*, 138(32): 1962-1966 (1976).
17. Vickery, D.M. et al. Effect of self-care education program on medical visits. *Journal of the American Medical Association*, 250: 2952 (1983).
18. Levin, L. & Idler, E.L. *The hidden health care system: mediating structures and medicine*. Cambridge, MA, Ballinger, 1981.
19. Fry, J., ed. *Health manual*. Lancaster, MTP Press, 1983.

FINDINGS FROM THE QUESTIONNAIRE

The questionnaire was mailed to every national health authority in each of the Member States in the WHO European Region to obtain an understanding of how non-prescription medicines are treated in the social and regulatory environment of the countries in the Region. The questionnaire was therefore limited to eliciting basic information. Without detailed knowledge of the regulatory requirements of the countries, little more could be made than a broad analysis of some of the similarities and the differences in the approaches adopted. This analysis was based on the facts gained from the responses of 31 Member States.

Legislation

In each of the responding countries, a separate department within the national government, dealing with health and/or social welfare, was responsible for the regulatory control of medicines. In the overwhelming majority of countries studied, the regulatory requirements took account of non-prescription medicines and were generally based on this national control. In Albania, Federal Republic of Germany and Switzerland, however, some aspects of the regulation of non-prescription medicines were delegated to more local jurisdictions. In every case, the health authorities compiled a list of active ingredients or of products that could be supplied on prescription only or without prescription. The number of non-prescription medicines varied considerably. In Czechoslovakia, for example, the list included 169 medicines. Countries also had mechanisms for regularly updating such lists, and regulations in the majority of cases were linked to them.

Almost without exception, countries regulated the manufacture of medicines and, in doing so, drew no distinction between prescription and non-prescription products. Controls on manufacture were usually

found to be national in scope, in most cases based on the principles of good manufacturing practice and largely in accord with the WHO guidelines on manufacturing.

Criteria for use of non-prescription medicines

Virtually every country recognized the differences between prescription and non-prescription medicines, reflecting these differences in its regulatory requirements. The suitability of medicinal products for non-prescription use was essentially a regulatory decision made by the competent health authority. The degree of discretion allowed to pharmacists in supplying products varied from country to country.

There are generally three separate legal categories of medicinal product:

- prescription medicines, which may be sold or supplied only by or under the supervision of a pharmacist and in accordance with a doctor's or dentist's prescription;
- pharmacy medicines, which may be sold only in pharmacies, by or under the supervision of a pharmacist;
- general sale medicines, which may be sold in a variety of outlets in addition to pharmacies.

Non-prescription medicines belong to the second and third categories. In some countries, such medicines could be sold only in pharmacies; this means that almost all medicines are sold in pharmacies. Other countries allowed non-prescription medicines not labelled *pharmacy medicines* to be sold in a variety of outlets. As could be expected, such a decision must be based on a number of related issues, including the safety of the active ingredients; the suitability of the indication for the purpose of self-medication; assessment of local customs and practice; the side effects, possibilities of abuse and the risks of dependence on the medicine; and the quality and efficacy of the medicine.

Few countries appeared to have formal, published criteria, these decisions being made by the competent health authority after a full assessment of the relative requirements for individual products or active ingredients.

These decisions must then be reflected in legally binding requirements, not least to enable their enforcement. The survey revealed at least two different approaches in meeting this need. A number of countries (Albania, Algeria, Belgium, Czechoslovakia,

Denmark, Greece, Hungary, Iceland, Netherlands, Norway, Poland, Portugal, Romania, Spain, Sweden, Turkey, USSR and Yugoslavia) had published lists of individual products available for direct sale to the public. This approach has the advantage of individual product assessment, not just of the active ingredients but also of the indications and information provided with the product. Other countries (Bulgaria, German Democratic Republic, Ireland and the United Kingdom) based their lists on active ingredients, although these lists could be combined with requirements for authorization for marketing individual products. Such lists do not require constant updating to include products containing active ingredients that have already been authorized for direct sale to the public. Some countries even listed active ingredients and indications for non-prescription products. Countries providing lists of active ingredients include Belgium, Hungary, Spain and Turkey. Those that list indications include Netherlands, Poland and Spain.

Categories of non-prescription medicines

In one section of the questionnaire, an attempt was made to compare the categories of products suitable for self-medication in the European Region. While the Member States varied considerably in the organization of health care services, they were remarkably consistent in the categories of non-prescription medicines to which the public had access. Table 1 indicates the kinds of non-prescription product and the number of countries in the survey in which they are acceptable.

Table 1. Number of European countries^a accepting certain categories of non-prescription products

Category of product	Number of countries
Antiseptics	31
Analgesics	31
Vitamin and mineral supplements	31
Cough/cold preparations	30
Indigestion products	30
Laxatives	30
Skin preparations	27
Eye preparations	23
Sleep aids	12

^a Thirty-one countries responded.

As Table 1 demonstrates, the major differences appear in only three categories of products: skin preparations, eye preparations and sleep aids. Most countries allowed skin preparations to be sold without prescription, except Albania, German Democratic Republic, Romania and the USSR. The majority of the countries also categorized eye preparations as non-prescription products, except Bulgaria, Finland, German Democratic Republic, Monaco, Poland, USSR and Yugoslavia. The Netherlands, however, limited these to eyewashes. In the case of sleep aids, the situation is reversed. Many countries prohibited the direct sale of this category, but those that permitted it include the Federal Republic of Germany, Greece, Iceland, Italy, Luxembourg and Switzerland. In Belgium, regulations were being prepared to restrict pure barbiturates associated with other hypnotic sedatives to prescription supply. While regulation was to become more restrictive for this whole group, exceptions would apparently be made for certain benzodiazepines.

The only country forbidding the direct sale of laxatives to the public was Greece.

Table 2 shows the active ingredients of sleep aids that may be supplied without a prescription in seven countries.

