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Issues Related to Monitoring the Safety of Over-The-Counter (OTC) Medicines

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Abstract

Pharmaceutical advances over the past 50 years have benefited many people in terms of disease prevention and management. However, probably without exception, most pharmaceutical products can cause adverse consequences of varying severity and frequency.

In the last 10 years, many medicines that were originally prescription only have now become available over the counter (OTC), either from pharmacies or other general retail outlets. The volume and value of OTC medicine sales have increased accordingly. These switches have been well regulated and based on clear criteria and evidence of safety. Benefits of the changes include increased convenience to patients, greater self-management of minor ailments and a reduction in government drug expenditure.

However, there are important differences between medicines supplied OTC and on medical prescription. With OTC medicines there is generally less healthcare professional input into the recommendation or ongoing monitoring of use. There is an absence of records *per se*, or linkage to other medication records elsewhere, and most countries allow direct-to-consumer advertising of the product. Taken together these differences can result in inappropriate expectations, demand and use of the OTC medicines, with limited opportunity for ongoing patient follow-up and monitoring of safety.

Methodologies for pharmacy-based epidemiological studies of OTC medicines need to be developed. Studies should be large enough to detect associations that might exist, and to consider other explanations for associations such as chance, bias or confounding. There have already been some pilot studies with encouraging results with respect to follow-up rates. Outcome data however have usually been self-reported and the studies have lacked a suitable comparison group.

Purchasers and suppliers of OTC medicines should also be made aware of, and encouraged to use, existing systems for spontaneous reporting of suspected adverse events, such as the Yellow Card Scheme in the UK.

While available OTC medicines are perceived to be generally safe, problems have occasionally arisen with some earlier switched products (e.g. terfenadine). There have also been concerns about some traditional herbal and homeopathic remedies such as St John's wort. While such adverse events are rare, they emphasise the need for healthcare professionals and the public to understand and manage such risks. Many doctors are unaware of the range of OTC preparations available, and therefore do not consider them as a possible cause of presenting symptoms. Neither do they take them into account when making a new prescrib-

ing decision. The public need to be aware that OTC medicines should be treated with the same care as prescribed medicines, and that advice on recommended dose, contraindications and interactions should be adhered to.

Every day, millions of people throughout the world benefit from disease prevention, improved quality of life or reduced risk of death because of pharmaceutical advances made during the past 50 years. For example, medical treatments have contributed towards reduced in-hospital mortality and improved long-term health of patients with myocardial infarction.[1] Some surgical procedures have become virtually redundant. For instance, peptic ulcer surgery has been extensively replaced by treatment with histamine H_2 receptor antagonists and proton pump inhibitors. None of the pharmaceutical advances, however, has come free of adverse consequences.

Drug safety is about maximising the benefits and minimising the risks of medicines. It depends on a drug being used for an appropriate indication, in the absence of contraindication(s), at the correct dosage, and with minimal potential for an adverse event. Traditionally, drug safety monitoring has focused mainly on prescribed medicines, although it should also apply to over-the-counter (OTC) preparations purchased from pharmacies and non-healthcare retail outlets such as supermarkets, service stations and the Internet.

At the moment there is little evidence of widespread safety problems associated with medicines supplied without prescription. However, their extensive, and increasing, use requires healthcare professionals and regulatory authorities to be vigilant for potential problems. This article considers some of the issues related to monitoring the safety of OTC medicines. It considers why this may be an increasingly important matter, how the issues differ from those related to medicines supplied by prescription, and what the implications of these differences might be. Finally, some recommendations for education and future practice are made.

1. Drug Regulatory Systems and Over-the-Counter (OTC) Medicines

In many parts of the world medicines are available only if they have marketing authorisation (a product license), awarded after the manufacturer has supplied extensive evidence of efficacy and safety. As part of the authorisation process, a legal status is conferred on a medicine, which governs its distribution and promotion, with the objective of balancing issues of safety in use and ease of access. In the UK, there are three legal categories for medicines. Prescription-only medicines (POM) can be supplied to the public only if they have been prescribed by designated healthcare professionals, usually doctors but in restricted circumstances also dentists, nurses, pharmacists and others. Pharmacy-supervised medicines (P) can only be sold from registered pharmacy premises under the supervision of a pharmacist. General sales list (GSL) medicines are available from any retail outlet. New drugs are automatically given POM status for 2 years. After this time, the product license changes to P status, unless the manufacturer applies for retention of POM status.

