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Benefits and Risks of Self Medication

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Abstract

Self medication is becoming an increasingly important area within healthcare. It moves patients towards greater independence in making decisions about management of minor illnesses, thereby promoting empowerment. Self medication also has advantages for healthcare systems as it facilitates better use of clinical skills, increases access to medication and may contribute to reducing prescribed drug costs associated with publicly funded health programmes. However, self medication is associated with risks such as misdiagnosis, use of excessive drug dosage, prolonged duration of use, drug interactions and polypharmacy. The latter may be particularly problematic in the elderly. Monitoring systems, a partnership between patients, physicians and pharmacists and the provision of education and information to all concerned on safe self medication, are proposed strategies for maximising benefit and minimising risk.

Self medication represents an area of healthcare in which the patient assumes a greater degree of responsibility for the management of a minor ailment, using a pharmaceutical product that is available without a prescription. The process may be supported by advice and counselling from a healthcare professional, in many cases, a community pharmacist. This involvement of pharmacists extends the participation of the pharmacy profession in rational management of minor illness and, as such, may prevent unnecessary physician appointments. An increasing number of former prescription-only products are now available for self medication in many countries, either through pharmacies or retail outlets, thereby extending the range and accessibility of these products to the population. However, self medication is not without risks despite the advantages associated with patient empowerment and the more effective use of pharmacist and physician skills. This paper will outline the role of self medication in healthcare, its associated benefits and risks, and how the latter can be minimised and the former maximised. In compiling this paper, the

following search strategy was adopted. BIDS, MEDLINE and International Pharmaceutical Abstracts (IPA) databases were searched using a number of key words such as nonprescription medication/ drugs, over-the-counter medication/drugs, counterprescribing, and these were combined with search terms such as risk, safety, benefits and economics. Reference abstracts were scanned for relevance to the topic of benefits and risks of self medication. Studies included in this paper have not been restricted to randomised, controlled trials as these have not been conducted extensively in this area. Policy- and practice-pertinent papers have also been included in this review as these sources often contain important professional and consumer perspectives.

1. Self Medication: The Current Situation

Self medication may be considered part of the larger self-care movement whereby individuals undertake activities with the intention of improving health, preventing disease, limiting illness and restoring health after injury or illness.^[1] Self medi-

cation has been largely associated with the use of nonprescription drugs (sometimes referred to as over-the-counter medications) which can be purchased in pharmacies and in retail outlets. The place of sale is largely dictated by legislation; in the UK and many European countries, a significant range of nonprescription drugs are only available from pharmacies (pharmacy-only medicines) and a number of these require direct pharmacist supervision and/or intervention and advice before the sale is made.^[2] A range of nonprescription drugs (described in the UK as general sales medicines) may also be purchased from retail outlets such as supermarkets, which have a restriction on the quantity and strength of medication which may be sold. [2,3] This is in contrast to the US where nonprescription drugs can be sold in a retail outlet irrespective of quantity or strength.[4]

The monetary value of nonprescription drug purchases is increasing as illustrated in figure 1, with year-on-year increases in all categories of products. Overall sales figures in the UK (excluding Northern Ireland) have also revealed an increase from £1275.8 million in 1996 to £1541.7 million in 1999. Figure 2 demonstrates the European dimension of the self-medication market, with Germany being the leading country in terms of overall spent in this area of healthcare, and a European Union (EU) sales total in excess of 13 billion European Currency Unit (ECU).^[6]

Table I lists examples of drugs, in the UK and US, which have been deregulated in the past decade from prescription-only category to availability without prescription. The deregulation process has been championed by the pharmaceutical industry, the pharmacy profession and government health policy makers and is supported by the acceptance that patients wish to have a greater role in their own treatment choices.^[7]

The range of drugs listed in table I represents potent medications which can provide effective management of a number of minor ailments or self-limiting conditions. In the case of levonorgestrel, the decision to deregulate this product in the UK has arisen from public health concerns regarding

