STICHTING AESGP FOUNDATION

Development of an information policy for medicinal products

Final Report

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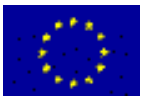

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1. INTRODUCTION

The research project entitled "Development of an information policy for medicinal products" has as main objective to examine the information needs of both the public and health professionals in case the range of conditions that can be treated with non-prescription medicines were to be extended to categories currently not available for treatment without the intervention of a medical practitioner.

The project has received the support of the European Commission under the programme of Community action on health promotion, information, education and training within the framework for action in the field of public health[1] (1996 to 2000), which was extended in 2001 until the end of 2002.

A range of non-prescription medicines provide the end user with a safe and effective way to prevent and treat medical conditions classified by the regulatory authorities as suitable for treatment without the obligatory intervention of a medical practitioner. Traditionally, these conditions are related to minor, short-term diseases.

However, the range of conditions has been expanded to certain short-term or long-term conditions by moving medicines with such indications from prescription to non-prescription status, and this is expected to continue in the future.

Any change in classification status of the medicinal products used in the treatment or management of these conditions needs to be carefully prepared in order to ensure that the individual has all relevant information in an understandable form. Information of, and cooperation by, all stakeholders is key to the success of any future move to expand the area of self-medication.

This project tries to identify the necessary stages in the development of a policy geared towards a citizen-centred approach to public health that would give individuals more responsibility in the management of their own health.

The recommendations at the end of this report aim to make a meaningful contribution to the discussions all over Europe to improve information on medicines and increase the safe practice of self-medication.

2. CURRENT LEGISLATIVE FRAMEWORK FOR MEDICINAL PRODUCTS IN THE EUROPEAN COMMUNITY

This chapter provides some background information on the legal provisions governing non-prescription medicines in the European Union.

What is a medicinal product?

In the European Community, a "medicinal product" is defined as:

> "Any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product" (Article 1 of Directive 2001/83/EC[2], also referred to as the "Community code").

Placing a medicinal product on the market

No medicinal product may be placed on the market of a Member State unless an authorisation has been issued by the competent authorities of that Member State in accordance with the provisions of the Community code or an authorisation has been granted in accordance with Regulation (EEC) 2309/93[3]. In order to obtain such a marketing authorisation, extensive documentation needs to be provided by the marketing authorisation holder (Article 8(3)(i) of the Community code), including results of:

- pharmaceutical (physico-chemical, biological or microbiological) tests,
- pre-clinical (toxicological and pharmacological) tests,
- clinical trials.

The Community code states in Article 10 that, in derogation of Article 8(3)(i), the applicant shall not be required to provide the results of toxicological and pharmacological tests or the results of clinical trials if he can demonstrate:

> "[…] that the constituent or constituents of the medicinal product have a well-established medicinal use, with recognised efficacy and an acceptable level of safety, by means of a scientific bibliography" (Article 10(a)(ii)).

Classification of medicinal products into prescription / non-prescription

Legal provisions

When a marketing authorisation is granted, the competent authorities are obliged to specify the classification of the medicinal product into:

- a medicinal product subject to medical prescription,
- a medicinal product not subject to medical prescription.

They do this according to precise criteria described in Article 71 of the Community code, which states that:

> "Medicinal products shall be subject to medical prescription where they:
> - are likely to present a danger either directly or indirectly, even when used correctly, if utilised without medical supervision, or

- are frequently and to a very wide extent used incorrectly, and as a result are likely to present a danger to human health, or
- contain substances or preparations thereof the activity and/or side effects of which require further investigation, or
- are normally prescribed by a doctor to be administered parenterally."

This indicates that the philosophy underlying the Community's classification rules is that all medicines are normally available without a prescription unless they meet one of the above criteria making their supply subject to medical prescription.

Conclusions from the Commission's report on the application of the classification Directive

The classification system appears to work satisfactorily in most Member States of the European Union. This became clear from the European Commission's 1997 *Report to the Council on the application of Directive 92/26/EEC*,[4] an important part of which was devoted to a description of self-medication and non-prescription medicines. The report stated that:

> "The Directive's implementation into national law has been carried out by all Member States. They all use the classification system set out in the Directive which consists of two main categories, non-prescription and prescription-only. However, within each of these main categories there are optional sub-categories which vary from one Member State to the next."

The Report confirmed the general feeling that the Directive had made a contribution towards achieving harmonisation in classification status throughout the European Union without however achieving full consensus on the classification details of many medicines:

> "Differences, between Member States, in the classification of medicinal products have decreased since the adoption of Directive 92/26/EEC. However, it is generally felt that the level of harmonisation achieved is not yet satisfactory. This may be due to the fact that Member States have been late in implementing this Directive, but it also probably reflects more fundamental differences in their approaches to self-medication."

Concerning the conditions for a change of classification status, the report mentioned that:

> "… efforts have been made at national level to improve switching procedures following adoption of the Directive. In several Member States, however, the Directive's impact has been minor. Neither the authorities nor the marketing authorisation holders have changed their previous practices significantly, and therefore there has been hardly any change with regard to legal status. The risk of losing reimbursement by the State-funded health service is often a factor discouraging marketing authorisation holders from applying for a switch."

Adoption of a "switch guideline"

In 1996, the Council of Health Ministers and the European Parliament each adopted a *Resolution on the outlines of an industrial policy for the pharmaceutical sector in the European Union*. Both resolutions called for a tightening of the classification system for medicinal products and the establishment of transparent switching procedures. In response, the Commission in September 1998 adopted detailed guidance with a view to harmonising the conditions for switching prescription-only medicines to non-prescription status for use in self-medication[5]. The guideline came into effect on 1 January 1999.

Information for the end user

It is evident that medicinal products, especially those available without a medical prescription, should be accompanied by clear information for the end user, i.e. the consumer / patient or the

parent in case of products approved for use in children. The legislation currently in force in the European Community foresees that such information should be made available in several forms:

On the product label

The product label, i.e. the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging, should mentioned the following particulars (Article 54 of the Community code):

(a) the name of the medicinal product followed by the common name where the product contains only one active ingredient and if its name is an invented name; where a medicinal product is available in several pharmaceutical forms and/or several strengths, the pharmaceutical form and/or the strength (baby, child or adult as appropriate) must be included in the name of the medicinal product;
(b) a statement of the active ingredients expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names;
(c) the pharmaceutical form and the contents by weight, by volume or by number of doses of the product;
(d) a list of those excipients known to have a recognised action or effect and included in the guidelines published pursuant to Article 65 [of the Community code]. However, if the product is injectable, or a topical or eye preparation, all excipients must be stated;
(e) the method and, if necessary, the route of administration;
(f) a special warning that the medicinal product must be stored out of reach of children;
(g) a special warning, if this is necessary for the medicinal product concerned;
(h) the expiry date in clear terms (month/year);
(i) special storage precautions, if any;
(j) special precautions for disposal of unused medicinal products or waste materials derived from such products, if appropriate;
(k) the name and address of the holder of the authorisation for placing the medicinal product on the market;
(l) the number of the authorisation for placing the medicinal product on the market;
(m) the manufacturer's batch number;
(n) in the case of self-medication, instructions on the use of the medicinal products.