The EU directive that guides UK practice gives four main reasons for retaining POM status:[2]

- there is direct or indirect danger to health if the medicine is used without medical supervision (e.g. the adverse effect profile is such that it needs a doctor to assess the balance of risks and benefits, or misdiagnosis might lead to the patient being put at risk);
- the medicine is frequently used incorrectly, leading to direct or indirect danger to health (e.g. the product is liable to misuse);
- the activity of the drug or its adverse effects requires investigations to be conducted before or during use;
- the drug is administered parenterally.

There is an underlying assumption that drugs not fulfilling these criteria become available to the public without prescription. Preparations available for purchase before licensing procedures were estab-

lished (such as aspirin [acetylsalicylic acid] and paracetamol [acetaminophen]) automatically received GSL status, even though there were only limited data about their efficacy and safety.

Over 60 drugs have been reclassified from POM to P status in the UK since 1984, and many have been deregulated further to GSL status. One of the earliest drugs to be switched from POM to P was ibuprofen in 1984, followed shortly afterwards by 1% hydrocortisone cream and loperamide capsules. Products now available include potent active ingredients such as topical nasal corticosteroids and second-generation antihistamines for allergic rhinitis, imidazoles for vaginal candidiasis, and mebeverine for irritable bowel syndrome. Candidates for future reclassification include the combined oral contraceptive pill,[3] with the levonorgestrel-only contraceptive pill already having P status for postcoital use. Although most changes have been towards non-prescription status, the reverse has happened (see section 5).

Most other countries have arrangements for regulating the supply of medicines, although there can be considerable differences between countries in the OTC availability of particular medicines. Countries also vary in the level of involvement pharmacists have in the supply of non-prescription medicines. In general, more medicines are available without prescription in developing countries than in more developed countries. In spite of these differences, there is a general trend throughout the world towards making a wider range of medicines directly available to the public.[4]

In addition to having easier access to conventional pharmaceutical products, the public is able to purchase an expanding range of herbal and homeopathic remedies. These preparations are not currently regulated in the UK although this may change if a proposed EU directive on traditional herbal medicinal products comes into force, perhaps by the end of 2004.[5] In the US, the US FDA already regulates some alternative therapies.

OTC medicines, therefore, are medicinal products that can be purchased directly by the public without prescription. They include conventional pharmaceutical products available for purchase before licensing regulations were established, newly reclassified pharmaceutical preparations, and herbal and homeopathic treatments not necessarily covered by licensing regulations.

2. The Increasing Importance of OTC Medicines

The volume and value of sales of OTC medicines have increased dramatically in recent years, so that self-medication products now account for an estimated 18% of the total global pharmaceutical market.[6] The proportion varies from country to country but is growing in all areas. North America has the highest proportion (30% of the total OTC market), with Europe a close second (27%). The fastest developing market is the Far East. The market for herbal and homeopathic products is also expanding rapidly. In the UK, nearly 20% of the population use so-called alternative therapies,[7] and it is believed that this proportion is increasing.[8] Some 81% of UK pharmacists have been asked by patients/customers for complementary remedies.[9]

One of the biggest drivers behind the policy of deregulating medicines has been the desire of governments to reduce their drug expenditure. By increasing direct public access to medicines governments hope to shift costs onto the user, although this may not always happen. Changing the availability of treatments for acute ailments (such as topical aciclovir for herpes simplex) can result in nearly all supplies of the medicine being purchased directly, virtually removing all their costs from government budgets. On the other hand, drugs used for chronic conditions (such as H_2 receptor antagonists for dyspepsia) may be tried initially by purchasing the drug without prescription, but once found to be effective may be obtained over the long-term by prescription, thereby minimising costs to the user. Rather than containing costs, the policy may simply increase the total volume of the medicine used.[10]