Table 2. Active ingredients permitted in non-prescription sleep aids in seven countries

Country	Active ingredients
Hungary	Phenobarbital (small amounts in combinations)
Iceland	Bromisoval (in 300 mg tablets, 5 tablets maximum)
Italy	Valerian, passion-flower, some antihistamines
Luxembourg	Diphenhydramine
Netherlands	Barbiturates (not exceeding 15 mg/unit dose)
Poland	Minor sedatives (not specified)
Sweden	Valerian

These countries also recorded some changes in the categorization of medicines. With a continuing review in each Member State to satisfy the criteria for safety, it was perhaps not surprising to learn of active ingredients that had been removed from non-prescription use on the basis of new evidence of harm. Table 3 indicates the active ingredients removed from non-prescription use by 15 countries.

Table 3. Active ingredients removed from non-prescription use
in 15 countries

Country	Active ingredients
Austria	Aminophenazone, bismuth salts, oxyphenisatine
Belgium	Phenacetin, noramidopyrine methanesulfonate sodium
Bulgaria	Sedalgin, ^a sedalgin neo, ^b Codterpin, ^c tincture anticholerica ^d
Finland	Amobarbital ^e
German Democratic Republic	Oxyphenisatine, aloe, hexachlorophene, boric acid, aminophenazone replaced by propyphenazone
Germany, Federal Republic of	Orphenadrine, noramidopyrine methanesulfonate sodium, 4-(isopropylamino)phenazone, ephedrine (over 10 mg), valdetamide, tromantadine, cathine, propylhexidrine, hydralazine, isoaminile, viquidil, organic nitrate, deanol, verapamil
Iceland	Benzoyl peroxide
Italy	Phenacetin, bismuth salts
Netherlands	Phenacetin
Norway	Ephedrine (1%, 10 ml)
Poland	Aminophenazone replaced by propyphenazone, Rx symphytif
Sweden	Codeine (5 mg in 25-pack), products containing 8-quinolinol derivatives, cinchocaine ointments for ophthalmic use containing 0.5% cinchocaine, theophylline derivatives, anti-anaemics, inhalation anaesthetics
Turkey	Aminophenazone, phenacetin, salicylamide, phenazone salicylate
USSR	Preparations reviewed every year "to keep list short"
Yugoslavia	Phenacetin replaced by paracetamol; aminophenazone replaced by propyphenazone

^a Active ingredients: phenacetin, phenobarbital, codeine, caffeine, acetylsalicylic acid.

^b Active ingredients: paracetamol, phenobarbital, codeine, caffeine.

^c Active ingredients: terpin hydrate, codeine, sodium bicarbonate.

^d Active ingredients: opium, menthol, origanum, hypericum, frangula bark.

^e Owing to the change in the Narcotics Act.

^f *Symphytum officinale*; comfrey root.

Evidence from some countries also showed that active ingredients previously limited to prescription supply were considered for non-prescription use. Surprisingly, few Member States reported such developments during the study (Table 4). Since its completion, more countries have transferred certain prescription ingredients to non-prescription status.

Table 4. Active ingredients released from prescription limitation in five countries

Country	Active ingredients
Germany, Federal Republic of Norway	Benorilate, piprozolin, nifuroxazide, ambroxol, nicofuranose, indanazoline, natamycin, econazole, haloprogin, midodrine, isoconazole Paracetamol, as an alternative to acetylsalicylic acid in limited quantities as tablets, suppositories and mixtures; oxymetazoline nose drops in single-dose containers; hydrocortisone 1% skin preparations for topical use; imidazole derivative skin preparations for topical use; sodium fluoride 0.5 mg/ml solution to prevent caries
Sweden	Dextromethorphan mixture in 3 mg/ml, 100 mg/ml and 200 mg/ml tablets, 30 mg, 25-pack; noscapine mixture 1 mg/ml, 300 ml and 500 ml mixture, 2.5 mg/ml, 300 ml mixture, 5 mg/ml, 100 ml, and tablets 25 mg and 50 mg up to 50 tablets; oxymetazoline nose drops 1 mg/ml, 50 one-dose disposables; skin preparations for topical use containing 1% hydrocortisone; anti-emetic products containing meclozine 10 tablets 25 mg; some antimycotics for athlete's foot (<i>tinea pedis</i>), including econazole 1%, 30 g or 30 ml; miconazole 2%, 30 g; and clotrimazole 1%, 20 g or 20 ml
USSR	List reviewed every year "to keep it short"
United Kingdom	Loperamide, ibuprofen

Some of the active ingredients that have been specifically removed from prescription control were available for non-prescription use in some of the other countries.

The responsibility for changing regulations on prescription restrictions apparently rested in all countries in the survey with the national government, in either the ministry of health or another legislative or administrative body, frequently advised by a national institute or committee of experts.

The following criteria were mentioned as factors in permitting active ingredients to be used in non-prescription medicines: health hazards, indications and contraindications for use, side effects, short-term use, risk of dependence or abuse, general experience, new ingredient without experience, great consumption, and toxicity.

Most countries had a standard mechanism for determining whether an active ingredient could be used in non-prescription medicines. The standard mechanism can be a scientific commission that advises the national government, such as the Rezeptpflichtkommission in Austria, or another scientific body, or a procedure by which the list of substances and pharmaceutical specialities is revised so as to decide which active ingredients may be permitted for use in non-prescription medicines and which pharmaceutical specialities should be included in the list of non-prescription medicines.

Non-prescription medicines and society

Manufacture

The first priority for Member States is the product itself. One question, "Are there particular regulations governing the manufacture of non-prescription medicines?", was answered with both yes and no, but in almost all countries the same regulations probably applied to both prescription and non-prescription medicines. The manufacturers must therefore comply with the standards of good manufacturing practice. Some countries (Albania, Austria, Belgium, Finland, German-Democratic Republic, Iceland, Italy, Luxembourg, Netherlands, Norway, Sweden, Switzerland, United Kingdom and Yugoslavia) had separate labelling regulations for all non-prescription medicines. In other countries (Bulgaria, Denmark, Federal Republic of Germany, Greece, Hungary, Ireland, Malta, Poland, Romania, Spain and Turkey), requirements for labels were introduced through marketing authorizations. In Portugal, separate regulations for the labelling of non-prescription medicines were under consideration, although much of the relevant information is already covered by that country's control of manufacture. In Czechoslovakia, only prescription medicines were labelled. If the package had no label reading "For medical prescription only", the medicine could be obtained without a prescription. The following information was required to appear on labels in most of the countries studied: composition (usually

active ingredients), name and address of manufacturer, instructions for use, indications and contraindications for use, dosage (with adult and children's doses differentiated where applicable), side effects and warnings.