In the package leaflet

Article 58 of the Community code specifies that all medicinal products should contain a package leaflet unless all the information listed in the points below (details in Article 59) is directly conveyed on the outer packaging or on the immediate packaging. The package leaflet should be drawn up in accordance with the summary of product characteristics (SmPC), a document approved during the registration process containing a detailed description of the medicinal product (Article 11 of the Community code).

The package leaflet should include, in the following order:

(a) for the identification of the medicinal product:
- the name of the medicinal product, followed by the common name if the product contains only one active ingredient and if its name is an invented name; where a medicinal product is available in several pharmaceutical forms and/or several strengths, the pharmaceutical form and/or the strength (for example, baby, child, adult) must be included in the name of the medicinal product,

- a full statement of the active ingredients and excipients expressed qualitatively and a statement of the active ingredients expressed quantitatively, using their common names, in the case of each presentation of the product,
- the pharmaceutical form and the contents by weight, by volume or by number of doses of the product, in the case of each presentation of the product,
- the pharmaco-therapeutic group or type of activity in terms easily comprehensible for the patient;
- the name and address of the holder of the authorisation for placing the medicinal product on the market and of the manufacturer;

(b) the therapeutic indications;

(c) a list of information which is necessary before taking the medicinal product:
- contra-indications,
- appropriate precautions for use,
- forms of interaction with other medicinal products and other forms of interaction (for example, alcohol, tobacco, foodstuffs) which may affect the action of the medicinal product;
- special warnings

this list must:
- take into account the particular condition of certain categories of users (e.g., children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions,
- mention, if appropriate, potential effects on the ability to drive vehicles or to operate machinery,
- detail those excipients, knowledge of which is important for the safe and effective use of the medicinal product and included in [special] guidelines […],

(d) the necessary and usual instructions for proper use, in particular:
- the dosage,
- the method and, if necessary, route of administration,
- the frequency of administration, specifying, if necessary, the appropriate time at which the medicinal product must be administered,

and, as appropriate, depending on the nature of the product:
- the duration of treatment, where it should be limited,
- the action to be taken in the case of an overdose (e.g., symptoms, emergency procedures),
- the course of action to take when one or more doses have not been taken,
- indication, if necessary, of the risk of withdrawal effects;

(e) a description of the undesirable effects which can occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case; the patient should be expressly invited to communicate any undesirable effect which is not mentioned in the leaflet to his doctor or pharmacist;

(f) a reference to the expiry date on the label, with:
- a warning against using the product after this date;
- where appropriate, special storage precautions;
- if necessary, a warning against certain visible signs of deterioration;

(g) the date on which the package leaflet was last revised.

How does the end user find out the existence of a medicinal product?

In the case of a medicinal product legally available only with a medical prescription, the end user / patient is usually obliged to consult a medical doctor in order to obtain a prescription for the supply of the product. Pharmaceutical companies will therefore direct their

information primarily towards these health professionals so that they may inform their patients and prescribe the product for the conditions approved by the regulatory authorities.

Public advertising

In the case of medicinal products available without a medical prescription, manufacturers of non-prescription medicines need to communicate directly with the end user, i.e. the citizen / patient, to make him / her aware of the existence and properties of the products they intend to place on the market. The European legislator has therefore foreseen that non-prescription medicines may be advertised to the general public in all media.

Advertising to the general public is subject to the following conditions set out in Article 89 of the Community code:

"[…] all advertising to the general public of a medicinal product shall:
(a) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product;
(b) include the following minimum information:
- the name of the medicinal product, as well as the common name if the medicinal product contains only one active ingredient,
- the information necessary for correct use of the medicinal product,
- an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, according to the case."

The following prohibitions apply to the public advertising of non-prescription medicines (Article 90 of the Community code):

"The advertising of a medicinal product to the general public shall not contain any material which:
(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;
(b) suggests that the effects of taking the medicine are guaranteed, are unaccompanied by side effects or are better than, or equivalent to, those of another treatment or medicinal product;
(c) suggests that the health of the subject can be enhanced by taking the medicine;
(d) suggests that the health of the subject could be affected by not taking the medicine; this prohibition shall not apply to vaccination campaigns […];
(e) is directed exclusively or principally at children;
(f) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;
(g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
(i) could, by a description or detailed representation of a case history, lead to erroneous self diagnosis;
(j) refers, in improper, alarming or misleading terms, to claims of recovery;
(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof;
(l) mentions that the medicinal product has been granted a marketing authorisation."

The control of public advertising

Article 97 of the Community code states that

> "Member States shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. Such methods, which may be based on a system of prior vetting, shall in any event include legal provisions under which persons or organisations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Directive may take legal action against such advertisement, or bring such advertisement before an administrative authority competent either to decide on complaints or to initiate appropriate legal proceedings."

This system of statutory advertising control may be complemented by the "voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings."

What happens if a problem occurs with the use of a non-prescription medicine?

The Community's legislation on medicinal products devotes an entire chapter to the reporting of problems in connection with the use of these products. In legal terms, this is called "pharmacovigilance." The Community code states in particular (Article 101) that:

> "The Member States shall take all appropriate measures to encourage doctors and other health care professionals to report suspected adverse reactions to the competent authorities.
>
> The Member States may impose specific requirements on doctors and other health care professionals, in respect of the reporting of suspected serious or unexpected adverse reactions, in particular where such reporting is a condition of the marketing authorisation."

Member States are moreover obliged to set up a pharmacovigilance system (Article 102). This system "shall be used to collect information useful in the surveillance of medicinal products, with particular reference to adverse reactions in human beings, and to evaluate such information scientifically."

Revision of the EC's pharmaceutical legislation

In the framework of the thorough revision the European Community's pharmaceutical legislation is currently undergoing, the European Commission is proposing a number of changes to the current legal provisions for medicinal products for human use[6].

In the area of product safety, the Commission is proposing that Member States make all appropriate pharmacovigilance information available to the other Member States and the European Medicines Evaluation Agency (EMEA). Moreover, the EMEA will have to set up a database with information on adverse reactions which should be permanently accessible by all Member States. The Agency should also make appropriate pharmacovigilance information available to the public.

Concerning the public advertising of non-prescription medicines, the current restrictions on mentioning certain diseases would be abolished, whereas the proposed changes in patient information requirements are very minor.

No modifications are foreseen in the area of classification, meaning that the main provisions applicable to the change of legal status of a medicine as well as the switch guideline are expected to apply unchanged.

Summary

It is clear from the description of the legal framework for medicinal products in the European Community in this chapter that medicinal products are among the most strictly regulated and controlled products in the marketplace. This holds particularly true for medicines classified as available for supply without a prescription. Generally speaking, the framework has been developed and improved over the last 35 years and has proven its effectiveness.

A thorough revision of the current system is going to be discussed shortly by the European institutions but is unlikely to bring fundamental changes to the criteria for the authorisation and classification of medicinal products or to the information requirements.