Another important impetus for the reclassification policy has been a wish to increase self-management of self-limiting, minor illnesses. Patients are thought to be empowered if they can purchase necessary medications directly without consulting a doctor. Many individuals are confident in their self-management of common minor ailments[11] and appreciate the convenience of non-prescription medicines. Professional groups are also influencing this policy. Community pharmacists value having an

extended range of effective medicines available to offer to individuals seeking their advice.[12] Many doctors welcome this policy in order to reduce the demand for medical consultations. The pharmaceutical industry also supports this policy as this helps to maintain or increase sales near the end of a drug's patent period, or assists the promotion of a brand also available on prescription.

Collectively, these powerful drivers mean that OTC medicines will continue to be an important part of healthcare provision in the future, throughout the world.

3. Important Differences Between Medicines Supplied OTC and on Prescription

3.1 Limited Healthcare Professional Input

A key consideration when deciding whether to permit OTC availability of a medicine is its perceived safety when used without medical supervision. The amount of assessment and advice provided by a healthcare professional before someone purchases an OTC preparation varies considerably and is often absent altogether, especially when the purchase occurs in a general retail outlet. Even P status medicines may involve only limited professional input, because while the regulations require pharmacists to be aware of the sale of such medicines, they do not need to actually conduct the sale. The generally limited healthcare professional input reduces opportunities to make sure that the medicine is used appropriately and safely. Perceptions of the public about the safety and efficacy of medicines are likely to differ from those of healthcare professionals. Place of purchase may influence these perceptions. For example, medicines that can be easily purchased without professional advice might be regarded as safer than those supplied on prescription. This could lead to a greater diversity of people using OTC variations of a medicine than prescribed forms, perhaps in greater quantities than recommended and with other contraindicated medicines. Evidence for this is reported in section 5.

3.2 Absence of Records

At present, purchases of OTC medicines are not recorded systematically and are not linked to other healthcare information about the purchaser. Furthermore, advisors of those purchasing OTC medicines rarely have access to full information about other concurrent medication or relevant medical history. The lack of an integrated, comprehensive record has two important implications. First, it can affect patient care. Without full information it can be difficult to make a full assessment of whether the OTC medicine is appropriate. This is increasingly undesirable now that many OTC medicines have the potential for important adverse effects (such as NSAIDs) or drug interactions (such as the antihistamines). In addition, healthcare professionals rarely ask about OTC medicines when seeing patients.[13] If a patient presents with a symptom induced by an OTC medicine and fails to spontaneously disclose use of such products, inappropriate clinical decisions may be made. Optimal care can also be hampered if symptoms are masked, or reduced in severity, by OTC medicine use, for example, investigation of prolonged dyspepsia is delayed because symptoms are suppressed sometimes by long-term use of OTC preparations which are not revealed to the doctor. The absence of linked records, together with the multiplicity of supply outlets, also severely limits opportunities to detect inappropriate prolonged use of a medicine, or deliberate abuse of a preparation.

The second important consequence of the lack of an integrated, comprehensive record of all OTC medicines purchased, is the lost opportunity to monitor the safety of these products. This is especially important given that many preparations are supplied by retailers without current monitoring systems. This situation is likely to worsen as more and more medicines are used without healthcare professional involvement.

3.3 Direct Advertising

Many countries allow the advertising of OTC medicines directly to the public. This may affect perceptions among the public about the safety and benefits of different products and can contribute to

major changes in the source of supply of particular medicines.

