

Reclassification Strategy

(Information and training needs concerning potential switch candidates
– abridged report)

The publication of the NHS Plan in July 2000 was the stimulus for this strategic review of reclassification in the UK. The NHS Plan committed the Government to introduce a wider range of over the counter (OTC) medicines by 2002.

Key stakeholders considered how to implement the NHS Plan commitment, involving;

- Medicines Control Agency (MCA)
- Industry (Proprietary Association of Great Britain (PAGB) and the Association of British Pharmaceutical Industry (ABPI));
- Professional bodies (Royal Pharmaceutical Society of Great Britain (RPSGB), the Royal College of General Practitioners (RCGP), and
- Patient representatives (Long-term Medical Conditions Alliance (LMCA)).

The stakeholders agreed that there needed to be a fundamental look at:

- The effectiveness of the existing reclassification process;
- Whether there were therapeutic categories of medicines traditionally supplied only under prescription that could be reclassified as Pharmacy medicines for supply under the supervision of a pharmacist; and
- The necessary information and training for health care professionals and patients needed to support any proposed reclassifications.

Three working groups were established with the MCA, RPSGB and PAGB.

The Proprietary Association of Great Britain led the Information and Training Stream within the Reclassification project and produced a detailed report.

Below are the essential details from that report covering some of the main concepts agreed by the stakeholders. The work of the Therapeutic Categories Stream should be read alongside the information and training concepts given in this paper. Many of the suggestions on the Therapeutic Categories list will need suitable support in the market place to ensure a successful switch.

Executive Summary

The Information and Training Stream working group included representatives of BMA, RCGP, RPSGB, RCN, MCA as well as patient bodies, academics and industry.

All parties present were very willing to work together to provide quality information to all members of the primary care group including the public and offered strong support for more medicines being made available over the counter as an alternative to, but not in place of, going to the doctor. The importance of this as the way forward in primary healthcare was recognised.

This can and should extend to chronic conditions because many patients want to be more involved in the management of their condition. The challenge for health care organisations is to provide the necessary support to enable people to do this effectively, with optimum use of resources.

There are benefits to both people and healthcare professionals if this process is encouraged and it will increase choice in self-management from the assortment of complementary medicines, food supplements and OTCs on offer now and in the future.

During the Regulatory process of approval of the change in legal status from Prescription Only Medicine (POM) to Pharmacy (P) sale and supply of certain medicines requiring the concerted management of the patient's well being by a Primary Care Team, the pharmaceutical company should be encouraged to work with all healthcare professionals and relevant professional bodies concerned with this process to ensure consistency of message and information from all likely sources. Professional bodies should be encouraged to observe communications over time to ensure continued consistency as new treatments and guidelines are developed.

The move to self-care also necessitates better record keeping and a cultural change in the relations between the doctor, the patient and other healthcare professionals towards sharing management. The future management of healthcare should be people-centred rather than doctor-centred as is the case presently.

INFORMATION AND TRAINING

Objective

The objective of this group was to:

- identify the conditions people currently consider suitable for self-treatment and the barriers to self-care from the individual's perspective;
- identify information that people need to enable them to safely manage conditions which are currently managed by their GP;
- consider different sources of information and their role;
- review the information and training needs of health care professionals to enable them to support and monitor their patients; and
- consider the role of industry in providing information to health care professionals and people.

Scope

In considering the potential for reclassification of certain medical categories, the group considered the following:

- the NHS Plan priority areas;
- Recommendations of the Therapeutic Category stream relating to indications;
- Consumer research into self medication;

- Available research into information provided to patients and health professionals, particularly that generated in previous POM to P work programmes and PGDs
- Available research into sources and timing of information and communication to consumers;
- Pharmacy and GP practice research in self-medication;
- Examples of information already supplied to support patients with chronic conditions; and
- ADR reporting schemes for doctors and pharmacists and proposals to extend these.

Methodology

- 1 A working group including representatives of the BMA, RCGP, RPSGB, RCN, MCA and industry and patient bodies met to consider options for improving the level of information available to patients who are self-managing their condition or illness and to the healthcare professionals who are involved in their care. Case studies were presented for the consideration of the information needs of patients on long-term medication which were used to develop the recommendations in the full report.

Summary of issues raised

- 2 The future management of healthcare should be centred on the patient. There is a need for more collaborative work to provide quality information in support of making more medicines available over the counter, as an alternative to, but not in place of, going to the doctor. This information should be available to both public and health care professionals.
- 3 Increased availability of information should extend to chronic illnesses, as some patients want to be more involved in the management of their condition. The challenge for health care organisations is to provide the necessary support to enable people to do this effectively, with optimum use of resources.
- 4 Pharmaceutical companies seeking approval for a change in legal status should be encouraged to work with healthcare professionals and relevant professional bodies, and self-help groups to ensure consistency of message and information.
- 5 Professional bodies should be encouraged to observe communications over time to ensure consistency as new treatments and guidelines are developed.
- 6 The move to self-care will necessitate better record keeping and a cultural change in the relationship between doctor, patient and other healthcare professionals towards sharing management.
- 7 There are potential benefits to the public and healthcare professionals if self-management of chronic conditions is encouraged and there is an increased choice from the range of products available over the counter.