Information about storage conditions and expiry dates is sometimes also required. Few of the countries applied mandatory package insert requirements. Although manufacturers in many countries could include inserts, this did not preclude their obligation to include information on the package, which was seen as the principal source of consumer information. When inserts were included, some countries (Czechoslovakia and Denmark) seemed to put greater emphasis on the distinction between inserts intended for non-prescription products used by consumers and those designed for the medical profession. One country reported that inserts addressed to consumers should contain information in a simple but comprehensive manner. In Algeria, additional information was required about interaction, such as that between certain cough or cold products or antihistamines and alcohol. In Ireland, data sheets were available, in addition to product inserts, that the pharmaceutical industry supplied separately to the health professions.

Advertising

When advertising to the public was permitted, it was almost without exception scrutinized before publication by some authority or organization. In a number of countries (Austria, France, Greece, Luxembourg, Malta, Switzerland and Turkey), advertisements were checked by the competent health authority. In the Federal Republic of Germany, Ireland, Sweden and the United Kingdom, this responsibility was delegated to an organization representing manufacturers of medicines. In some instances, Member States (Belgium, Denmark, Finland, Italy, Netherlands and Portugal) performed this clearance through an independent body and a competent health authority. Some countries (Denmark, Federal Republic of Germany, Ireland and the United Kingdom) had an advertising code, and the manufacturers' association in Spain was considering the adoption and application of a voluntary code of standards of advertising practice. In some countries, the advertising of non-prescription medicines to the public was prohibited. This was mostly in accordance with the general policies of the countries concerned: Albania, Algeria, Bulgaria, Czechoslovakia, German Democratic Republic, Hungary, Iceland, Poland, Romania and Yugoslavia. In these countries, information reached the public through government publications or through communication with health professionals.

Studies on demographic and behavioural aspects

Since self-medication is of growing importance in quite a number of countries in the European Region, studies of the demographic characteristics of users of non-prescription medicines are most useful when they describe the age, sex and regional differences, as well as consumer use of such medicines. Only a few countries (Bulgaria, France, Federal Republic of Germany, Switzerland and the United Kingdom) reported studies published since 1975 on such characteristics. Most countries reported that there were neither published nor unpublished studies of this kind.

Health education

A wide variety of comments were received on health education and the use of non-prescription medicines. In most countries, however, this was not a very important area of health education. Evidence from Austria, France and Sweden showed a growing emphasis on publications produced by health authorities to inform the public on both prescription and non-prescription medicines.

In some countries in which health services are organized by the state and there is virtually no advertising of medicines, such as eastern European countries, education on the use of non-prescription medicines and self-medication was the responsibility of the state. In countries with a more pluralistic health care system, pharmacies and the pharmaceutical industry were also involved in such health education.

Distribution

Strong emphasis was placed in all countries on the supply of medicines through pharmacies, although there were exceptions to this general requirement in a number of countries. Some medicines could be obtained through drug stores or supermarkets in Denmark, Federal Republic of Germany, Greece, Ireland, Netherlands, Poland, Switzerland and the United Kingdom. Non-prescription medicines could be sold from hospitals and/or dispensaries, including physicians' surgeries, in Algeria, Austria, Denmark, Greece, Hungary, Malta, Poland, Portugal, Romania, Turkey and Yugoslavia. In Bulgaria, however, non-prescription medicines were available through hospitals, but only to inpatients. Non-prescription medicines could be obtained through vending machines in the Federal Republic of Germany and the United Kingdom, while medicines could be supplied only by pharmacies in Albania, Algeria, Austria, Belgium, Bulgaria, Czechoslovakia, Finland, France, German Democratic Republic, Iceland, Luxembourg, Malta, Norway, Romania, Spain, Sweden and the USSR.

Payment for non-prescription medicines

Most countries in the European Region either completely or partially reimbursed the cost of prescription medicines. This applied either generally or to certain classes of patient. The survey was not, however, intended to provide detailed information on medical care.

The public could also purchase some prescription medicines directly in many countries. The legal category of the products did not appear to affect reimbursement for them in most countries. On the other hand, a medical prescription was the prerequisite for reimbursement, and no country appears to refund money paid by an individual in purchasing medicine without a prescription.

Special interest groups

Groups in some countries showed a special interest in influencing the use of non-prescription medicines and self-medication in general. These included manufacturers' associations and associations of pharmacists, as well as groups of patients with specific opinions about certain kinds of medicine. These groups communicated their views to legislators and administrators and published information for the public.

Attitude towards and future of self-medication

Two questions in the questionnaire were related to current issues in the role of non-prescription medicines: the role of self-medication in health care and the attitude of governments towards this practice. Answers to these questions revealed controversial attitudes as well as the impression that a single perspective towards non-prescription medicines and the role of self-medication in health care had not yet been formed. The response from Albania, for instance, stated that self-medication was not encouraged, since it could be very dangerous to health, and that it was unnecessary because physicians were accessible even in isolated areas and everyone had access to prescription medicines.

Algeria favoured self-medication in remote areas with insufficient health care and discouraged it in areas with good medical care. In addition, non-prescription medicines were considered to lack any real effect. The Government's policy was therefore to reduce their number. Austria stated that self-medication was considered justified where a hazard to health could be excluded and where self-medication saved time for physician and patient.

The Government of Ireland respected the right of the individual to self-medication because health is primarily a personal matter.

In the German Democratic Republic, non-prescription medicines were considered necessary; such medicines made up about 20% of the total number of registered medicines. However, it was assumed that this would be reduced because newly admitted medicines would generally be available only on prescription.