3. RECENT HISTORY OF SELF-MEDICATION

Evolution of the last 50 years

An analysis of the development and acceptance of self-medication in the second part of the 20th century shows that, until around 1980, only a quite limited range of conditions were generally considered as suitable for treatment without the intervention of a medical practitioner. They included mild to moderate pain, cough and colds, constipation and minor skin problems such as cuts and bruises.

In the period 1980-2000, individuals all over Europe showed a growing willingness to take responsibility in health-related matters. This change in attitude was reflected by a gradual change in European health policies, indicating that governments recognised the importance of developing and taking advantage of the potential offered by this change in attitude on the part of their citizens. Governments actively encouraged this increased individual responsibility for health, especially in the early part of the 1990s, by initiating or approving the move of a growing number of ingredients from prescription-only to non-prescription status.

These developments have led to a situation where, at the end of the 20th century:

- Non-prescription analgesics can often be used for rheumatic pain and migraine in addition to mild to moderate pain.
- Allergic conjunctivitis and the prevention and treatment of hayfever had been added to the list of conditions that can be treated with cold / anti-allergy agents used in non-prescription medicines.
- In the gastrointestinal area, diarrhoea, haemorrhoids, acid indigestion / heartburn and irritable bowel syndrome had been added for consumer self-treatment.
- Ingredients to treat skin conditions such as vaginal thrush, cold sores, eczema, male pattern baldness and acne had gained their place in the self-medication arena.
- Other notable areas available for consumer self-treatment were smoking cessation, prevention of neural tube defects, temporary insomnia and, more recently, emergency contraception.

Commission Communication recognising these changes

The ***Communication from the Commission on health promotion*** of 1 June 1994[7] issued as part of the Community's public health policy contained some important statements concerning the growing importance of self-medication within the healthcare systems in the European Community:

"Recent years have seen the emergence of an increasing trend towards the use of over-the-counter medicines which are available to the public without prescription. This is partly a result of people's desire to take responsibility for their own health and partly due to the large number of messages transmitted through the media on the subject of self-medication. Sensible self-medication may also help to reduce health expenditure by cutting the number of medical consultations. The trend towards self-medication must be accompanied by a strengthening of information measures if it is not to have an adverse effect on people's health. Thus giving the people more choice and responsibility must also involve ensuring that they are equipped to make sensible choices."

"This practice is of particular benefit in the treatment of minor ailments and can provide relief from these for the persons concerned. However, the people must be made aware and properly informed of the need to consult a doctor if symptoms persist or doubts exist. It may occur

that after initial diagnosis and prescription, self-medication is possible with the doctor delegating control while retaining an advisory role such as in the case of diabetes and asthma. Information in all these cases must be easily accessible and easily understandable. Other aspects of the use of products involved in self-medication must be emphasised and taken into account, such as repeated and excessive use of certain types of drugs and the protection of children from accidental poisoning."

The role of health professionals such as pharmacists and medical doctors in self-medication was also recognised in this ***Communication***:

"Pharmacists have a key role to play in providing assistance, advice and information to the public about self-medication products and the circumstances in which a doctor should be consulted. To help them perform this role they will require specially-tailored information material and appropriate training."

"Doctors who prescribe medicines can have an important role in raising people's awareness concerning the consumption of medicines and, indirectly, in the efforts to control health costs. Providing information to doctors and pharmacist about availability of different pharmaceutical treatments may also lead to a cheaper treatment with equal results. Providing sufficient information to consumers can also contribute to a more sensible use of medicines."

Building on past collaboration and consensus

The European Commission took several initiatives in the framework of the Community Action Programme on health promotion[8] to support the collaboration between stakeholders in the provision of responsible self-medication in an active manner. Thus, it provided an important impetus for the organisation of a number of meetings, involving - amongst other parties - the Standing Committee of European Doctors (CP), the European Union of Medical Specialists (UEMS), the European Union of General Practitioners (UEMO), the Pharmaceutical Group of the European Union (PGEU) and the Association of the European Self-Medication Industry (AESGP).

The current research project should be considered as a continuation of the different consensus meetings on the role of health professionals in pharmaceutical developments and healthcare described below.

PGEU-AESGP agree on key role of the pharmacist

At a meeting in October 1994, PGEU and AESGP discussed the perspectives for pharmacies in Europe, particularly in relation to the increasing importance of self-care and self-medication, as a follow-up to the Charter of Collaboration signed by the two organisations on 6 May 1993[9].

The meeting agreed that one of the key issues for the future development of self-medication is communication with the population. In addition to the general information provided by industry through advertising and the information on the pack and in the leaflet, the pharmacist is the key individual to give advice whenever needed. This was becoming particularly relevant at a time when products were increasingly being switched from prescription to non-prescription status, as was the case in several European countries following implementation of the EC directive on the classification of medicinal products.

It was agreed that there was a need to supply the pharmacist with comprehensive information related to self-medication medicines. The meeting discussed models for the appropriate

education of pharmacists at university and post-university levels and how pharmaceutical staff can be properly trained in this respect.

How to improve information for health professionals

A symposium in January 1996 entitled "Self-Medication in the European Healthcare Systems – Changing Roles For All Partners" looked particularly at how to improve information for *health professionals* concerning self-medication products. The meeting was sponsored by the European Commission and chaired by Ursula Schleicher, then Vice-President of the European Parliament. Participants were the Standing Committee of European Doctors (CP), PGEU and AESGP. European Commissioner Pádraig Flynn, who was at that time responsible for public health, gave the keynote presentation. The meeting agreed on an intensified dialogue between the institutions with the objective of proposing common rules and guidance.

This was then leading to a second joint symposium in Brussels in February 1997 at which the Standing Committee of Medical Doctors in Europe (CP), the European Union of General Practitioners (UEMO), the European Union of Medical Specialists (UEMS) and AESGP presented a common position on self-medication in Europe[10]. The symposium also provided an excellent opportunity for an exchange of views on the subject of self-medication with several patient / consumer groups.

In his keynote presentation at the meeting, Commissioner Flynn called the paper "an extremely positive contribution in the area of public health." Mr Flynn called on the parties represented to communicate the ideas contained in it to a broader public. The Commissioner emphasised the importance of responsible self-medication for the European Commission's health policy and indicated that, for example, better accessibility to non-prescription medicines would further the development of self-medication. This in turn would allow the national health systems to benefit more from the cost-saving potential of self-medication.

Medical doctors and manufacturers develop consumer brochure

In response to the Commissioner's request, the three European umbrella organisations of medical doctors, medical specialists and general practitioners and the self-medication industry agreed in the months following the Symposium on a consumer brochure on self-medication as well as on the conditions in which it is appropriate. This brochure was translated and printed in all 11 Community languages. It was widely publicised, both in print and in electronic form.[11]

Cooperation continues

The relationship of cooperation between the different stakeholders in the area of self-medication is continuing in several forms. Officials of the European and national competent authorities as well as representatives of the European and worldwide associations of medical doctors, pharmacists and non-prescription medicine manufacturers regularly participate in each other's conferences and meetings, which are usually held on an annual basis.

Other contacts on specific themes or projects such as the World Health Organization's Tobacco Free Initiative contribute to fostering the good relationships mentioned above.

