Increasing the number of drugs available over the counter: arguments for and against

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SUMMARY. Many drugs previously restricted to prescription only status are being reclassified as pharmacy only status and hence are becoming available over the counter to patients. A general practitioner should make enquiries about a patient's self-medication practices before deciding on treatment for the patient. Over-the-counter medicines are considered safe and their increased use indicates that patients are taking greater responsibility for their own health and possibly taking some of the financial burden of drug treatment from the National Health Service. The retention of their restriction to pharmacy only sale provides some additional protection for patients and promotes the role of pharmacists in the care of patients. However, having more drugs available for self-treatment may encourage patients to believe that there is a drug treatment for every ailment. Increasing the range of drugs available over the counter increases the risks of interactions and adverse reactions and of self-treatment being undertaken when medical aid should have been sought. For general practitioners to recommend positively use of over-the-counter preparations may involve some medicolegal risks, and the potential savings to the NHS may prove illusory. Education for patients and better communication between general practitioners and community pharmacists are required to allow easier availability of modern medicines to patients in order to bring the benefits anticipated.

Keywords: non-prescription drugs; patient use of medication; prescribing; management of disease.

Introduction

THERE have always been a proportion of medicines available directly to the public without the need for a doctor's prescription but over the last decade there have been worldwide moves to increase the number and range of such medicines. For example, the European Community *Directive for medicines classification* (92/26/EEC) obliges member states to review the legal status of medicines every five years and to allow a drug to be sold without a prescription unless: it is dangerous if used other than under medical supervision; it is frequently used incorrectly; it is a new chemical entity and needs further investigation; or it is usually administered by injection.

In the United Kingdom, medicines are classified as PoM (prescription only medicine), P (pharmacy only medicine — sold only in pharmacies under the supervision of registered pharmacists) or GSL (general sales list — available from a wide range of retailers, such as supermarkets). New drug entities are first licensed by the Medicines Control Agency with a temporary prescription only status. All temporary prescription only medicines revert to pharmacy only status after two years unless application is made to the Medicines Control Agency, usually by the licence holder, to retain the prescription only status. In practice, the Medicines Control Agency regularly reviews temporary prescription only medicines well before the licence renewal date and the prescription only status is usually retained. However, at this point the licence holder may supply the Medicines Control Agency with additional data to support the default pharmacy only status. Reclassification at a later date requires an application to the Medicines Control Agency. The procedure whereby drugs can be reclassified has been reviewed and streamlined.[1] An application for reclassification which previously could take up to five years can now occur in less than a year. As a result, many drugs have been reclassified as pharmacy only medicines and hence there has been an increase in the number of drugs available for the public to buy 'over the counter'. These moves have been promoted by the government,[2] encouraged by the Royal Pharmaceutical Society of Great Britain[3] and given a muted blessing by the Royal College of General Practitioners.[4] At the grass roots level, support among general practitioners seems more equivocal,[5,6] although community pharmacists have been broadly supportive of the moves.[7]

The criteria for the change of status from prescription only medicine to a pharmacy only medicine are that the drug should be of proven safety and of low toxicity in overdose, and should be used for the treatment of minor, 'self-limiting' conditions.[8] Efficacy is also considered but is usually presumed to have been established if the drug is already available as a prescription only medicine for the same indications. Historically the distinction between prescription only and pharmacy only status was less clearly defined and drugs such as theophylline, aspirin and paracetamol that would not fulfil today's criteria were allowed to be, and can still be, supplied over the counter. Even in the current supposedly more safety-conscious era, drugs may be deregulated in a way that, with hindsight, seems to have been inappropriate. For example, newer drugs such as beta$_2$-agonists, suspected of causing some serious problems in certain circumstances, have been made available, as inhalers, without prescription in Australia,[9] although this is being reconsidered. Nevertheless, the clamour for deregulation of products continues unabated and prescription only drugs more recently proposed for pharmacy only status include oral contraceptives,[10] postcoital oral contraceptives[11] and chloramphenicol eye drops.[12]

Increased availability of over-the-counter medicines: consequences for general practitioners

General practitioners should be aware that medicines are increasingly available over the counter to patients, without a prescription, as there are several ways in which this can play a role in or influence consultations.