Denmark, along with the other Nordic countries, had had a tradition of rather restrictive prescription rules compared with other European countries. This restrictive attitude had relaxed, however, in the previous five to seven years. The Government's attitude was that liberalizing the prescription rules would promote self-medication as far as it was healthy and safe. Self-medication would relieve some of the burden on the primary health care system, and the Danish Government hoped it would reduce the expense of health care. The Government thought that more education and information about the use of medicines and the treatment of minor illnesses, with or without non-prescription medicines, would be useful.

According to the response of Malta, a specific list of non-prescription medicines existed, although the role of self-medication was not defined. Further, while self-medication was promoted within limits, caution was considered necessary, and the public had to be educated about when to stop self-medication and seek medical advice.

Conclusions

There was a growing awareness of self-medication in a number of countries. Most governments seemed to accept the need and growing demand for non-prescription medicines in addition to prescription medicines.

The regulations that encompassed non-prescription medicines appeared to correspond with the regulations applied to prescription medicines in each of the responding Member States.

Major differences in regulations seemed to result from cultural and social attitudes towards the distribution and advertising of non-prescription medicines to the public.

One trend emerging from the survey appeared to be the developing appreciation of the differences between communication through labelling and leaflets. Some countries had arrangements for an assessment of active ingredients suitable for removal from prescription control; other countries tended to reduce the number of active ingredients permitted for non-prescription medicines. The question arises with respect to a number of countries as to whether there is a sincere effort to scrutinize active ingredients for suitability for over-the-counter products.

RESULTS OF THE IN-DEPTH STUDY OF CENTRAL EUROPE:
FRANCE

Presentation of non-prescription medicines

In March 1982, the *Code des bonnes pratiques d'information* [Code of good information practices] was published by the French Association of Pharmacists. The code was established by a commission composed of members of the Association, the pharmaceutical industry and advertising companies. This code has to be adhered to. It deals with:

- the type of information given for medicines: the information must be exact, adequate, legal and true;
- the presentation of the pharmaceutical product: the information given on the package and on package inserts must be clear and objective and written in a comprehensible form;
- the texts on the packages: their form and even their colour must be designed in such a way as to eliminate the possibility of confusion in the dispensing of a product;
- the information for physicians;
- the information for the public: this must meet certain ethical requirements concerning the advertising of medicines and must be worded in terms that can be easily understood by the consumer; it must contain nothing that could lead to error concerning the product's properties and may not include any exaggeration; it must not encourage abuse; it must not be addressed directly to children; it must preserve the serious character of the type of product and not devalue it in the eyes of the consumer; and it must not encourage incorrect use of medicines;

- the information for pharmacists: the pharmacist must obtain all the information about the use of a product before he can sell it.

Furthermore, there is a commission set up by the pharmaceutical industry where all advertisements have to be checked. This checking is a kind of pre-control; later, a further checking process is carried out at the Ministry of Health.

These regulations form a supplement to government regulations and they are totally adhered to. Sometimes the voluntary codes of practice are even stricter than the government regulations.

The educational content of advertisements depends on the media. In television, the advertisements are relatively short, so the educational content is low. It relates to the identification of symptoms and the mode of use of the medicine in question. Furthermore, a recently established legal regulation requires that advertisements recommend that a physician be consulted if symptoms persist.

Written advertisements also contain information on the identification, the dosage and the correct use of the medicine. In addition, legal regulations require information on contraindications, side effects and precautions. Sometimes even the chemical formula of the active ingredients is given in advertisements.

The quality of the educational content included in the advertisements for non-prescription medicines receives differing assessments. Representatives of the pharmaceutical industry are of the opinion that a considerable amount of information is included in advertisements. In particular, written advertisements are considered as having an educational standard that promotes the correct use of medicines. On the other hand, some of the interviewees criticize the advertisements for non-prescription medicines.

In particular, the French Association of Consumers is against any medicine advertising, as it is of the opinion that advertising medicine leads to superfluous consumption. The Association does not accept the claimed educational content. Television advertisements are especially regarded as misleading and intended only to promote sales of over-the-counter products. Moreover, products that are advertised are bought more often, although they are normally more expensive than other medicines.

In a survey (1), 2000 people were asked in April and May 1982 about their attitude towards advertising. Sixty-one per cent had a positive attitude towards advertisements for medicines, whereas only 51% had a positive attitude towards advertising in general. Only 9%

of those surveyed said that medicines could be used in a proper manner on the basis of the information given in advertisements. According to this survey, 89% of the interviewees said that advertisements for particular products would not change their purchasing habits. This includes medicines.

Inserts are generally included in medicine packages. They repeat the indications and must be officially approved. The French Association of the Pharmaceutical Industry has suggested that all inserts carry a warning to the effect that medicines are, on the one hand, commercial products and, on the other hand, different from ordinary commercial products. This request has generally been complied with. In association with consumer and pharmacists' organizations, new inserts have been developed in an attempt to facilitate understanding of the mode of use of certain types of therapeutics. Up until now, consumers have considered the wording of these instructions as too technical or scientific and therefore not informative enough.

For very strong medicines (category A), no package inserts are included. All information about these medicines has to be given by a physician.

Distribution

In France, non-prescription medicines are exclusively sold in pharmacies. Consequently, no special regulations for the distribution of non-prescription medicines are necessary. Pharmacies must respect the general regulations about the selling of goods. The distribution system of over-the-counter products guarantees that only recently manufactured medicines are sold in pharmacies. There are therefore no problems with the freshness of non-prescription medicines.

Generic non-prescription medicines are available, such as acetylsalicylic acid and ascorbic acid. Their distribution is subject to the same regulations as all other medicines. Generics do not play an important role. Their share in the turnover of over-the-counter products is even less than their share in the prescription market. This might be surprising, as generics are relatively cheap. The situation can be explained by the relatively few advertisements for generics and the scepticism of medical professionals and pharmacists towards the quality of generics.

Economics

Until 1977, there was strict price control on all medicines. Thereafter, this regulation was changed for medicines not paid for

by social health insurance. As a consequence, the price of these medicines has been rising faster than that of prescription medicines.

Nowadays, there are considerable price differences between prescription medicines and those not refunded by social health insurance. The extent of these differences depends on the category of medication. For example, the difference is about 50% for nose drops and throat pastilles.^a A cough mixture costs about FF 25.