4. Methodological Issues Relating to Pharmacoepidemiological Studies of OTC Products

An important role of pharmacoepidemiology is to determine whether an association exists between an exposure (drug) and outcome (e.g. hospital admission, symptom or death). The association can be detrimental (e.g. deterioration in health), beneficial (e.g. improvement in health) or non-existent (e.g. no effect on health). Researchers need to design pharmacoepidemiological studies that are large enough to be able to detect associations that really do exist and which are unlikely to reach erroneous conclusions because of chance, bias or confounding. Even if these alternative explanations for an observed association can be excluded with reasonable confidence, other evidence of causality (such as size of association, dose gradient, consistency, specificity and biological plausibility) is needed before drawing final conclusions. There are, therefore, a number of prerequisites for robust pharmacoepidemiological studies, including good data on exposure(s), outcome(s) and possible confounders; adequate size; and an appropriate comparison group. The OTC environment presents a number of challenges to these requirements, which makes the conduct of high quality pharmacoepidemiological studies difficult.

Without comprehensive information about the use of OTC medicines from all sources of supply, there may be important errors in the exposure data. Information obtained directly from users may be prone to problems such as forgetfulness (particularly if the period of use was brief, perhaps sometime ago), failure to recognise that a non-prescribed medicine is still a drug, and sometimes a desire to conceal usage (especially if the OTC product was used for a personal matter, against professional advice or contrary to product labelling). These problems tend to lead to some users of an OTC drug being wrongly classified as non-users, a bias that tends to artificially diminish the size of association between exposure and outcome. Conversely, many individuals purchasing OTC medicines do not use them. Incorrectly classifying non-users as users would tend to artificially inflate the size of an association. Recall bias also occurs if one group of study participants (perhaps those who developed an illness [cases in case-control studies]) remember more fully previous OTC medicine use than another group who have less incentive to think about past medication usage (e.g. those who have not experienced the illness, i.e. controls).

Pilot studies have been undertaken to recruit cohorts of individuals purchasing OTC medicines from community pharmacies, at the point of sale.[14,15] This method of recruitment is attractive since exposure information is collected prospectively but problems can still occur if the same drug is obtained on prescription or from other retail outlets, and information about this additional usage is not collected. Furthermore, there may be concerns about whether results relating to individuals purchasing a medicine from a pharmacy reflect the experience of people obtaining the same preparation from other sources.

Outcome data can also be difficult to obtain. Patients who experience an adverse event after using an OTC product may not seek help from a healthcare professional. If they do, they may not consult the person involved in the original purchase. It may be difficult, therefore, to establish the link between exposure and outcome (symptoms/medical problem). Associations obviously cannot be made if the healthcare professional who is consulted does not have access to information about use of OTC medicines, or fails to ask about such use. The chances of detection are increased if the user recognises, and reports, information about both OTC medicine use and subsequent health problems. However, heightened awareness of possible problems with a drug, perhaps because of recent media or personal interest, can lead to the reporting of symptoms or problems unrelated to the exposure. Healthcare professionals are also prone to external influences, as shown by increases in the number of adverse drug reaction reports after case reports appear.[16]

Problems that have not been suspected before are more difficult to detect. Early suspicions arising from case reports (such as adverse drug reactions reported to regulatory authorities) or from theoretical considerations about biological mechanisms, need to be followed by case-control or cohort stud-

ies that can test hypotheses. Cohort studies can also generate hypotheses as they often collect data about multiple outcomes in the exposed and unexposed groups. This approach avoids individuals having to recognise a link between exposure and outcome(s). So far, much of the information about the safety of OTC medicines comes from extrapolations of experience when used as POM medicines. There have been very few safety studies of products formulated for OTC use. When designing such studies, care must be taken to ensure that they can detect rare but clinically important problems. Conventional wisdom states that postmarketing studies of newly marketed prescribed products should include about 10 000 individuals in order to have a good chance of detecting a rare event in users of a medicine (i.e. occurring in more than 1 in 3333 users).[17] Safety studies of OTC medicines are likely to need at least the same number.

Epidemiological studies of the risks and benefits of medicines require a suitable comparison group. Symptoms reported by exposed individuals may result from the underlying problem for which the medicine was used in the first place, natural fluctuations in the occurrence of symptoms in the population studied, or because of the medicine itself. Choosing and recruiting a suitable comparison group can be difficult in all pharmacoepidemiological research, and is particularly challenging in the OTC environment. One major benefit of the comparison group in a cohort study is the ability to calculate absolute as well as relative risks, thereby enabling researchers to put observed associations into perspective. Large relative risks (e.g. 4) for rare outcomes (e.g. 1 per 10 000 in the unexposed group) mean few individuals are harmed (or benefited) [in this case 3 per 10 000 users], whereas modest relative risks (e.g. 1.5) for common outcomes (e.g. 100 per 10 000 in the unexposed group) results in more individuals being affected (in this case 50 per 10 000 users).