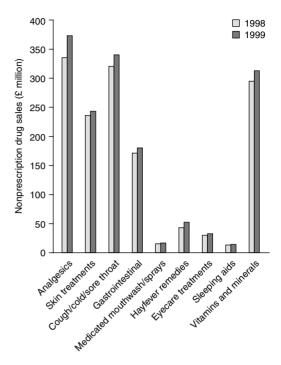


Fig. 1. Nonprescription medicine sales by therapeutic category pharmacies and grocery outlets in the UK (excluding Northern Ireland) during 1998 and 1999.^[5]

the number of unwanted pregnancies and terminations in the UK.[9,10] Pilot studies have examined the provision of emergency hormonal contraception in a number of UK sites with positive findings,[11] but this has proved to be a contentious area for ethical and professional reasons. Harper and Barrett, [12] using in-depth interviews with 18 community pharmacists and 6 general practitioners in South-East England, reported opposition to deregulation from almost all interviewees. Concerns were expressed regarding irresponsible and inappropriate usage of emergency contraception, therapeutic safety and training and information needs of pharmacists and patients, respectively. However, a more recent postal survey of almost 2000 pharmacists in Britain demonstrated that they were in broad agreement with deregulation of emergency hormonal contraception and considered the deregulation of levonorgestrel as extending the pharmacy's role within primary care.[13]

1.1 Rationale for Deregulation

From a regulatory standpoint, there are a number of criteria which must be met before a medicine, that was previously available on prescription only, can be deregulated. These criteria are:

- safety
- efficacy
- provision of information leading to safe use and, which includes warnings and advice on duration of use.^[7]

In fact it has been argued in some quarters that, if a drug meets the above criteria, it should be deregulated. The EU has sought to harmonise the conditions governing deregulation of drugs. He is the view of the EU that every 5 years the legal classification of a drug should be reviewed and amended if the following criteria are met: the drug is not dangerous if used without medical supervision, it is usually used appropriately, it is not a new chemical entity and it is not an injectable preparation. However, it is important to consider the benefits and risks of deregulation and extending self medication from a number of perspectives as outlined below, and broadly summarised in table II.

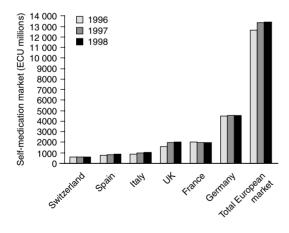


Fig. 2. Nonprescription medication sales in selected European countries [European Currency Unit (ECU) millions] 1996 to 1998. Data for 1999 cannot be included due to changes in the evaluation basis for a number of countries.^[6]

2. Benefits of Self Medication from Different Perspectives

2.1 The Pharmaceutical Industry

It is generally recognised that activity on all aspects of self medication is expanding within the pharmaceutical industry. [15] The advantages to the industry are that access to their products is increased, a switch to nonprescription status may protect against generic competition, and an existing brand that is also available on prescription may be promoted. [7,16]

2.2 Healthcare Professionals

The strategic policies of many pharmacy professional bodies is also driving increased deregulation and promoting self medication. The area of self medication, particularly within some European countries, is the unique domain of pharmacy. Research has shown that pharmacists are supportive of deregulation as it enables them to fulfil a more clinical role, increases therapeutic options, promotes greater involvement with patients and enhances their professional status.^[17]

For physicians, enthusiasm is more tempered, perhaps due to concerns of reduced contact with patients, incorrect diagnosis by a patient/pharmacist of a medical condition and inappropriate use of nonprescription drugs. [3,18] However, in the UK for example, medical practice has changed dramatically with doctors being faced with greater clinical and administrative demands. Therefore, there is greater realisation that unnecessary consultations with patients who have minor symptoms could be avoided through appropriate and effective self medication. [2,19] Indeed, doctors in the UK and Europe have become more supportive of self medication and further deregulation, which may reflect their increasing confidence in the deregulatory process and in the ability of the pharmacist to diagnose, treat and refer patients to a doctor when necessary.[20,21]

Table I. Examples of recently deregulated drugs, their indication and year of deregulation

Drug	Indication	Year of deregulation	
		UK ^[7]	US ^[4]
Clotrimazole (topical)	Vaginal candidiasis	1992	1990
Miconazole (topical)	Vaginal candidiasis	1992	1991
Fluconazole (oral)	Vaginal candidiasis	1995	Not deregulated
Aciclovir (topical)	Herpes simplex (cold sore)	1993	Not deregulated
Naproxen sodium (oral)	Analgesic/anti-inflammatory	Not deregulated	1994
Minoxidil (topical)	Alopecia	1994	1997
Cimetidine (oral)	Dyspepsia, indigestion	1994	1995
Ranitidine (oral)	Dyspepsia, indigestion	1994	1995
Famotidine (oral)	Dyspepsia, indigestion	1994	1995
Ketoconazole (topical)	Prevention and treatment of dandruff and seborrhoeic dermatitis	1995	1997
Levonorgestrel (oral)	Emergency hormonal contraception	2001 ^[8]	Not deregulated