Nevertheless, in the period between 1977 and 1981, the total over-the-counter market increased by an average of 18%. However, the relatively high increases in the prices of non-prescription medicines accompanied a reduction in the reimbursement of prescription medicines by social health insurance. In 1977, reimbursement for first-category medicines, which contain, for example, tonics, was reduced from 70% to 40%. In 1980, a similar change was made for cold remedies, and again in 1982 for medicines used for minor illness, such as analgesics. Although there are exceptions for those suffering from chronic diseases (these people continue to receive 100% reimbursement for certain medicines), people generally receive a lower rate of reimbursement for medicine.

The trend of sales by category of medication is given in Table 5.

Dermatological preparations and wound dressings recorded the highest increase in turnover between 1977 and 1982. Furthermore, the turnover of vitamins, tonics and analgesics expanded relatively strongly. On the other hand, the increase in sales of medicines used for the treatment of the digestive system was relatively low.

Products for self-medication can be divided into two groups. The first group consists of all products that are not paid for by social health insurance; 283 million packages of these medicines were sold in 1982. This amounted to a total turnover of approximately FF 2250 million at manufacturers' prices and FF 4000 million at retail prices. In addition to this expenditure, in 1982 about 300 million packages of medicine were sold that could have been prescribed by a physician and reimbursed by social health insurance but which were bought without prescription and paid for by the consumer. These 300 million packages correspond to a turnover of about FF 5000 million. During that year, the public purchased a total of about 600 million packages of medicine at a cost of FF 9000 million (at retail prices).

^a Information provided by the Proprietary Association of France.

Table 5. Trend of unit sales of non-prescription medicines, 1977-1982

Non-prescription products	Share of the market in 1982 (%)	Average growth of total turnover between 1977 and 1981 (%)	Growth of total turnover in 1982 (%)
Medicines for the treatment of respiratory tract infections	24.8	22.0	6.0
Skin preparations, wound dressings	15.2	24.0	22.0
Toothpaste	11.0	15.0	14.0
Deodorant preparations	10.7	15.0	18.0
Medicines for the treatment of the digestive system	9.9	12.0	9.0
Vitamins and tonics	5.9	20.0	16.0

Source: Proprietary Association of France (unpublished).

According to information from the Proprietary Association of France, the total turnover of the over-the-counter market increased by about 18% per year between 1977 and 1981. In 1982, the increase was about 13%.

In a study on the pharmaceutical market, the National Institute of Consumption presented the development of self-medication in relation to the whole pharmaceutical market. Whereas in 1960 about 20% of the total turnover of medicines was paid for by the consumers themselves, this proportion decreased to 12% in 1970. By 1975, the proportion had increased again to 20% (2).

There are no exact figures available that specify the proportion of non-prescription medicines imported from foreign countries. It can be assumed that the role of imported medicines in general and also that of non-prescription medicines is relatively insignificant. There are several reasons for this. Until recently, it was relatively difficult to import medicines, as there were very strict regulations. Furthermore, the price level of medicines in France is considered to be low, so that many foreign pharmaceutical manufacturers are not interested in selling their products there.

There are no differences between prescription and non-prescription medicines in terms of legal regulations and government policy. Above all, the quality of the active ingredients and the pharmaceutical form of imported medicines are checked. Reimbursement is effected by social health insurance unless the price of the medicine is considered excessive. Companies that export medicines to France are inspected by a commission of the Ministry of Health. The companies have to obtain a certificate stating that their medicines are manufactured according to the standards of the Ministry of Health. Without this permit, the import of medicine is not allowed.

Public interest in and acceptance of non-prescription medicines

Trends influencing self-medication

There is a certain interest in the subject of self-medication as reflected in the popular press and media. There are more articles on health and on self-medication nowadays than there were some years ago. Nevertheless, considering the range of media coverage of health, self-medication is not a dominant subject.

Health education had no important role in the social health insurance system in the past. It is now considered an important part of social health insurance, and activity in this field is increasing.

There are a number of health care guides and popular books on medical subjects. These books partially deal with self-medication, including home remedies and herbal medicines. To provide objective information, a book that provides information on all types of non-prescription medicine has been produced (3). It is a health care guide that informs people about potential responses to health problems, and especially the use of non-prescription medicines.

There are trends towards decentralization and deprofessionalization connected with a movement towards natural health methods. However, there was no unanimous opinion among the interviewees as to whether these movements essentially influence self-medication at all.

Do-it-yourself health technology is not of much importance in France, and it is normally used only on the recommendation of a physician. No empirical studies on such practices could be obtained, but blood pressure cuffs are relatively often used.

Some interviewees felt that individuals generally need further education to use such technology. In addition, the French Association of Consumers has reservations about the quality of the blood pressure cuffs in particular. They are often bought by mail

order and are often imported from south-east Asia. The quality, which is often below standard, can be ascertained only after purchase, and then it is difficult to return the merchandise.

Self-reliance, combined with self-medication, is apparently gaining in importance. Self-medication is often practised as a supplement to prescription medicine. This applies particularly to people with chronic disease.

Health movements, such as those promoting alternative healing strategies, have become more and more popular in recent years. It is doubtful, however, whether these movements really influence public interest in self-medication. It is considered more probable that such movements promote greater use of herbal medicines and homoeopathic remedies. It is therefore assumed that self-medication is more influenced by social trends than by health movements. This particularly applies to the use of chemical medicines, which are rejected by many of those who believe in alternative living and in alternative healing strategies.

Consumer-initiated complaints regarding non-prescription medicines are put forward mainly by the French Association of Consumers. The intensity of these complaints has clearly decreased in recent years as more and more people accept self-medication. Nevertheless, some points of contention remain, such as the use of laxatives and the previously mentioned opposition to the advertising of medicine. The Association, as well as the French Medical Association, started a campaign to demonstrate the risks of extensive use of laxatives.

Furthermore, there has been discussion concerning the prices of non-prescription medicines. Some people think that making money by selling medicine is immoral. Since the price of non-prescription medicines has increased far more rapidly than the price of prescription medicines in recent years, the discussion is focused especially on over-the-counter products.