4. STATUS QUO ANALYSIS

In order to put possible future developments in the area of self-medication into perspective, it appeared necessary to carry out a status quo analysis of the current situation in the Member States of the European Community and in Norway.

Table of current classification of active ingredients

In order to obtain an in-depth overview of the acceptance of self-medication in the different healthcare systems around Europe, a list of about 200 active substances was identified. These ingredients were selected based on their wide use in the non-prescription sector and/or their potential interest for some emerging indications in the self-medication area (e.g. sex hormones used for non-prescription emergency oral contraception). A few common combinations were also included although it was agreed that the table should be kept as simple as possible and that multiple entries should be avoided.

The aim of the exercise was to identify the legal status (i.e. the classification as prescription or non-prescription) of the medicinal products containing the selected ingredient in each European Union Member State.

The table was compiled internally by the AESGP based on the information available in-house (official national compendia). It was then circulated to AESGP member associations in the European Union. The information thus collected was edited and incorporated into a table and published[12] after the acceptance of the Interim Report.

During the consultation with AESGP member association, it rapidly became obvious that the legal status of an ingredient was sometimes subject to certain restrictions (indications, dosages, age, etc.) and that such information should not be neglected. Wherever possible, this additional information is provided in footnotes. It is however very important to note that the absence of a footnote does not mean that there are no particular restrictions. In other words, wherever further clarification was provided, this was added as a footnote. There are more than 500 footnotes which, for reasons of clarity, appear in order of appearance, as created by the computer, at the end of the table.

In order to clarify the table and to avoid a tedious inventory of 200 selected ingredients in alphabetical order, it was decided to classify ingredients into groups of activity. It was not possible to group the ingredients according to their indication(s), as the same ingredient can be used for different indications in different Member States. To avoid any subjectivity, the ingredients were classified according to their use or action according to the ATC classification described in *Martindale (31st edition)*[13]. This was done with the aim of clarifying the legibility of the table and should not be interpreted as a recommendation from AESGP.

Survey of the switch climate

At the time the information for the table mentioned in the previous paragraphs was gathered, AESGP member associations and some member associations of the World *Self*-Medication Industry (WSMI) were asked to answer certain questions concerning the switch climate in their country.

The outcome of this research has brought to light some factors that may influence the decision of individual manufacturers of non-prescription medicines whether or not to initiate a

"switch" application, i.e. an application to the competent authorities for a change of legal status for a medicinal product from prescription-only to non-prescription.

Pricing

In Greece, the price of non-prescription medicines is controlled by the national authorities. This deters certain manufacturers from applying for non-prescription status for their products, as they cannot rely on normal market mechanisms to determine the "right" price for their product. Other countries such as Austria and Belgium have notification procedures which may undermine pharmaceutical companies' interest in applying for a switch if the system does not work properly.

The use of the same brandname for the prescription and non-prescription version is not allowed

Some countries such as Austria, Ireland, Portugal and Spain do not allow manufacturers to use the same brand name for a product switched to non-prescription status in case one or more versions of a product with the same ingredient remain available as a prescription-only medicine. This practice was criticised on many occasions by different institutions and bodies. A reference was also made in the Commission's Report on the implementation of the classification Directive:

> "Some Member States (e.g. Portugal and Spain) require the name of the medicinal product to be changed when a product, which was previously prescription-only, becomes available without a prescription. It appears that this requirement is not entirely based on safety, quality or efficacy considerations but is sometimes linked to concerns that advertising of a non-prescription medicine which has the same name as a prescription medicine may increase the prescribing of the prescription-only product and this impacts on the state-funded health service. Data available, so far, from industry, does not support this concern."

Public advertising is either not allowed or leads to loss of reimbursement

Somewhat linked to the previous issue (the use of the same brandname for the prescription and non-prescription version of a medicinal product) is the fact that some countries do not allow some switched medicinal products to advertise to the general public (e.g., Italy, Portugal and Spain). In other countries, non-prescription medicines automatically lose reimbursement in case the manufacturers advertise in the general media (e.g., Ireland, Italy, Norway, and Spain). This loss of reimbursement sometimes even applies to the prescription-only form of the medicine.

Disharmony in approved indications

There is a certain degree of disharmony in the indications approved for certain products in the different countries. This may discourage manufacturers from applying for non-prescription status for their products, especially through the decentralised procedure, for fear of ending up with the lowest number of indications available anywhere in the European Community.

Switch is ingredient-related / no data exclusivity

In a non-negligible number of countries, switch applications are ingredient-related and not product-related. This means that all products containing a particular ingredient would benefit from the successful switch application of one manufacturer. Moreover, a switch in the United States, is eligible for three years of data exclusivity if the "new drug application" (or "supplemental new drug application") for the switch contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and the investigations are conducted or sponsored by the applicant. Current provisions in the EC's legislation do not provide such data exclusivity

Conclusions from the status quo analysis

The situation with regard to the availability of ingredients for self-medication differs to some extent in the countries examined, meaning that the availability of indications or conditions that can be treated by citizens without first seeing their doctor is also different.

The environment for medicinal products switched from prescription-only to non-prescription status – in particular with regard to pricing, the use of trade names and public advertising – does not encourage manufacturers to submit switch applications in a number of countries examined.

There are no provisions in the current EC legislation providing the protection of data relevant to the switch of a medicinal product.

5. PROPOSALS FOR NEW INDICATIONS

Establishment of a dedicated Task Force

The focal point in the current project was to examine how a possible expanded role for self-medication could be achieved and how this expanded role could best be communicated to all interested parties, and in the first place to the millions of European citizens.

In order to carry out these aspects of the project, a Task Force was set up of around 20 persons responsible for medical affairs within their respective pharmaceutical company and / or pharmaceutical trade association.

The Task Force held three different meetings during the project: 1 February 2001, 5 April 2001 and 2 July 2001. The issues were then followed up by the AESGP Regulatory Affairs Committee and the AESGP Board.

Work undertaken by the Task Force

In order to prepare valid proposals for bringing certain indications into the realm of self-medication, the Task Force first examined the current legislative framework. As mentioned in Chapter 2 of this report, the regulatory requirements to obtain a change of classification status or "switch" of a medicinal product are laid down in the provisions concerning classification in the Community code[2] and in the 1998 switch guideline. The Task Force considered these provisions to be adequate but concurred with the conclusions of the Commission's report that the implementation of these provisions and guidelines was uneven in the various Member States.