2.3 Healthcare Costs

In some countries, an extension of self medication is seen as a way of constraining healthcare costs, particularly where the government is the main payer of services.^[7] Thus, encouraging patients to purchase nonprescription medications may lead to savings in the drugs bill. From the patient's point of view, this may also be to their advantage as some nonprescription products may cost less than a prescription levy. However, in the UK, many groups of patients are entitled to receive free prescribed medicines (e.g. those over the age of 60, those with certain chronic medical conditions such as diabetes mellitus and those on low income) and this entitlement will include some medicines which can be purchased without a prescription. Therefore, there is little incentive, for these patients to buy such products other than one of convenience. In other countries, such as Italy, nonprescription drug costs are not reimbursed by the state, [22] while in Canada, many public health insurance plans do not provide coverage for this category of drugs.^[23] This will promote self medication especially if a fee is payable for visiting a general medical practitioner.

Pharmacoeconomic analysis may provide evidence for the cost effectiveness of self medication compared to other interventions. Tasch et al., [24] using decision analysis methodology, compared the direct medical costs associated with the treatment of patients with heartburn/non-ulcer dyspepsia

under two scenarios: (i) no availability of nonprescription famotidine (a histamine H2 receptor antagonist); and (ii) the availability of this product without a prescription. The analysis was performed from the perspective of society and a third party payer for healthcare in Canada. This study was considered to be timely as Canadian authorities were considering the deregulation of famotidine. From the societal cost perspective, the availability of famotidine without a prescription did not generate any savings compared with maintaining prescription status of the drug. However, from the perspective of the third party payer, it was estimated that substantial savings could be made by deregulation of famotidine. However, the authors qualified their findings by stating that such results could only be confirmed by prospective studies which would measure how deregulation impacted on patient care and outcomes.

At a general level, Stearns et al.^[1] reported on another model of care (patient monitoring of urine, blood pressure or pulse) which resulted in significant reductions in Medicare expenditure over a 2-year period in a sample of US adults over the age of 65 years. However, there has been no major prospective research conducted on the cost effectiveness of self medication versus other models of care provision. This will be one of the major challenges for the future.

2.4 The Patient

Self medication has been part of family healthcare for many years and with the enthusiasm of the industry, professions and governments to promote this area of healthcare, this is likely to increase. Encouragement of self care is seen as giving patients every opportunity to take responsibility and build confidence in their capacity to manage their own health.[3] Patient empowerment is viewed as a positive step in the development of the patient-clinician partnership, [25,26] with doctors and pharmacists being seen as collaborators with patients in the management of health problems rather than controllers of access to medicine.^[27] Reports have indicated that patients find greater access to nonprescription medicine to be more convenient with no need to visit a doctor, effective and economical.[3] This has been confirmed by a major survey in the UK by the British Market Research Bureau International. [28] This work was commissioned by the Proprietary Association of Great Britain (the trade association representing manufacturers of nonprescription medicines and food supplements) and published in 1997. Over 2000 individuals were interviewed and almost 80% reported that it was important to have nonprescription medicines for minor health problems, 67% reported that such medicines were just as effective as those obtained from a doctor and 86% stated that they would purchase again, the same medication that they had previously used. [28] A survey of the general public involving 1000 people in Northern Ireland [29] on the role of the community pharmacist and community-based pharmaceutical services, sought information on how individuals would self treat a number of minor ailments. Headache, indigestion, constipation, cough/phlegm and colds/flu were reported as conditions which patients would prefer to self treat. [29]

These results suggest that the public have confidence in self treatment of certain conditions and the available products. Clearly, patients see self medication as offering convenience and effectiveness. Further support to this belief is seen in the sales figures for antifungal agents, used in the management of vaginal candidiasis, which have escalated rapidly in the US since deregulation of these products. [30] In terms of safety, an overview of implications of deregulation of H₂-receptor antagonists concluded that, nonprescription availability did not result in significant increases in drug consumption or adverse drug reactions and no apparent changes in the pattern of hospital admissions for ulcer complications. [31]