Finally, some people apparently regret that there is no greater choice, especially for medicines for common ailments such as digestive problems, toothache and insomnia. According to their view, convenience of access is inhibited by the existence of lists specifying medicines that can be obtained only by prescription.

Some mutual aid groups receive subsidies for their work and therefore have resources to buy non-prescription medicines. These groups are not legally allowed to recommend certain non-prescription medicines.

Influences on the choice of non-prescription medicines

Symptoms and previous illness experience always influence the public's perception of the appropriateness of non-prescription medicines, home remedies and prescription medicines.

The discussion concerning the financial situation of the social health insurance system has apparently changed the attitude of many people. Until recently, people expected all medical services to be paid for by social health insurance. Nowadays, people are aware of the financial problems of social health insurance. They accept more responsibility for themselves, including financial responsibility, and are therefore more inclined to deal with minor symptoms by themselves, including self-medication. According to the interviewees, this tendency may be strengthened by the increasing public sophistication in health knowledge in recent years.

The main reason people buy non-prescription medicines in pharmacies is probably the convenience in obtaining medicine for a minor illness. If symptoms persist or seem to be dangerous, the pharmacist will normally send people to a doctor.

All non-prescription medicines are sold exclusively by pharmacies, but it is easy to reach pharmacies in all regions of the country. The density of pharmacies is apparently high and the distribution is sufficient. For many people, it is therefore convenient to go direct to a pharmacy to buy non-prescription medicine. This avoids the inconvenience of seeing a doctor.

It can be assumed that people generally regard prescription medicines as stronger and more effective. Non-prescription medicines are believed to be less dangerous, causing fewer side effects.

According to the interviewees, various criteria are applied in judging the benefits of non-prescription medicines. Evidently, a low rate of side effects, convenience, quick results for certain health complaints, and avoidance of a physician's consultation are considered the main advantages of non-prescription medicines.

Referring to past experience and to the opinions of those interviewed, a certain influence of the relative cost on consumer choice is apparent. However, it can be assumed that individual differences are high.

It is assumed that these two developments, price increases for non-prescription medicines and a drop in the reimbursement rate for certain categories of medicine, offset each other. As a consequence, the relative market share of non-prescription medicines has remained unchanged.

Although no studies are available that reveal the level of public knowledge of non-prescription medicines, a representative survey showed that 88% of the population said that they receive competent advice from pharmacists on the correct and effective use of medicines (1).

This study confirms the opinions of various interviewees that people perceive and use pharmacists as a source of advice on the selection and use of medicines, including non-prescription medicines.

Consumers' use of non-prescription products

Patterns of use

The patterns of use of non-prescription medicine vary according to sex, age, social status and presence in an urban or rural environment.

Women buy more non-prescription medicines than men, the only exceptions being medicines for minor injuries, for which both sexes had about the same ratio: 14% of the men and 13% of the women (1).

It seems that older people tend to buy less non-prescription medicine than younger people (Table 6). For example, the use of headache analgesics decreased from 57% among people aged under 25 years, and 59% in the age group 35-49 years, to 38% among people aged 65 years and over. The only exception is for laxatives. A higher proportion (11%) of people aged 65 years and over bought laxatives than any other age group.

No studies are available on the use of non-prescription medicine by elderly people. It can be assumed, however, that older people normally have several physician consultations per year and receive most of the medicine they need by prescription. However, as elderly people tend to have more health problems than the population as a whole, they also sometimes use non-prescription medicine as a first reaction to symptoms. People in this age group are also more aware of their health situation, and they try to promote health by using certain types of non-prescription medicine such as tonics or vitamins. Apparently, ascorbic acid is relatively often used by elderly people.

Out of the total medicine expenditure, the proportion spent on non-prescription medicine ranges from 8% among those with no higher educational degree to 21% among those with a higher professional degree. Expenditure on non-prescription medicines decreases as the number of people living in the same household increases. There is a

Table 6. Proportion of respondents with particular health complaints who bought non-prescription medicines within a period of 12 months, according to age

Health complaints	15-20 years	21-24 years	25-34 years	35-49 years	50-64 years	65 years and over
Headache	57	56	54	59	47	38
Digestive complaints	10	11	10	18	18	11
Constipation	3	7	7	9	10	11
Sore throat, coughs	33	44	39	35	28	22
Colds, influenza	18	23	25	26	21	14
Tooth and gum complaints	20	20	14	14	8	6
Muscular pains, stiffness	9	13	9	19	19	15
Minor injuries	14	13	16	18	11	7
Eye irritation	5	5	7	6	8	6
Tiredness/fatigue	7	8	11	9	10	6
None	23	16	19	19	25	30

N = 290 N = 189 N = 446 N = 550 N = 451 N = 426

Source: *Publicité et conseil* (1).

distinct decline when the number of household members is more than six. Finally, a slight positive correlation was noticed between income and non-prescription medicine purchases (2).

Families in which the head of the family has higher job status generally buy more non-prescription medicines (Table 7). Particularly "cadres supérieurs" (higher management, civil servants, professionals, etc.) and "cadres moyens" (lower-ranking civil servants, teachers, employees, etc.) use non-prescription medicines relatively often. For example, 42% of "cadres supérieurs" bought cough or sore throat remedies during a 12-month period, while only 22% of the unemployed did so. The only exception for this group was

Table 7. Proportion of respondents with particular health complaints who bought non-prescription medicines within a 12-month period, according to social status

Health complaints	Farmer/ farm workers	Small shop- keepers	"Cadres supér- ieurs"	"Cadres moyens"	Manual workers	Unem- ployed
Headache	61	54	55	56	55	39
Digestive complaints	13	10	22	16	13	11
Constipation	6	7	9	6	8	11
Sore throat, coughs	34	36	42	37	34	22
Colds, influenza	20	24	29	28	20	16
Tooth and gum complaints	16	11	9	15	16	7
Muscular pains, stiffness	16	12	17	16	14	15
Minor injuries	11	17	22	16	14	8
Eye irritation	4	2	9	8	6	6
Tiredness/ fatigue	8	11	13	9	9	6
None						
<hr/> N = 205 N = 148 N = 204 N = 447 N = 752 N = 596						

Source: *Publicité et conseil* (1).

toothache remedies. Only 9% of the "cadres supérieurs" bought this kind of over-the-counter product, whereas the average amounted to 12%.