Establishment of a chart mapping indications

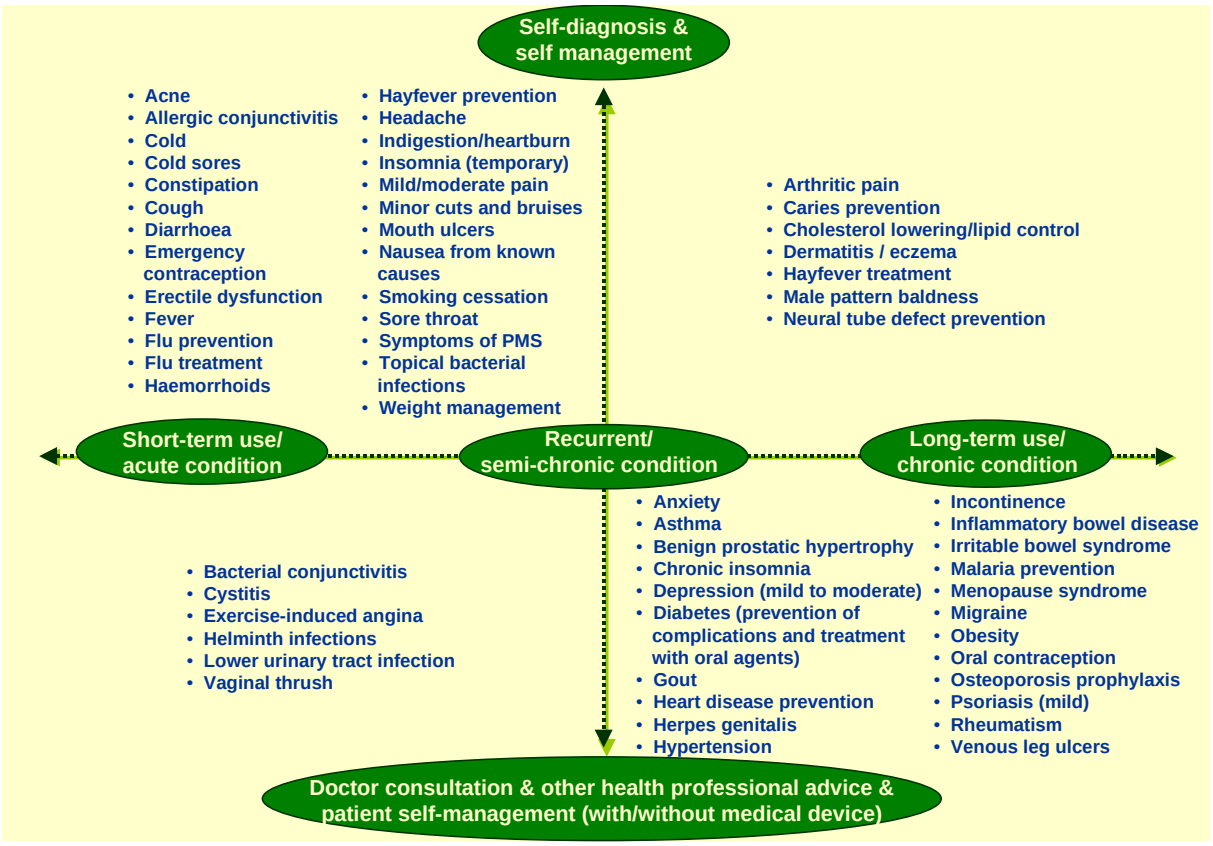
The Task Force then proceeded to establish a suitable way of describing indications currently available in self-medication together with indications or conditions that might be considered for self-medication in the future.

This resulted in the establishment of a chart (see below) in which indications were mapped according to the following criteria:

1. Is it an acute condition requiring short-term use of a medicinal product, is it a semi-chronic condition requiring recurrent use of a medicinal product or is it a chronic condition requiring long-term use of a medicinal product?
2. Is it a condition that can easily be self-diagnosed and self-managed or is it a condition that requires prior consultation of and diagnosis by a medical doctor?

For indications in the top half of this chart, i.e. the traditional self-medication area, the following questions are usually asked to determine whether these indications are suitable for self-treatment:

- Can the condition be easily self-diagnosed?
- Is the illness self-limiting?
- What underlying conditions might be masked by self-treatment?
- Does the product have a wide safety margin?
- Can the product be used safely without medical supervision?
- Will the use of the product lead to misuse, abuse or dependence?
- Will the product present a hazard to the community if used unsupervised?



Collaborative care

The Task Force noted that conditions in the bottom left-hand quadrant are becoming gradually available for self-medication in certain countries, often in a "collaborative care" setting. This means that people often go to the doctor when presenting symptoms of these conditions for the first time. Once the doctor has established a first-time medical diagnosis, people are often capable of recognising the symptoms when they recur and will treat the condition with a medicinal product available without a prescription. The pharmacist can in this setting provide valuable information and advice on appropriate treatment and the need to consult a doctor again in certain circumstances that will vary according to the condition.

New indications currently not available for self-medication

The bottom right-hand quadrant of the chart includes the conditions identified by the Task Force as possible new candidates for treatment in this collaborative care setting. According to the Task Force, there is a need to ask the following additional questions to determine if these new indications would be suitable for self-treatment:

- Is the illness life threatening?
- Can the management of the condition / disease be enhanced by greater access of medicinal products available without a prescription?
- Can patients adequately self-monitor (through the use of a device) and self-treat asymptomatic diseases?
- Is the illness stable over the recommended treatment period?
- Is the treatment regimen simple and easy to follow or does it require dose titration?
- What is acceptable compliance / non-compliance for treatment of the disease?

6. SEEKING CONSENSUS AMONG STAKEHOLDERS IN HEALTHCARE

Discussion of the project at the AESGP Conference in Rome

The project was for the first time discussed at a Round Table on "Access to market" held during the AESGP Annual Meeting in Rome on 7 June 2001. Apart from a large audience including a large number of stakeholders, participants around the table included:

- Mr Miguel Andrade, Chairman of the Management Board, Infarmed, Portugal
- Prof. Alain Baumelou, President, Self-Medication Group, AFSSAPS (Health Products Safety Agency), France
- Mr John Ball, Vice President, Global Category Management, Warner Lambert Consumer Group
- Dr Geeta Lingam, Global Head of Clinical and Regulatory Affairs, Roche Consumer Health
- Assoc. Prof. L'udevit Martinec, PhD, Director, State Institute for Drug Control, Slovak Republic
- Dr Wolfgang Michtner, Federal Ministry of Social Security and Generations, Austria
- Dr José Felix Olalla, General Subdirector for medicines for Human Use, Spanish Medicines Agency
- Dr Marianne Petersen-Braun, Bayer Vital Consumer Care, Germany
- Mr William Quaeyhaegens, Vice-President SelfMedication, IMS Health
- Mr Christian Riché, President, Pharmacovigilance Commission, AFSSAPS (Health Products Safety Agency), France
- Dr Milan Šmíd, Director, State Institute for Drug Control, Czech Republic
- Mr Noël Wathion, Head of Unit, Post-authorisation evaluation of medicines for human use, European Agency for the Evaluation of Medicinal Products (EMEA).

Conclusions from the Round Table in Rome

The discussions showed that the participants in the Round Table were concerned not so much about the principle of a wider availability of indications but rather about safeguarding public health. A key issue in this was adverse-effect reporting, which could and should be improved according to many of the authorities around the table. Industry participants expressed frustration with the different interpretation of the EU switch guideline by some national competent authorities.

In order to meet some of the concerns expressed during the session, participants agreed on the following proposals:

Adverse Effect Reporting

- Pharmacists to take a more active role in post-switch reporting through a system to be developed by the key stakeholders (industry, regulators, doctors, pharmacists)
- Evaluate the possibility of introducing an adverse effect report card as part of the label / leaflet to complement the manufacturer pharmacovigilance database.