- 8 There is a need for greater awareness by doctors of products available both over the counter as well as by NHS prescription. However, reclassification should not restrict patients accessing medicines from their general practitioner.
- 9 Products available over the counter are suitable for self-medication and can be advertised to the public subject to existing regulations. The current regulatory and self-regulatory provisions should continue to apply, including guidelines in the areas of specific therapeutic categories to ensure responsible advertising. In applications for change of legal status, applicants are encouraged to consider the need for guidelines in the areas of specific therapeutic categories to demonstrate the parameters within which product claims will be made to ensure responsible advertising.

Proposals

The group made proposals in the following areas:

Health professional training

- 10 Manufacturers should demonstrate that they have addressed the issue of health professional training when planning to implement a change of classification and that there are adequate training procedures already in place or in development with the appropriate training organisations. This could be enshrined in a Reclassification Code of Practice. Where manufacturers are the sole providers of training materials, representatives of the health professions and specialisms relevant to the use of the product should ideally be involved in developing or reviewing the training materials.
- 11 Training for health professionals should include information about the product, how it is used in the context of current treatment options, common questions likely to be raised by users, the information to be given on side-effects, alternative treatment options where appropriate and self-help options.

Consistency of information, messages and advice on usage

- 12 As part of the application to change the legal status of a product from POM to P status, information concerning the safe usage of the product under normal conditions and in misuse, must be addressed by the pharmaceutical company. In addition, the consistency of information for healthcare professionals involved and those for whom the product is intended should ideally be addressed jointly by the pharmaceutical company and relevant professional bodies following a change in legal status.
- 13 The applicant is an important source of information about the product and its appropriate use, and will be expected to demonstrate as part of the application that the consumer has the necessary information and access to advice to ensure that the product can be used appropriately without close medical supervision.

- 14 For example, in addition to the basic product information leaflet and pack, the applicant should include or reference with the application other intended information and support materials concerning:
- use of the product;
 - management of the underlying condition (where applicable);
 - self-help advice;
 - treatment protocols,
- 15 Information and training material for healthcare professionals, professional bodies, self-help groups and other bodies concerned with primary care need not be submitted with an application for a change of legal status but should be developed in collaboration with those for whom they are intended.
- 16 Within the proposed communication package the pharmaceutical company should provide an explanation of the information and support materials to be provided. Official or accepted evidence-based consensus guidelines, or an agreed approach for assessing expert opinions concerning management of the underlying condition should be taken into account. In addition to scientific evidence and the opinions of expert clinicians, practice guidelines must take account of the resource implications and feasibility of interventions.
- 17 If appropriate, a draft treatment guideline should be proactively developed in co-operation with the relevant responsible professional body for use by pharmacists and other healthcare professionals who may be expected to come into contact with people who will use the product. Guidelines developed by nationally recognised self-help groups and other widely used reference points (such as NHS Direct and the National Electronic Library for Health) should be taken into account, the goal being consistency of information.
- 18 Applicants for reclassification must demonstrate that consideration has been given to the presentation of information and treatment guidelines bearing in mind the nature of the change of legal classification. In some cases, for example, where a condition is normally expected to be managed by the doctor, people may be unfamiliar with terminology and medical practice.
- 19 Whilst it can never be demonstrated that a change in legal status will be entirely problem free, applicants should demonstrate a clear strategy leading people to the level of knowledge required to be able to judge the severity of the condition, appropriate intervention, issues over use of multiple medication and the point at which a return to the healthcare professionals for advice and/or intervention is necessary. The applicant must be able to argue convincingly that people will in general be able to make appropriate use of the product without medical intervention such that the level of expected side-effects or misuse is unlikely to be significantly greater than while the product was still a Prescription Only Medicine.

Patient records

- 20 When applying for a change of legal status the applicants should refer to the methods of record keeping and take steps to demonstrate that they have taken account of any special requirements that may arise as a result of this, including, but not exclusively, the reporting of adverse events and /or known interactions with other medications (including complementary and alternative treatments) whether doctor or self prescribed.
- 21 Within the information to be provided to people and healthcare professionals, the need to inform doctors and pharmacists who are giving advice about all medical and quasi-medical interventions should be stressed. The aim is to ensure that healthcare professionals being asked for advice by people who are self-medicating should have access to information on the nature and level of medical intervention to date, including complementary and alternative therapies.
- 22 In addressing this, applicants are not expected to provide the means for total recording and reporting of all information that may be relevant for a healthcare professional. However, applicants will be expected to ensure that information to users provides clear encouragement to people considering self care to take a note of those medicines and other therapies being pursued and to report these to a healthcare professionals when medical advice is sought. Similarly, healthcare professionals should be encouraged in support materials to enquire about other self care options that people may be following although the methods must not invade the inherent privacy of the individual.

Disease awareness campaigns

- 23 There could be more inter-company co-operation to develop accurate and consistent generic information. All the branded and generic messages should be consistent.

**The Proprietary Association of Great Britain
January 2002**