Epidemiological associations do not necessarily mean causality. Alternative explanations for an association, principally bias and confounding, need to be considered. Interpreting results from a study can be difficult if detailed medical information about the user is missing, particularly relating to their current and past medical history, and concurrent use of prescribed medicines. Such information can help distinguish between problems arising from inappropriate use of an OTC preparation and inherent problems with the drug itself. Even if medical records are available, some information about other potential confounders, such as demographic factors, lifestyle, use of complementary medicines and food supplements, is likely to be missing or out of date. Without good information about these factors, erroneous conclusions may be reached. Experimental studies (randomised clinical trials) minimise bias and confounding but are rarely possible for assessing drug safety, partly because they require very large numbers to detect rare adverse effects. Observational pharmacoepidemiological studies, therefore, are likely to be the mainstay for determining the risks and benefits of OTC medicines. They are likely to use information collected from a number of sources, often directly from users themselves.

Traditional pharmacoepidemiological approaches include spontaneous reporting, signal generation in various databases, postmarketing surveillance studies, and hypothesis-based case control and cohort studies.[18] While all of these approaches could be used to study non-prescribed medicines, few have been used so far. Many adverse events to OTC medicines are likely to go unrecognised, particularly given the perceived safety of these products. In the UK, doctors, pharmacists and, most recently, nurses can spontaneously report suspected adverse events to the Medicines and Healthcare products Regulatory Agency (MHRA – previously the Medicines Control Agency [MCA]), using the Yellow Card Scheme. There are also ongoing pilot studies to assess patient reporting direct to the MHRA. In all countries with spontaneous reporting systems, under-reporting of events is a common phenomenon. For example, data from the US suggest that the average physician sees one serious and seven moderate drug reactions each year, yet in 1986 the FDA received only 12 reports of any type for every 100 practising doctors.[19] In a pilot study of a new method for enabling patients to report symptoms thought to be related to prescribed drugs, 5033 symptoms were reported by 607 respondents who had received venlafaxine or tramadol, yet the UK Committee on the Safety of Medicines (CSM) received only 23 reports from the 79 participating

practices during the study period.[20] Opening up spontaneous reporting systems to the public may increase the speed with which possible problems are identified, although patient supplied information is often crude and incomplete in comparison with that supplied by healthcare professionals.[21] Very few of the events reported to statutory authorities relate to OTC drugs, although some of the adverse events discussed in section 5 were identified though spontaneous reporting. One of the last times a serious adverse drug reaction was connected to an OTC ingredient was in 1986 when aspirin was linked to Reye's syndrome in children.[22]

5. Examples of Actual Risk

No medicine is switched to OTC availability without sound evidence of safety. Nevertheless, problems have still emerged, even after extensive experience of prescription use. Terfenadine is a non-sedating antihistamine, which at one time was one of the most widely used treatments for hay fever/allergic rhinitis. It was one of the first products to become available OTC in the UK, but was returned to POM status after reports of cardiotoxicity, particularly when used concomitantly with grapefruit juice or other drugs such as ketoconazole.[23,24] This rare event only became apparent after terfenadine had been used extensively OTC by a less selected population than when available only on prescription. While it is unlikely that there will be many similar occurrences in the future, this example emphasises the need for systems that identify such problems quickly.

The UK also switched availability of the head lice treatment, carbaril, from P to POM when evidence of possible carcinogenicity emerged.[25] Changes in one country, however, do not necessarily result in changes in another. The US withdrew the OTC ingredient phenylpropanolamine in response to evidence of an increased risk of haemorrhagic stroke in users,[26] but this did not occur in Europe. This was because the lower maximum dose in European OTC preparations (100mg compared with up to 150mg in US products) was not considered hazardous.