First, in the course of providing the history of the presenting complaint, the patient may give details of self-medication; the general practitioner may or may not encourage this self-medication.[13]

Secondly, rather than issue a prescription, the general practitioner might suggest that the patient purchase appropriate medication.

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Thirdly, the general practitioner might want to check whether the patient is taking an over-the-counter medicine that might interact with proposed treatment. For some treatments, such as warfarin, it should be recommended that patients should not self-medicate without conferring with their general practitioner, because of the risks of interactions.

Fourthly, the possibility of self-medication, or of interactions between over-the-counter medicines and prescribed medicines, causing the patient's problem might be considered.

Fifthly, as new medicines are reclassified and become available to the public they are more widely promoted. Such promotion may give rise to two causes for concern: it may encourage patients to believe in a system of a 'pill for every ill', that is, that there is a drug treatment for every ailment; and patients may become familiar with a wide range of powerful drugs which they may begin to seek on prescription from general practitioners instead of buying them over the counter.

Finally, as professionals generally concerned with health issues, general practitioners should have an interest in how all medicines are used by patients.

Asking patients about their use of over-the-counter medicines

A survey conducted on behalf of the Proprietary Association of Great Britain showed that 16% of adults with a minor ailment would usually purchase an over-the-counter medicine to deal with it and a further 14% would use an over-the-counter medicine that they already had in the house.[14] Other national and international surveys similarly point to the fact that for every one prescription medicine taken there is probably at least one non-prescription medicine consumed.[15]

As the number and range of pharmacy only medicines available increases, it can be predicted that the probability of a patient having taken a medicine before consulting a general practitioner will increase rather than decrease. Furthermore, as the distinction between prescription only and pharmacy only medicines diminishes in terms of potency and potential for clinically important interaction, it becomes important that the general practitioner enquires in detail into the medicines that patients may have taken on their own initiative. Problems resulting from interactions between prescription and over-the-counter medicines have been reported.[16]

If general practitioners do start to enquire more consistently and diligently into patients' self-medication practices, they must learn how to interpret the data that are gathered. General practitioners have been greatly assisted in this by the publication of the *OTC directory* that lists 816 products said to represent 95% of the market.[17] The bewildering array of over-the-counter medicines available and the particularly alarming fact that preparations with essentially the same name can contain different ingredients make determination of what the patient has taken difficult in some cases.[18] General practitioners should encourage patients to bring the packaging of their self-medication to consultations. Furthermore, if general practitioners ask patients about their self-medication, patients will inevitably ask whether or not they approve.

Over-the-counter medicines: arguments for recommending use

One argument in favour of recommending that patients use over-the-counter medicines is that increased purchase of medicines by patients themselves, without prescription, would save the National Health Service money. Figures for the increase in use of drugs over-the-counter and decline in their use on prescription following reclassification, and the consequent financial savings to the NHS, encourage this view. For example, Ryan and Yule have estimated that changing the status of loperamide, from prescription only to pharmacy only, saved the NHS £0.13 million in 1985, £0.15 million in 1986 and £0.32 million in 1987.[19]

A less mercenary argument is that patients should be given every opportunity to take responsibility for their own health. Therefore, they should not be unreasonably denied access to the means to make and carry out decisions about their own health. Encouraging patients to treat themselves builds self-confidence in their capacity to manage their own illnesses. This is ultimately empowering to patients. The survey commissioned by the Proprietary Association of Great Britain noted that patients are, by and large, responsible in their use of over-the-counter medicines.[14] In up to 45% of minor ailments, patients took no treatment. Where an over-the-counter preparation was used, the evidence pointed to appropriate use. Furthermore, in spite of the wide variety of such medicines available, patients most often used only one product at a time to treat one predominant symptom. Use of over-the-counter medicines could also benefit patients in that they would save the time and other costs involved in visiting a general practitioner and then a pharmacy. It may be cheaper for a patient who is liable to prescription charges to buy the medicine over the counter than to pay a prescription charge. The *Drugs and Therapeutics Bulletin* regularly publishes a list of medicines that cost less over the counter than an NHS prescription charge.[20]

A straightforward case for recommending use of over-the-counter medicines may be made on the grounds that such medicines currently available are safe and effective. The lack of safety of some older drugs available over the counter has already been alluded to but, for drugs recently changed from prescription only to pharmacy only status, safety was the prime concern of the Medicines Control Agency when considering suitability for reclassification.[8]