However, patient confidence and preference for self medication does not mean that the use of non-

Table II. Benefits and risks of self medication from the perspective of key stakeholders

Key stakeholder	Benefit	Risks
Pharmaceutical industry	Access to products increased Protection against generic competition Promotion of prescription brands	
Healthcare professionals pharmacists	Increasing advisory role for patients Greater involvement with patients Enhancement of professional role	
physicians	Avoidance of unnecessary consultations	
Healthcare payers	Can constrain healthcare costs, especially in countries where the government in the main payer of services	
Patient	Empowerment and responsibility for own health	Incorrect and inappropriate use of products Delay in treating a serious medical condition Masking of symptoms by using a nonprescription product Polypharmacy Drug interactions Undermining of patient-physician relationship

prescription drugs is always optimal or even appropriate in all cases. The latter fact, has long been the major concern of promoting nonprescription drug use and will be considered in the next section.

3. Risks of Self Medication

Nonprescription products are generally considered for short-term use in the management of a selflimiting condition: it is not unreasonable that some products, such as paracetamol (acetaminophen), can also be used for the long-term treatment of certain chronic conditions such as self management of osteoarthritis. However, in the latter case, this approach may be recommended once diagnosis has been made by a physician.^[32] Clearly, this is not advisable with many nonprescription products which may not be potent enough or appropriate for long-term use. It has been generally recognised that the risks which result from self medication are largely due to some form of inappropriate use. Sometimes this is described as misuse or abuse, terms which are often used interchangeably, but which have distinct meanings.

The term misuse is applied to the use of a drug for medical purposes, but in an incorrect manner, for example, use over an extended period of time or at an increased dosage. Abuse, on the other hand, is used to describe the use of drugs for nonmedical purposes, for example, to experience their mindaltering effects or to achieve bodyweight loss.[33] All drugs have the potential to be misused while abuse is largely associated with those products containing opioids, antihistamines and laxatives.[33] It should be noted that it could be difficult to classify the inappropriate use of a product by an individual as being abuse or misuse. It is also possible that the initial misuse of a product by an individual for a genuine medical purpose, but at an increased dosage, may develop into abuse.

The literature is full of examples of individual case studies highlighting problems with self medication using nonprescription drugs. The overall extent of the problem in the population is very difficult to quantify. This is partly due to the fact that there is little record keeping or monitoring associ-

ated with nonprescription drug transactions, and hence, doctors and pharmacists may be unaware of patients who are using products incorrectly. This incorrect use may stem from incorrect self diagnosis in the first place. The management of vaginal candidiasis has generated concern in this respect.^[34-36] Ferris et al.[30] assessed the ability of women (with and without a previous physician-confirmed diagnosis of vaginal candidiasis) to diagnose this condition based on the reading of a classic case scenario. A minority of patients were able to diagnose correctly upon reading the case scenario; a previous diagnosis had only a moderate impact on the patient's ability to correctly diagnose a case. The authors concluded that women may be using antifungals to treat conditions which may have similar symptoms to vaginal candidiasis, but are potentially more serious.[30]

Other concerns regarding risks associated with self medication include a potential delay in treating a serious medical condition,^[3] masking of symptoms of a serious condition through the use of a non-prescription product,^[3] increased polypharmacy^[37] and interactions with other regularly used medication.^[38,39] Table III illustrates potential drug interactions involving nonprescription medications and other drugs.

Older people are often viewed as a population which may be at increased risk from self medication due to concomitant medication and medical conditions. Chrischilles et al.[41] reported multiple analgesic product use in older people (>65 years of age) in rural Iowa, USA; nonprescription drug products were significant contributors to extensive analgesic use. Batty et al. [42] have also surveyed the use of nonprescription medications by in-patients over the age of 65 years in the UK. It was reported that these patients generally did not volunteer information on the use of nonprescription medications, that there was little if any documentation of pre-admission use of nonprescription medicines in clinical notes, that patients continued to use these products in hospital and that they were unaware of the possibility of adverse drug effects. Another unique atrisk population is children who differ from adults

Table III. Examples of potential interactions involving nonprescription medications^[40]