Switch Criteria

- Extension of the centralised procedure to certain switch applications to ensure consistent assessment
- National / mutual recognition route to remain an option for switch applications.

Discussion of the project at a special Workshop on 13-14 September 2001

A special Workshop on 13-14 September 2001 in Brussels was dedicated to discussions on the availability of new indications for self-medication and related information needs in the framework of the project. Participants in the workshop included representatives of European associations of stakeholders in primary healthcare (consumers, medical doctors, pharmacists and industry) and officials from the Directorates-General Health and Consumer Protection and Enterprise of the European Commission and from national authorities.

Prof. Dr Fritz Kemper (Chair)	Institute for Pharmacology & Toxicology, University of Münster
Prof. Alain Baumelou	Agence Française pour la Sécurité Sanitaire des Produits de Santé (AFSSAPS)
Mr Nils Behrndt	European Commission, DG Enterprise
Mr Dirk Broeckx	Association Pharmaceutique Belge / Algemene Phamaceutische Bond, Belgium
Mr James Copping	European Commission, DG Enterprise
Mrs Charlotte de Roo	Bureau Européen des Unions de Consommateurs (BEUC)
Dr Simon Fradd	Doctor Patient Partnership, UK
Dr Leonard P. Harvey	Standing Committee of European Doctors (CP)
Dr Eric Klasen	Director, Head of Global Drug Regulatory Affairs, Novartis Consumer Health SA
Mr Horst Kloppenburg	European Commission, DG Health and Consumer Protection
Mr Alan Li Wan Po	Aston University, UK
Dr Geeta Lingam	Global Head of Clinical and Regulatory Affairs, Roche Consumer Health
Dr Stephen Mann	Johnson & Johnson MSD Consumer Pharmaceuticals - Europe
Dr Isabelle Moulon	European Medicines Evaluation Agency (EMEA), Safety and Efficacy
Prof. Giuseppe Nisticò	Member of the European Parliament
Mr Aidan O'Shea	President, Pharmaceutical Group of the European Union (PGEU)
Mrs Catherine Pouletty	Association Française de l'Industrie Pharmaceutique pour une Automédication Responsable (AFIPA), France
Dr June Raine	Director, Post-Licensing Division, Medicines Control Agency (MCA), United Kingdom
Dr Christian Riché	Chair, National Committee on Pharmacovigilance, France
Ms Sunayana Shah	Proprietary Association of Great Britain (PAGB)
Dr Ross Taylor	Royal College of General Practitioners, University of Aberdeen, United Kingdom
Dr Helga Warminski	EU Regulatory Affairs, Bayer Consumer Care
Dr Ralf Zerban	Head, Medicine and Drug Regulatory Affairs, Consumer Health Care, Boehringer Ingelheim GmbH
Dr Hubertus Cranz	Director General, AESGP
Prof. Jasmina Mircheva	Director, Regulatory and Scientific Affairs, AESGP
Mrs Mary Coronel	Communication and Public Relations, AESGP
Ms Alexia De Perlinghi	AESGP

Summary of presentations and debates

The two sessions of the workshop included a certain number of formal presentations, each time followed by lively and constructive debates.

Mr Horst Kloppenburg of the European Commission's Public Health Directorate, Directorate-General Health and Consumer Protection explained the place of the project in the wider context of the Community's health policy. He stressed that any recommendation made in the course of the project should be geared towards meeting consumer needs, and that communication with the consumer and between health professionals and industry was key to the success of any new switches.

Mr Nils Behrndt of the European Commission's Pharmaceutical Unit, Directorate-General Enterprise introduced the audience to the EU's current legal classification framework for medicinal products. He also explained how the planned revision of the Community's pharmaceutical legislation is likely to affect the marketing authorisation, labelling, patient information leaflet and advertising provisions within this framework for non-prescription medicines.

Three new indication areas were presented at the workshop.

Emergency contraception

Mr Dirk Broeckx of the Belgian Pharmacist Association APB gave a presentation on the introduction of *levonorgestrel* as a non-prescription medicine for emergency contraception in Belgium. He explained that the ingredient had already been available in Belgium for many years, and that data showed that emergency contraception was not only used by teenagers but also by women in their twenties and thirties.

Following favourable advice from the Medicines Commission, the Belgian Minister of Health in early 2001 announced plans to approve the switch of *levonorgestrel* to non-prescription status. The availability of the emergency pill without a prescription was considered important as data showed that a 12-hour delay in taking the pill increased the risk of pregnancy by nearly 50%. One of the indirect objectives was to reduce the number of abortions (mainly in the younger female population) as a result of improved availability of emergency contraception.

At the same time, the Minister asked that the switch of the emergency pill be accompanied by an information campaign about contraception in general. The information should make it clear that emergency contraception should be considered as a last resort and be the exception rather than the rule. Information to the public should therefore concentrate on regular methods of contraception. In this context, the Minister planned to entrust the pharmacy profession with the provision of this important information to prospective contraceptive users.

Mr Broeckx said that this provided the Belgian pharmacist association with the considerable challenge of developing adequate information materials on contraception for both pharmacists and consumers in the extremely brief period of only two months. He gave details of how his association had proceeded in order to meet this challenge, in particular through intensive consultations with the medical profession, industry and the Ministry of Health. The "key element" in successfully and rapidly developing the necessary material was the establishment and collaboration of a group of multidisciplinary experts who were willing to set aside "political" or opportunistic objections and focus on the needs of the patients. During these consultations, obstacles raised included resistance on the part of certain doctor associations, questions in Parliament and ethical objections from circles within the pharmacy profession.

APB managed to finalise the information materials in time for the launch of the product as a non-prescription medicine in June 2001. The patient package made available for prospective users in all pharmacies included:

- A folder about safe sex
- A brochure about sexually transmitted diseases and AIDS
- A folder about uncontrolled micturition
- A list of addresses of family planning centres
- A brochure about *Norlevo*®
- A folder about emergency contraception
- A preservative.

Mr Broeckx mentioned that these materials would be continuously improved once enough feedback had been gathered.

To familiarise pharmacists with the non-prescription availability of the emergency pill, the APB organised a series of information sessions in June 2001. The association also dispatched an information package especially geared towards the pharmacy profession as well as a poster to be shown in pharmacies.

Although experience with the non-prescription availability of *levonorgestrel* was still limited at the time of the workshop, Mr Broeckx said he was confident that the switch was going to be a success and that it would contribute to the improvement of public health in his country.

Primary prevention of coronary heart disease through self-medication with cholesterol-lowering agents

Dr Stephen Mann of the AESGP Task Force on New Indications for Self-Medication presented the case for primary prevention of coronary heart disease (CHD) by making cholesterol-lowering medication available for use without a prescription.

At present, a certain group of the population presenting an annual risk of between 1.5% and 3% of developing CHD is not covered by social security provisions anywhere in the world. In the United Kingdom, this group alone represents around 16.2% of the population or four million people (see *Annex 1*: preparatory paper on primary prevention of coronary heart disease (CHD) through self-medication with cholesterol-lowering agents).