Most drugs that are reclassified still retain their pharmacy only status, that is, they are available only through pharmacies and are not general sales list medicines. This means that there should always be a pharmacist available at the point of sale. Having access to a greater range of more effective drugs enhances the pharmacist's position and, perhaps, opens up new opportunities for the pharmacist to become more closely involved in patient care. Pharmacists are said to be the most accessible member of the primary health care team, they are highly trained and, evidence suggests, underused.[21] However, a recent small survey by the Consumers' Association was not reassuring about the amount of supervision by pharmacists actually occurring with respect to pharmacy only drugs.[22]

Over-the-counter medicines: arguments against recommending use

Contractual considerations

To recommend that patients should treat themselves with some remedy available over the counter seems a reasonable way to manage minor, self-limiting conditions and it may even seem churlish to question this practice. However, some general practitioners see this practice of making recommendations about treatment rather than prescribing for the patient as being in breach of their terms of service. This is a rather rigid interpretation of paragraph 43 of the terms of service that states that a doctor 'shall order any drugs or appliances which are needed for the treatment of any patient to whom he is providing treatment under these terms of service by issuing to that patient a prescription form'.[23] A statement in 1993 from a minister of health to the effect that recommendation of an over-the-counter preparation would be

appropriate and not in breach of the terms of service so long as the patient was not actually denied a prescription on the NHS form FP10[24] has not reassured all doctors. Some have demanded an amendment to the terms of service before they will change their practice.

Consultation and clinical considerations

Even if this difficulty over the terms of service were resolved, there is still the problem that always recommending or prescribing a drug encourages belief in the 'pill for every ill' mythology. Furthermore, other opportunities created by consultations, for example to review all existing medications and the progress of existing conditions, may not be exploited fully for several reasons. First, time may be lost within individual consultations if general practitioners explain to patients why buying a medicine is being recommended rather than a prescription being written, which medicine to buy, how to buy it over the counter and that the pharmacist will ask the patient questions. Secondly, if general practitioners and/or patients increasingly adopt the 'pill for every ill' system then a pattern of short consultations may develop in which the agenda becomes focused on the recommending/ prescribing of medicines. Thirdly, if patients find over-the-counter medicines to be successful in treating minor ailments, their frequency of contact with their general practitioners may be reduced. Counselling about lifestyle and other opportunistic health promotion activities would also be curtailed.

The wider availability and use of some drugs with considerable interaction potential, for example H_2-antagonists, might increase the risk of drug interactions. As the number and range of drugs available increase, drug interactions between simultaneously taken over-the-counter medicines and between over the counter medicines and prescribed medicines will inevitably increase. The potential for such problems is particularly great among elderly people:[25,26] they are generally more ill,[27] more likely to self-medicate[14] and more likely to be already taking more prescription medicines than younger people.[28]

Another concern is that patients will use over-the-counter medicines for what are in reality serious, life-threatening illnesses, thereby masking symptoms and delaying further intervention. Other potential problems are that: patients may buy the wrong preparation of the drug for the condition; the drug may be administered or taken incorrectly; or the drug may be taken in higher or lower doses, or for a longer or shorter time, than is recommended or intended. Furthermore, patients may not refer to general practitioners when they should. These problems would be reduced, of course, if patients adhered to the instructions and information on the packaging or on the accompanying sheet or to any advice given by a pharmacist. However, it is not realistic to expect that patients are so attentive to details and are willing to be so regimented. Incorrect use of prescription drugs causes substantial iatrogenic morbidity,[29,30] and to some it seems foolhardy to suggest increasing the range and availability of drugs to patients in the face of such widespread misuse of the drugs currently available on prescription.

Economic considerations

Economic arguments, in terms of savings to the NHS, for recommending that patients obtain medicines over the counter are not as clear cut as might first be supposed.[31] As mentioned earlier, one possibility is that patients, through over-the-counter availability of a medicine, may gain experience of a drug. If they find it effective they may be tempted, particularly by the larger quantities usually obtainable on prescription, to seek further supplies of the drug from their general practitioners. It would be difficult for a general practitioner to resist such a request (assuming that the drug is available on NHS prescription) and yet it might not have been the general practitioner's initial or most cost-effective choice for treating the patient. This kind of process could lead to a surge in patient-initiated prescribing which could be further exploited by the pharmaceutical industry to stimulate sales.