Nonprescription drug	Interacting drug	Possible outcome
Aspirin (acetylsalicylic acid)	Warfarin	Increased risk of bleeding
	Methotrexate	Methotrexate toxicity
Cimetidine	Warfarin	Increased risk of bleeding
	Carbamazepine, phenytoin, valproic acid (sodium valproate), theophylline	Toxicity
Fluconazole	Sulphonylureas	Hypoglycaemia
	Pimozide	Ventricular arrhythmias
	Simavastatin	Myopathy
Ibuprofen	Warfarin	Increased risk of bleeding
	Lithium	Lithium toxicity
Phenylephrine, phenylpropanolamine, pseudoephedrine	Monoamine oxidase inhibitors	Hypertensive crisis

in their response to drugs. This is particularly the case with neonates, in whom toxicity is manifested through enzyme deficiencies and differing target organ sensitivities.^[40] A number of nonprescription products are not recommended for use in children of a certain age. Kogan et al.[43] documented that nonprescription drugs were commonly used in preschool-age children; over 50% of all 3-year-old children had been administered nonprescription medicine in the 30 days prior to the survey. The most common medications used were analgesics and cough and cold products, but appropriateness of use could not be judged. Kacew^[44] in an extensive review of the effects of nonprescription drugs on the unborn child, indicated that self medication increased signficantly during pregnancy, largely as a result of effective advertising of products. The general rule of avoiding all drugs during pregnancy was advocated by this author.

From the professional perspective, the general practitioner (GP) may feel that the use of a nonprescription drug may undermine his/her relationship with patients. Many GPs in the UK have expressed concern that recommending a nonprescription product is in breach of their National Health Service contract, although the government's view is that this is not the case. [3] Research has demonstrated that patients are generally receptive to doctors making recommendations about nonprescription drugs, although patients who are exempt from prescription charges are less supportive of such an intervention. [45]

GPs have also stated that their prescribing decisions may be influenced by patients' demands for prescription supplies of nonprescription products which they had previously purchased and found to be effective. [3] This patient experience-led prescribing may interfere with the physician's treatment plan for the patient, leading to inappropriate prescribing decisions and perhaps continued use of both a prescription and nonprescription supply of the same product by the patient.

4. Minimising the Risks and Maximising the Benefits of Self Medication

The current drive towards continuing deregulation of prescription medicines and promoting self care in patients will continue, but clearly, the risks of self medication must be recognised and managed. This may require a multifaceted approach, rather than relying on a single system to highlight problems.

4.1 Monitoring Systems

Several countries have sophisticated pharmacovigilance and adverse drug reaction reporting systems in place. The spontaneous reporting system (also known as the 'Yellow Card System') operated by the Committee on the Safety of Medicines (CSM) in the UK enables doctors and pharmacists to report on adverse reactions of both prescription and nonprescription drugs. This has been exemplified by the nonsedating antihistamines, terfenadine

and astemizole. Reports received by the CSM in the UK and similar bodies throughout the world have revealed that ventricular arrhythmias, leading to death in some cases, have resulted from the use of high doses of these antihistamine drugs alone or in combination with other drugs such as erythromycin or ketoconazole. [46] Terfenadine and astemizole, which had been deregulated, were returned to prescription-only status and eventually withdrawn from the market. Therefore, it is not a case of 'once deregulated, always deregulated' and careful monitoring and spontaneous reporting through national bodies such as the CSM can help assess relative safety.

Most community pharmacies in the UK record details relating to patients' prescription medication on computer systems^[47] and these patient medication records (PMRs) are an important monitoring tool that could be exploited in nonprescription drug pharmacovigilance. However, a minority of community pharmacists use PMR systems to store information relating to nonprescription use.^[48] This may be facilitated in the future by developing electronic links from cash registers in pharmacies to pharmacy computer systems and thus, the sale of a nonprescription medicine could be automatically recorded in the PMR of a patient at the time of drug purchase. This would be particularly valuable in those patients receiving multiple drug therapy, thereby checking the suitability of a nonprescription drug product.

It has also been proposed that community pharmacies may be able to contribute further to nonprescription drug pharmacovigilance through the establishment of a pharmacy network. In a pilot study in Scotland, [49] community pharmacists monitored patients who had purchased ibuprofen for their own use. These patients were asked to record details of symptoms experienced during the week, related to drug use. Patients were followed-up, through the use of questionnaires, for a period of 12 months. This study led to the identification of issues related to the long-term use of ibuprofen, contraindications, adverse effects and excessive dosage with ibuprofen. In a recent research paper, Sanz et al. [50] reported

on the development of computer programmes and other technology support systems in European pharmacies, which would provide information and training for both pharmacists and patients on self medication. Participant opinion in pilot studies has been positive.