There is a clear role for the pharmacist in the screening of blood pressure, diabetes and cholesterol levels and advice on lifestyle improvement. In case of high-risk or occult diseases, referral to a medical specialist would be indicated. However, pharmacists could be invaluable in the management of education, record keeping, follow-up, tailoring of advice and therapy in areas such as smoking cessation, cholesterol reduction, etc. Issues to be addressed by pharmacists are patient education, lifestyle changes, a single patient record, the availability of screening tools (sometimes requiring a rule change) and pharmacy training / certification. It is important to make provisions for those that need and wish to treat but cannot afford to pay for the necessary medication.

Conclusions included that:

- CHD prevention is the largest challenge facing European health care systems
- Large-scale testing and treatment would be necessary to treat populations at moderate risk that should be treated

- Pharmacy provision of screening and preventative care for healthy but at risk people is an attractive option
- Successful collaborative care has the potential to produce great benefit to public health

Overactive bladder / urge incontinence

Dr Alberto Paredes Díaz of the AESGP Task Force on New Indications for Self-Medication / Whitehall International had prepared a presentation and documentation materials on the indication overactive bladder / urge incontinence (see *Annex 2*: preparatory paper on the indication overactive bladder / urge incontinence). In this paper it was explained what could be the criteria for the acceptance of this indication for self-medication. In the absence of Dr Paredes Díaz, the presentation was given by Dr Ralf Zerban.

For obvious reasons, sufferers are often afraid to divulge their condition, even to the most intimate relatives and friends. They often wait for a long time before consulting their doctor. This means that the real number of sufferers is many times larger than what is usually assumed. The prevalence of the conditions is as follows:

TYPE	MEN	WOMEN
Stress incontinence	8%	49%
Urge incontinence	73%	22%
Mixed incontinence	19%	29%

Diagnosis and treatment of overactive bladder / urge incontinence can be made by a large number of health professionals, including primary care physicians, nurse practitioners, geriatricians, gerontologists, urologists, gynaecologists, paediatricians, neurologists, physiotherapists, continence nurses and psychologists.

Patients are usually able to establish a clear distinction between overactive bladder / urge incontinence and stress incontinence, a condition less suitable for self-medication.

Increased information about overactive bladder / urge incontinence could help to remove the stigma surrounding the condition and make citizens aware that help at an early stage can usually prevent the condition from worsening.

The conclusion of the presentation was that overactive bladder / urge incontinence can be switched to an OTC manageable condition for the following reasons:

- It is a highly prevalent condition that affects millions of people and negatively impacts their quality of life
- The need to help patients who suffer in silence and do not inform their doctors about their condition because of embarrassment
- The condition has proven to be self-recognisable by the citizen
- Delay in its diagnosis does not present an overt health risk to the citizen.

The daily practice of a switch regulator and conditions for successful switches

Dr June Raine of the United Kingdom's Medicines Control Agency (MCA) provided an insight into what the EU's current provisions for classification together with the 1998 switch guideline mean in the daily practice of a national authority responsible for switch decisions and planning.

The UK's national health plan has set clear targets to move a number of indications / products from prescription-only to pharmacy status. It was described how patient expectations are

changing with increasing information and knowledge and how disease patterns shift towards chronic non-communicable diseases such as coronary heart disease, diabetes, cancer and asthma. This indicates that there is a trend in OTC indications from symptomatic relief to the treatment of chronic conditions to prevention (e.g. antiviral treatment, smoking cessation and emergency contraception).

Self-medication could move towards an enlarged scope provided certain strategic success factors are met as preconditions for a successful reclassification policy:

- New industry approach – a product life-cycle should include reclassification where appropriate
- Stakeholder consensus on new therapeutic areas
- High-quality, accessible information and training
- Appropriate protection of the data gathered to support innovative switches, requiring a change in the regulatory framework.

In the area of information and training, any reclassifications to non-prescription status should be supported by:

- Core information accessible to all stakeholders
- User-tested patient information
- Record keeping and shared access
- A personalised programme for patient self-management where appropriate.

There might be a need for a specialist pharmacy status, where certain pharmacies obtain a certification in certain conditions such as diabetes, CHD, intestinal or pulmonary problems, etc.

Summary:

- New medicines and indications for self-medication are achievable and in the interests of patients and public health.
- A co-ordinated specific problem-solving approach by all stakeholders will be necessary to achieve consensus on each switch.
- Validated information communication strategies will be essential.

General conclusions from the Workshop

Apart from the presentations summarised in this chapter, the participants held a lively and partly controversial debate about the possibility of enhancing the self-medication area with new indications. It was recorded that there are considerable differences between Member States' health systems, their approach to self-medication and non-prescription medicines and the reasons for these different approaches. These differences are also reflected in the attitudes of general practitioners (GPs), pharmacists and patients / consumers in the various Member States.

Ensuring the safe use of non-prescription medicines was seen as the most important issue for all stakeholders. Whereas patients' needs for proper information were in the centre of the debate and deserve a prominent place, it was mentioned that patients – even expert patients – are not doctors and self-medication should not be used to create a situation where patients are left on their own to treat themselves.

Participants agreed that any initiatives to move prescription medicines to non-prescription status (also called switching) should not be driven by a policy to ration healthcare expenditure.

The representatives of medical doctors expressed a certain degree of caution with regard to the capacity of patients / consumers to self-manage certain conditions. They insisted that the therapeutic action / toxicity ratio as well as the possibility that symptoms of certain serious disease are masked be examined appropriately before medicines are considered suitable for self-medication.

It was moreover felt that treatment is generally dependent on an accurate diagnosis following history, examination and investigation. Self-medication is limited treatment based on certain symptoms. Most chronic conditions require review and revision of therapy from time to time. In between, there is a place for pharmacists and nurses provided there is accurate record keeping with strict guidance.

There is always a problem with patient compliance, but particular attention is needed to ensure regular review once a medicine is available without prescription.

Although participants agreed that many well-informed patients affected by certain chronic conditions already manage their condition in a quite responsible manner, opinions were divided on whether the conditions for self-care should really be enlarged. Participants could nevertheless see certain well-defined patient segments taking more autonomy for an enlarged number of chronic conditions in the future. This may allow the switching of certain prescription medicines to non-prescription status on condition that such moves are accompanied by the appropriate amount of information in a collaborative effort by manufacturers, medical doctors and pharmacists.

The need for appropriate information of stakeholders in self-medication, and in particular the patient / consumer, means that any switch needs to be carefully prepared by the interested manufacturer to allow appropriate assessment by the regulatory authorities. This will be the basis for comprehensive information to be provided to medical doctors and pharmacists, who have an instrumental role in informing and guiding the patient / consumer as completely as possible concerning all relevant issues related to the switch.

Independently of any enlargement of self-medication through new indications, many participants spoke out in favour of strengthening the system of adverse reaction monitoring and reporting (pharmacovigilance).

Participants pointed out that manufacturers would be encouraged to carry out additional investigations to prove the suitability of a certain product in self-medication if the results of these investigations were to be granted a certain period of data protection or data exclusivity.