Over-the-counter products were not used at all by 17% of the "cadres supérieurs", 16% of the "cadres moyens" and 16% of the farmers included in the survey. Manual workers and the unemployed used non-prescription medicines far less than the other social groups.

People from the eastern part of France use less non-prescription medicine than average. In this region, 34% had not used any over-the-counter products in the 12 months before the interview.

There is a positive correlation between city size and the per capita purchase of non-prescription medicine (Table 8). In rural areas, the use of non-prescription medicines is below average in almost all categories (an exception is headache analgesics). People from the Paris area use medicine for minor injuries less often than those from other cities. All other types of medicine are used more frequently than average by Parisians.

Table 8. Proportion of respondents with particular health complaints who bought non-prescription medicines within a 12-month period, according to size of town of residence

Health complaints	Environment				
	Rural (%)	Town of 2 000-20 000 inhabitants (%)	City of 20 000-100 000 inhabitants (%)	City of ≥100 000 inhabitants (%)	Greater Paris (%)
Headache	53	49	51	51	53
Digestive complaints	11	12	15	16	15
Constipation	7	7	8	9	11
Sore throat, coughs	29	28	37	34	37
Colds, influenza	19	19	19	22	28
Tooth and gum complaints	12	11	14	13	13
Muscular pains, stiffness	10	16	13	18	18
Minor injuries	11	12	16	16	13
Eye irritation	4	6	8	7	8
Tiredness/fatigue	7	4	8	11	12
None	24	25	19	21	22
	N = 628	N = 361	N = 307	N = 650	N = 405

Source: *Publicité et conseil* (1).

There are no figures available on the use of home remedies and non-allopathic medicines. According to the interviewees, it can be assumed that these medicines are preferred by people living in rural areas and by older people.

Although there are no figures available, the majority of the interviewees assumed that non-prescription medicines are shared among family members. In particular, medicines for common complaints such as headache or cough are used by different members of the same family.

It might be a problem that the use of medicine by the general population is not based on adequate health knowledge. Health education is regarded as inadequate, but it has been given more attention during recent years.

Although family history may still influence the use of non-prescription medicines, family tradition is decreasing. In previous times, families were larger and different generations lived together. Therefore, medical traditions could easily be transferred to the younger generation. With the change in family structure, family lifestyle is no longer of such significance in the choice of non-prescription medicines.

When are non-prescription medicines used?

Non-prescription medicines are mostly used as an initial response to symptom onset. Besides this, they are also used for health promotion. The types of symptom that were most frequently self-medicated are shown in Table 9.

Similar research was carried out by the European Health Panel. According to this research, predictors for the use of non-prescription medicines (in order of frequency) were headache, colds, influenza and chills, sore throat and coughs, constipation, digestive complaints, rheumatic pains, tiredness, skin problems and minor injuries, toothache, and circulation problems (4).

Both studies show that the chief health complaints treated with non-prescription medicines are headache, colds and influenza, coughs and sore throat.

A recent study showed that 39% of the medicines taken for influenza, fever and cough are non-prescription (2). Between 15% and 23% of the medicines for pain, constipation and digestion or tonics are bought direct from a pharmacy. Other categories of medicine are bought direct far less frequently; with antibiotics, the figure is less than 1%.

Table 9. Proportion of respondents with particular health complaints who bought non-prescription medicines within a 12-month period, according to sex

Health complaints	Men (%)	Women (%)	Both sexes (%)
Headache	48	55	51
Digestive complaints	13	14	14
Constipation	3	13	8
Sore throat, coughs	29	36	32
Colds, influenza	21	22	21
Tooth and gum complaints	12	13	12
Muscular pains, stiffness	15	15	15
Minor injuries	14	13	14
Eye irritation	5	8	6
Tiredness/fatigue	7	10	9
None	25	19	22
	N = 1145	N = 1206	N = 2351

Source: *Publicité et conseil* (1).

Apparently, symptoms such as cough and fever are not regarded as being that dangerous, and many people consider them to be curable with non-prescription medicines.

The European Health Panel has published information on vitamins and minerals, with the following conclusions: mineral supplements are used principally for tiredness, nervousness and insomnia, heart complaints and various other health problems; tonics are chiefly used for tiredness, nervousness, lack of appetite and certain pains.

In the opinion of the interviewees, vitamins and mineral supplements are not very popular. Only ascorbic acid and magnesium are purchased relatively often by consumers.

The European Health Panel concluded that, in a given month, about 33 million people suffer from some kind of health complaint. This is equivalent to an annual total to 5900 million days of sickness, of which about 87% are treated in some way, including 13% by self-medication (4).

However, divergences are apparent among the various types of health complaint. Some 22 500 million people suffer from pain, equivalent to 1600 million days of sickness. Treatment was administered on 73% of these days, out of which 19% consisted of non-prescription medicines. Complaints in connection with the respiratory tract symptoms were treated on 81% of the total of 800 million days. Self-medication is relatively popular in this case, covering 33% of the total number of days. For digestive complaints, which amounted to 1000 million days, treatment was applied on 87% of the days, with 20% consisting of non-prescription medicines. Although the number of days involving circulation problems was relatively high (2000 million) and treatment was carried out on 97% of these days, practically no non-prescription products were used. Skin irritation, accounting for 200 million days, was treated on 75% of the days. Self-medication was relatively frequent: 30%. For the general feeling of discomfort, out of 1300 million days, about 82% were treated, but only 5% with non-prescription preparations. The remaining ailments accounted for 1600 million days, and these were treated in 86% of cases. Over-the-counter products were used for only 6% of these days.

It was not possible to determine the length of time people continue the use of non-prescription medicines in the case of persistent symptoms. The interviewees assumed, however, that it does not exceed a few days. The view is that people normally go to a doctor if symptoms persist.