Particular concern has been expressed about the risks associated with OTC NSAIDs because of their potential for adverse effects,[27] widespread use and a perceived lack of awareness of risk.[28] A recent study compared the tolerability of paracetamol, aspirin and ibuprofen when prescribed in general practice for various common acute pain problems, at doses recommended for OTC use and for short periods.[29] In these circumstances, ibuprofen and paracetamol were tolerated better than aspirin. These results, however, might not reflect use of these analgesics in the OTC environment, since it is recognised that a proportion of users of OTC medicines do not follow manufacturers' guidance, sometimes take doses above the recommended daily intake and continue to use alcohol with these preparations.[30] Prolonged use of OTC analgesia by a proportion of users has also been observed.[31] In a Scottish study of OTC ibuprofen users, 4% of users had an active or past history of peptic ulcer, and 7% of users had an active or past history of asthma.[14]

Adverse events associated with the use of traditional homeopathic and herbal remedies and foodstuffs have also been reported. In the 1990s, the National Poisons Unit in London conducted a pilot survey to investigate the frequency and severity of adverse events/toxicity from these preparations reported to the unit.[32] Of the 5563 identified enquiries made to the unit, 78% involved vitamin or amino acid preparations and 19% herbal extracts, royal jelly and pollen preparations, enzyme, hormonal and glandular products. Some 268 of the reports about herbal preparations related to tranquillisers, with reported symptoms including drowsiness and vomiting. A probable link between exposure and adverse event was made in 42 cases, and a highly probable link in two. The authors concluded that in addition to improved quality control and labelling of these products, further surveillance is needed in order to provide a full assessment of their safety. A recent US study found that one-third of 489 adverse reports thought to be associated with dietary supplements were more severe than mild, and involved a number of new and previously reported associations that included myocardial infarction, liver failure, bleeding, seizures and death.[33] Verifying possible associations between dietary supplements and adverse events was difficult if the product contained more than one ingredient, and because information systems were incomplete.

The herbal medicine kava kava has been linked with 68 cases of suspected hepatotoxicity worldwide, including three deaths and six liver transplants. This evidence lead to the CSM prohibiting products containing this ingredient pending further enquiries.[34]

The interaction between St John's wort (*Hypericum perforatum*) and many prescription medicines is also potentially serious.[35] St John's wort is an inducer of various drug metabolising enzymes, resulting in reduced blood concentrations of some commonly prescribed drugs, including warfarin, cyclosporin, oral contraceptives, digoxin, indinavir and theophylline. Clinically important interactions are also likely with other HIV protease inhibitors, HIV non-nucleoside reverse transcriptase inhibitors and anticonvulsants (e.g. phenytoin, carbamazepine and phenobarbital [phenobarbitone]). St John's wort also interferes with the neurotransmitters in the brain leading to interactions with selective serotonin reuptake inhibitors. It has been difficult to respond fully to this newly identified problem because St John's wort is an herbal preparation and therefore, in the UK, does not need a product licence. In the absence of a regulatory framework St John's wort remains available for purchase although action has been taken to raise awareness of the problems, particularly among pharmacists and doctors.[35]

5.1 Particular Groups at Risk

Certain groups of the population may be more prone to problems from OTC medicines than others. Aging processes affect the metabolism of drugs, so that the actions of drugs in the elderly may be greater than those in the younger users. Doses of drugs that are normally therapeutic in younger people may become toxic and have higher potential for drug interactions in the elderly. The elderly tend to take more prescribed and OTC medications than younger individuals. A review of OTC medicine use found that 31–96% of US residents >65 years of age were using OTC preparations.[36] A Finnish study designed to reduce the number of prescribed drugs used by the elderly, found that when the number of prescribed medications was reduced patients tended to compensate by taking more OTC preparations.[37] Age-related pharmacodynamic and pharmacokinetic changes, therefore, may be important, especially in relation to potential interactions between drugs with similar effects.