The recommendations for an effective communication policy in the area of new indications for self-medication are laid down in Chapter 7 of this report.

7. POLICY RECOMMENDATIONS

The availability of comprehensive and well understandable information on medicines is a prerequisite for their safe and efficient use. While this principle applies to all medicines, it is particularly relevant for medicines available without a medical prescription.

As the list of conditions that could be treated with non-prescription medicines is being considered for expansion, additional efforts are necessary to provide guidance to the sufferer. Any increased responsibility on the part of the individual should however not be seen as an alternative to professional help, but as an additional option which could be of benefit depending on the person's knowledge and situation. The possibility to refer to professional help, and in particular to the medical doctor, should always be kept in mind and should be actively communicated.

Enlarging the scope of medicines available without prescription should not be related to possible measures to reduce reimbursement of medicines. It is the objective of the debate around new indications for self-medication to increase personal responsibility for health and disease-related issues, with as a final objective the provision of healthcare services in the most efficient manner.

Generally speaking, all future management of healthcare should be more centred on the patient / consumer than is the case today. There is a need for more collaborative work to provide quality information in support of making medicines available without a prescription as an alternative to, but not in place of, going to the doctor. This information should be available to both the public and healthcare professionals.

Increased availability of information should extend to chronic illnesses, as some patients may want to become more involved in the management of their condition. The challenge for partners in healthcare such as medical doctors, pharmacists, nurses, patient organisations, regulators and industry is to provide the necessary support to enable people to do this effectively, with optimum use of resources.

The university and post-graduate training of health professionals should provide information about medicines, including non-prescription medicines. This should include information on possible new indications and how medicines are used in the context of current treatment options as well as common questions likely to be raised by users and alternative treatment options that do not entail the use of a medicine. This information needs to be provided in an accurate and consistent form, which requires appropriate co-operation between academia, professional bodies and concerned medicine manufacturers.

In the context of the training of health professionals, modern information methods should be used wherever possible. Research projects supported e.g. by the European Commission's Directorate General on Information Society may provide useful references. In a project entitled TESEMED (Telematic Systems for Responsible Self-Medication in pharmacies), training protocols were developed in particular for pharmacists in relation to advice on self-medication by using modern IT possibilities. Beside general information on the management of underlying conditions and self-help options, concrete procedures for advice were laid down in treatment protocols in order to guarantee quality standards when individual advice is provided. Particular emphasis was put on adequate communication techniques – an area often regarded as insufficiently covered in training programmes in university and post-graduate courses for all health professionals, including in particular pharmacists and medical doctors.

Patient or sufferer help groups are nowadays widely established in most European countries. These groups are increasingly interacting on behalf of their members with outside institutions. It is recommended to involve such groups in case an indication relevant to a group is made available for treatment with medicines available without prescription.

Medicine manufacturers providing a medicinal product in an area so far unknown to self-medication have of course a wide-ranging responsibility. In the first place they need to respect the general legal requirements concerning proof of quality, safety and efficacy. In order to obtain approval to change the legal status of a medicinal product, they need to submit a sound application to the competent authorities. The legal provisions included in the chapter on classification in the Community code as well as the Guideline on changing the classification status[5] are in this respect important basis documents allowing the acceptance of indications considered for non-prescription medicines without the need for further amendments.

Communication on medicines remains a particular responsibility and challenge for medicine manufacturers. This includes the provision of consumer-understandable labels and leaflets in line with the results of scientific research in the area of labelling design. Good labels and leaflets provide comprehensive information in order to create trust in a medicine by providing the best possible guidance for appropriate use.

All information provided in relation to non-prescription medicines should clearly refer to professional help whenever needed. Public advertising for such medicines also needs to respect the general legal requirements as well as any self-regulatory provisions and should always take into account that advertising should make a medicine known for an appropriate condition in an honest and truthful way.

As part of the general provisions with regard to the safety of medicines, efficient adverse-reaction reporting (or pharmacovigilance) is important for all medicines including non-prescription medicines used in a new indication area. Such reporting by health professionals and patients should be encouraged and professionally coordinated in order to allow relevant conclusions by the companies concerned and the authorities whenever adverse events occur. In the framework of the revision of the EU's pharmaceutical legislation, there are advanced plans to strengthen the Community's pharmacovigilance system under the aegis of the European Medicines Evaluation Agency (EMEA). A reinforced system of pharmacovigilance would certainly contribute to making a success of any future move of a medicinal product to the self-medication area.

A comprehensive information system related to issues of health, disease and appropriate use of medicines should also be integrated in school curricula and public education programmes. This has so far been widely neglected due to other priorities but might be reconsidered in light of the growing importance that the public institutions attach to health.

8. LIST OF ANNEXES

1. Preparatory paper on primary prevention of coronary heart disease (CHD) through self-medication with cholesterol-lowering agents.

2. Preparatory paper on the indication overactive bladder / urge incontinence.

9. ENDNOTES

[1] See http://europa.eu.int/comm/health/ph/programmes/health/oj96-645.htm

[2] European Parliament and Council Directive 2001/83/EC, of 6 November 2001, on the Community code relating to medicinal product for human use (OJ No L 311 of 28.11.2001, p. 67) – http://europa.eu.int/eur-lex/pri/en/oj/dat/2001/l_311/l_31120011128en00670128.pdf

[3] Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ No L 214 of 24.8.1993, p. 1)

[4] Report of the European Commission of 14 November 1997 to Council on the application of Council Directive 92/26/EEC on the classification for the supply of medicinal products for human use (COM (97) 581 final).

[5] Guideline on changing the classification for the supply of a medicinal product for human use of 29 September 1998 – http://pharmacos.eudra.org/F2/eudralex/vol-2/C/gl981003.pdf.

[6] Proposal for a Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products; Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use; Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products (COM(2001) 404 final) - http://pharmacos.eudra.org/F2/review/doc/finaltext/011126-COM_2001_404-EN.pdf.

[7] Communication from the Commission and Proposal for a European Parliament and Council Decision adopting a Community action programme on health promotion, information, education and training within the framework for action in the field of pubic health (COM 94/202/EEC) of 1 June 1994.

[8] Decision No 645/96/EC of the European Parliament and of the Council of 29 March 1996 adopting a programme of Community action on health promotion, information, education and training within the framework for action in the field of public health (1996 to 2000) (OJ No L 095 of 16/04/1996, p 1) - http://europa.eu.int/comm/health/ph/programmes/health/oj96-645.htm.

[9] See http://www.aesgp.be/PGEU-AESGP/Charterofcollaboration1993.pdf.

[10] See http://www.aesgp.be/CPME-AESGP/Commonposition1997.pdf.

[11] See http://www.aesgp.be/brochure/brochure.html.

[12] See http://www.aesgp.be/Ingredients/EUTable.pdf, http://www.aesgp.be/Ingredients/Non-EUTable.pdf and http://www.aesgp.be/Ingredients/WorldTable.pdf.

[13] Martindale: The complete drug reference, Royal Pharmaceutical Society of Great Britain, 31st edition, London, 1996.