Effects of self-medication

Although there is no unanimous opinion about the relative degree of necessary versus unnecessary use of professional care resources, it was the opinion of all interviewees that the use of non-prescription medicine reduces the use of professional care resources. According to one expert, 10-15% of all cases of self-medication obviate a physician consultation.

Storage, misuse and interactions of non-prescription medicines

In 1979, a representative study was undertaken to determine which medicines are stored at home. Table 10 shows the proportion of the total medicine stored at home represented by certain categories of medicine.

A total of 55% of all medicines stored in cabinets at home consisted of analgesics and remedies for fever, respiratory infections and indigestion (Table 10). These medicines are

Table 10. Percentage of different categories of medicine out of the total stored in medicine cabinets at home

Category of medicine	Percentage of total medicines stored in cabinets
Analgesics for relief of pain and fever	21.3
Respiratory tract medication	18.3
Digestives	15.1
Skin remedies	8.9
Cardiovascular preparations	7.4
Remedies for nervous and mental diseases	5.6
Antiseptics and disinfectants	5.0
Vitamins and tonics	4.1
Preparations for varicose veins	3.2
Eye drops	1.8
Glucocorticoids	1.7
Antihistamines	1.4
Urological remedies	0.7
Antiparasitic preparations	0.5
Contraceptives	0.2
Various	1.5
Undefinable	1.8

Source: Touchard (4).

relatively often bought without prescription. This confirms the opinion of some interviewees that non-prescription medicines are often stored in the home.

It is believed that storage is proper in most cases. However, the reuse of these medicines might be dangerous, as people are not always aware for which health conditions or complaints a certain remedy should be used. For this reason, a campaign was initiated by the pharmacists' and consumer associations. They produced a leaflet with the aim of educating consumers on the careful storage of medicines.

There has been some evidence of considerable abuse with medicines containing barbiturates and benzodiazepines, which have sometimes been combined with alcohol, a combination that turns out to be very dangerous. The above-mentioned substances are therefore

nowadays available only on prescription. This also applies to phenacetin. However, codeine is obviously still often abused.

Numerous interactions can occur between non-prescription medicines and food or other medications. It seems, however, that in practice these interactions are of minor importance. According to the interviewees, the following interactions are known: non-prescription medicines containing minerals can raise blood pressure and can therefore interact with other medicines, such as antihypertensives; there are some interactions with analgesics, such as the possibility of interactions with anticoagulants and gastrointestinal remedies; interactions with medicines containing alcohol and sedatives; some non-prescription medicines can lead to allergic reactions (for example, the use of aspirin can lead to bronchial blockage or asthma attack); people under treatment for diabetes may experience problems with preparations containing sugar.

Health professionals and self-medication

According to a representative of the pharmacists, self-medication, and in particular the function of advising their clients, is seen as an important element in the pharmacist's professional activities. However, it is considered to be neither their original nor their main function.

In 1976, the managing director of the Control Pharmacy Board pointed out that, in view of an increasing tendency towards self-medication, the Minister of Health had a duty to protect the population against the abuse of medicines bought without prescription (2).

For some pharmacists, self-medication might have a certain economic importance, since non-prescription medicines are not subject to strict price controls.

It was the unanimous opinion of all the interviewees who contributed to this study that the subject of non-prescription medicines is hardly dealt with in the curriculum of medical schools. Home remedies and herbal preparations are practically ignored. Medical students are therefore not properly trained in these subjects because they are not considered important.

The level of physicians' knowledge of non-prescription medicines is generally insufficient. As a rule, physicians are not in favour of self-medication. Some physicians fear that, through self-medication, pharmacists can extend their professional activities to areas that have exclusively been the responsibility of physicians. For example, the book previously mentioned, which deals with all available non-prescription medicines and is written for both

consumers and pharmacists (3), allows consumers to locate a remedy suitable for a particular disease or symptom. General practitioners particularly disapprove of this. One of their reasons is apparently the fact that the prescription of medicines is one of their main therapeutic tools. They reject the possibility of people going direct to a pharmacy for advice. Specialists such as surgeons are obviously less concerned about the consequences of this book.

Pharmacists are increasingly in favour of self-medication. They make substantial efforts to obtain more knowledge about non-prescription medicines, particularly through postgraduate education.

As the knowledge of many physicians concerning non-prescription medicines is regarded as being insufficient, they generally do not get involved in self-medication. Most physicians are apparently not prepared to recommend non-prescription medicines or advise people on their use. Most interviewees were of the opinion that physicians' attitudes on this matter need to change and that more advice about these medicines should be given by physicians.

References

1. *Publicité et conseil*. Paris, edited by the Association Française des Producteurs de Spécialités Grand Public, 1982.
2. *Communications économiques et sociales. Etude documentaire sur les spécialités "grand public" et la médication familiale*. Paris, 1981, p. 25.
3. Giroud, J.P. & Hagège, C.G. *Dictionnaire des médicaments vendus sans ordonnance*. Monaco, Editions du Rocher, 1984.
4. Touchard, A.T. La place de la médication familiale dans le système de soins français. In: *Les procédés du Congrès National des Pharmaciens*, Lille, 1982. Paris, Association Française des Producteurs de Spécialités Grand Public, 1982.

Interviewees for the study report on France

Dr M. Bruneau
Physician

Mr J. Cherioux
Senator

- Dr Daubinet
Vice-President, French Medical Association
- Dr H. Désarménien
Director-General, French Association of the Pharmaceutical
Industry
- Mr Gombeaud
Medical journalist
- Mrs M. Kagnan
Member, Central Committee of the French Communist Party
- Mr J.L. Keene
Vice-Director, Ministry of Industrial Affairs
- Mr H. Lanrezac
President, Proprietary Association of France
- Mr Marouby
French Association of Pharmacists
- Mr Orillard
Member, Board of the Proprietary Association of France
- Mr M.P. Quatremarre
Vice-Director, French Social Security System
- Mr Semler-Collery
Director, French Association of Consumers
- Mr A. Touchard
Director-General, Proprietary Association of France
- Mr Vidal
Officer, Pharmaceutical Department, Ministry of Social Affairs
and Social Security