Legal considerations

A further concern that might discourage general practitioners from making recommendations to patients to obtain their medicines over the counter is the question of legal liability if a recommendation is made and the result for the patient is less than satisfactory. The Proprietary Association of Great Britain has sought legal opinion on this question (personal communication). Liability on the part of general practitioners in respect of their recommendations to patients for over-the-counter medicines is no greater than in the case of prescribed medicines. A general practitioner's vulnerability to litigation may be reduced if three precautions are taken. First, the general practitioner should write down in the patient's medical records which medicine is being recommended. Secondly, it should be recommended to patients that they also confer with the pharmacist before deciding on whether or not they will use the over-the-counter preparation. Thirdly, the general practitioner should recommend that patients always carefully read instructions and information on the packaging and/or the package insert. These simple precautions will substantially reduce medicolegal risk exposure when making recommendations about over-the-counter medicines.

Guidance on recommending over-the-counter medicines

All the indications are that the reclassification of drugs from prescription only to pharmacy only status will continue. This might, in the long term and if not handled properly by general practitioners and pharmacists, generate additional drug-related morbidity in patients. In order for patients to gain the benefits of drug reclassification and yet avoid the pitfalls it is important that general practitioners respond to the new challenges presented by the emerging liberalization of drug classifications.

First, it should become part of a general practitioner's routine history taking to seek information from patients on previous and current self-medication for both presenting symptoms and concurrent symptoms. This information should also be noted in patient records. Ideally this should occur in a way that would alert the general practitioner to any potential adverse reactions or interaction risks. Thus, for instance, computerized prescribing systems that include drug interaction alerts may need to be modified to include interactions with concurrent over-the-counter drugs. As mentioned earlier, the names of any over-the-counter medicines recommended should be written down in patients' medical records.

Secondly, there is a need for a patient education campaign, about medicines generally and about the safe and appropriate use of over-the-counter medicines in particular.[32] Such health education should be done in the context of ordinary general practitioner consultations but should also be backed up by media publicity and by education in schools. This patient education requires to cover when and how to seek medical help for symptoms and when it would be equally effective to seek the advice of a community pharmacist. Patients should also be taught when there is no need to take any drug at all and that some drugs, including most over-the-counter preparations, are merely palliatives to ease symptoms while natural recovery occurs. Patients also require education about the number and range of highly effective and useful over-the-counter medicines available to them and how such medicines can most safely be used. Patients

need to be convinced that such drugs, by being available over the counter, are no less powerful than those available on prescription. The necessity of reading the instructions and information on the package/package insert should also be emphasized to patients, as should the availability of further advice and information from the community pharmacist.

Finally, there is a requirement for improved communication between general practitioners and pharmacists about the use of over-the-counter medicines. Indeed, the safe extension of patients' capacity to self-treat into the new areas, for which there have been no over-the-counter medicines previously available, that are opening up with the liberalization of drug classifications requires the forging of new links between general practitioners, pharmacists and patients. This new method of working has been piloted in Scotland.[33] A multidisciplinary group consisting of a gastroenterologist, general practitioners and community pharmacists developed an algorithmic guide for the management of dyspepsia. Guidelines on the use of standard antacids and H_2-antagonists and on referral from pharmacists to general practice were produced. This has been generally well received by general practitioners and pharmacists in the Grampian region of Scotland. As well as producing the guidelines, this interprofessional contact did much to improve mutual understanding of each other's *modus operandi.*

Conclusion

As a result of national and international developments, reclassification of drugs from prescription only to pharmacy only status will continue. There are many advantages for the patient, general practitioner and NHS, as well as providing an opportunity for a more integrated primary health care role for the community pharmacist. If general practitioners become aware of how and when they should advise patients to use over-the-counter medicines, of the possibility of patients already using such medicines, and of the need for patient education and for communication with pharmacists then all interested groups will reap the benefits of the changes without suffering the possible adverse consequences.

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Food for thought...

'...practices that had a trainee [registrar] in 1982 were more likely to be innovative despite the fact that they were already more developed, indicating that non-training practices were not only failing to catch up with training practices, but that the gap between them became wider in the period 1982-90.'

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