Another group at particular risk is the young. One study found that 36% of parents denied knowing about possible adverse effects associated with the medicine recently administered to their child,[38] and only 28% were aware that OTC products might produce adverse effects. The recommended doses for children's medicines often relate to broad age ranges, for example 1–5 years and 6–10 years. The scientific basis for these recommendations is often unclear. Children at either end of the age range might be over- or under-dosed. In addition, only a limited range of OTC medicines have a product license for children, largely because of the ethical difficulties with conducting clinical trials in children, leading to an absence of the data available for the regulatory authorities. As a result, some children may receive adult preparations at doses that are estimated as being appropriate rather than based on scientific study.

6. Clinical Implications

Evidence is emerging that a proportion of OTC medicine users have contraindications to the drug's use or may use drugs in excessive doses and/or for prolonged periods. A number of users are likely to experience adverse effects as a result of their self-medication, even during correct usage. Although many of these symptoms are experienced without seeking help from a healthcare professional, some will be reported. It is important, therefore, that all healthcare professionals enquire about current or recent OTC medication use as part of the routine diagnostic process. When asking about such usage, it is important to make sure that the patient understands what is meant by the term OTC medicine. Such questioning is likely to become increasingly important, as the range of OTC medicines expands.

If an adverse drug event is suspected, it should be reported to the regulatory authority responsible for ensuring the safety of medicines in that country. Case reports are often the first vital step in the process of identifying an important health hazard.

Given the widespread availability of OTC medicines, healthcare professionals also need to be aware of the range of products that can be purchased

locally. This information will enable them to advise patients with particular medical and drug histories about the suitability of different OTC preparations.

7. Raising Awareness

Educational material is needed for healthcare professionals that informs them about the range of drugs available OTC and which emphasises the need to consider OTC medicine use as a possible cause for any presenting symptoms, and as a potential contributor to drug interactions.

The public needs to be made aware that although OTC medicines are generally safe they can cause problems in certain instances and should be treated as carefully as prescribed medicines. Thus, they need to be educated about the safe use and storage of OTC medicines, and of the importance of disclosing use of these preparations when consulting a healthcare professional. This information could be conveyed by manufacturers in their literature and advertising materials. Public awareness campaigns could also be conducted through poster displays in healthcare settings as well as other targeted locations.

In addition to making educational material available to healthcare professionals and purchasers of OTC medicines, manufacturers need to maintain continued surveillance of their products for any emerging problems. This may be particularly challenging given the market-driven nature of the OTC environment, and the methodological problems associated with studying self-medication products.

8. Future Developments

Many of the issues identified in this article would be addressed if there were better documentation of OTC sales, ideally as part of an integrated electronic patient record. In the UK, the electronic transfer of prescription data is scheduled for widespread introduction by 2004–2005.[39,40] Proposals, and limited developments, exist in other European countries. A fully integrated electronic patient record would include medicines purchased for self-medication as well as primary and secondary care data. Access to the record would vary depending on the level of consent provided by the patient, and the information needs of different healthcare professionals. Major issues, such as patient confidentiality, security and access, technical feasibility and fears of data overload,[41] need to be addressed before such a system can be introduced. Furthermore, such solutions will not capture the use of OTC medicines purchased from non-pharmacy outlets and may be perceived by some to be contrary to a fundamental concept underlying OTC availability i.e. increasing freedom for consumers. Work needs to be done, however, to see whether these challenges can be overcome in order to increase the chances of maximising the benefits and minimising the risks associated with OTC medicines.

9. Conclusion

In recent years the range of medicines available OTC has expanded dramatically, and is likely to continue for the foreseeable future. Safety and effectiveness in use are essential maxims for all medicines, including OTC preparations. Although rare, examples of problems associated with the use of OTC drugs provide powerful reminders of the importance of monitoring OTC medicines. Researchers and regulators undertaking such monitoring, however, face a number of major challenges. A particular challenge is the need to identify the rare occasion when OTC medicine use compromises patient safety, without exaggerating perceptions about the risk and so threatening the self-empowerment, convenience and economic benefits associated with these products.

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