4.2 Patient-Physician-Pharmacist Partnership

The promotion of patient empowerment and their involvement in their own healthcare has already been alluded to (see section 2.4), but this fact should not be seen in isolation from those who provide healthcare. Partnership in healthcare has been advocated in the literature in relation to decision making and this includes medicine taking.[51] However, there are major gaps in the knowledge on how patients, physicians and pharmacists view self medication. It has been reported that patients do not always consider nonprescription medication to be drugs^[52] and this may be compounded if such medications are bought from a retail outlet rather than a pharmacy. As mentioned earlier, research has shown that patients do not report nonprescription drug usage to doctors and equally, doctors do not ask about the use of such products.^[42] It has also been highlighted that GP knowledge of nonprescription drugs is quite poor, [18] although the profession is becoming more supportive of this area of healthcare. [20] This could clearly lead to further iatrogenic disease, perhaps leading to the so-called 'prescribing cascade'. [53] The patient may obtain a supply of nonprescription medication from a nonpharmacy source. An adverse effect triggered by inappropriate use of a nonprescription drug may not be recognised as such by a doctor. The patient does not inform the doctor of product consumption and the doctor does not ask. This could lead to the prescribing of a prescription-only medication which will be supplied by the pharmacist, who may not be aware that the patient is taking other medication. The prescription medication may interact with the nonprescription product or may not alleviate the adverse effects precipitated by the nonprescription product. The patient therefore returns to the doctor for further consultation.

Clearly, lines of communication need to be established and clarified between the key players in self medication. Comprehensive record keeping by pharmacists and physicians, in addition to prudent and comprehensive questioning may help to complete the picture regarding medicine taking. However, this strategy must be supported by education and information, particularly focused on patients.

4.3 Education and Information Relating to Self Medication

In order for patients to be able to make appropriate decisions about their own health, they must have the necessary knowledge. Very often, misuse of nonprescription medications arises from a lack of information and knowledge on the part of the patient. This has been reported from a pilot study that was conducted in Northern Ireland in which community pharmacists attempted to intervene in cases of misuse and abuse of nonprescription medicines.^[54]Patients who were identified as misusing nonprescription medications often stated that they were not aware of the limits of duration of drug use or the maximum dosage. In a survey of US consumers (n = 1202), a third of all respondents admitted taking more than the recommended dosage of a nonprescription product because they believed they needed to do that in order to treat their condition effectively and 21% said that they rarely or never read the label on such products.^[55] Other studies have revealed that patients continuously self medicate (in some cases, for years) for dyspepsia,[56,57] and pain,[39] and that elderly patients are chronic consumers of vitamin and mineral supplements.^[58,59] Herxheimer^[15] noted that with the expanding self-care industry, consumers need to be educated on rational drug use and doctors and pharmacists need to guide patients increasingly to the kinds of information they need.[60]

In this era of evidence-based practice, rational selection and supply of products by pharmacists and their staff should also be emphasised. Smith and Feldman^[61] reported that there is a lack of scientific proof for the effectiveness of cold remedies. Certain cough products contain an illogical combi-

nation of suppressants and expectorants and should not be recommended to patients.^[62] Pharmacists have a duty to care for their patients and to supply the most appropriate and effective product to patients for the management of self-limiting conditions. By adopting this strategy, patients will have greater confidence in self medication as a legitimate intervention.

5. Conclusion

It has been reported that between 70 to 90% of all illnesses are handled by some form of self treatment and may not be brought to the attention of a health professional.^[63] Importantly, self medication with nonprescription drugs is a central part of this treatment strategy and can have major benefits from the perspective of the patient, physician and pharmacist. However, self medication may also be considered an inappropriate response if signs and symptoms are misdiagnosed or if treatment involves excessive dosage and duration. To improve the effectiveness, doctors and pharmacists must be more pro-active in monitoring self medication and in providing advice to patients. Equally, patients need to appreciate that nonprescription drugs must be used in accordance with the individual product recommendations and that minor ailments may not always require drug treatment. Finally, partnerships between patients, physicians and pharmacists need to be strengthened, with the ultimate aim of minimising risk and maximising benefit.

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