

# General Policy Issues

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## The benefits and risks of self-medication\*

It is widely accepted that self-medication has an important role to play in health care and, with the continued improvement in people's education, general knowledge and socio-economic status, self-medication has been successfully integrated into many health care systems throughout the world.

Self-medication products are those not requiring a medical prescription and which are produced, distributed and sold to consumers for use on their own initiative. Responsible self-medication can be used to prevent and treat symptoms and ailments that do not need medical consultation or oversight. This reduces pressure on medical services, especially when these are limited. For those populations living in rural or remote areas where access to medical services may be difficult, patients are able to control their own conditions to a greater extent. Only if the condition fails to respond, persists, or becomes more severe will the patient need to seek professional medical care.

Other factors have also contributed to prescription drugs being deregulated to over-the-counter (OTC) sale and new drugs with specific pharmacological action have been successfully reclassified from prescription to non-prescription status in many countries. For example, in the United States of America, products containing over 80 active ingredients of different therapeutic groups were switched from prescription-only to OTC status between 1976 and 2000. In many cases, restrictions imposed on reimbursement of prescription drugs have provided the impetus for authorities to evaluate and deregulate self-medication products to OTC status.

Although many countries categorize medicines as either OTC or prescription-only, research data indicate that sale of self-prescription products (i.e. buying prescription-only drugs without a prescrip-

tion) is far more common than sale of OTC drugs. It is a reality that medical personnel are in very short supply in many parts of the world and legislation is lacking. Also, the cost and time of visiting a licensed medical practitioner may seem prohibitive for many patients if they do not consider the illness or condition serious enough.

According to a consumer interview study carried out in six Latin American countries, only 34% of dispensed medicines were classified as OTC (1). It was concluded that a relatively high percentage of drugs were being dispensed without medical prescription or follow-up and this was attributed to lack of access to medical care. Of equal concern is the fact that, in many countries, although OTC medicines are provided with a patient information leaflet the self-prescriber does not receive any information whatsoever on how to use a prescription medicine.

Interestingly, it is the increase in competitive promotion of self-medication products which has enhanced consumer and patient awareness of the availability of products. Worldwide promotion and cross-border sale of medical products via the Internet is another factor affecting consumer behaviour which is set to boost demand. Already, the Internet offers a considerable amount of websites promoting mail order pharmacies (as of 7 May 2000, a count using the search engine Yahoo identified 16 966 and WebCrawler identified 244 546). Many of these sites are not secure in terms of guaranteeing the safety and quality of the products. However, there is no doubt that in the future self-prescription product sales through the Internet will increase enormously. This could create additional demand to switch prescription products to OTC status.

However, there are several critical issues that must be explored before promoting the potential benefits of self-medication. Any self-medication product should be safe for use. This implies the availability of appropriate consumer information and avoidance of any delay in diagnosis and treatment of diseases not suitable for self-medication. Furthermore, self-medication drugs are known to interact with many prescription-only drugs, alcohol and foods. How can interactions be avoided in the event of self-medication? Unfortunately, before making out a prescription, many doctors do not enquire whether patients

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are also using self-medication products. Additionally, promotional messages through the media and the Internet tend to convey a feeling of confidence in the safety of the product and often give the impression that self-medication products are just another consumer article. In other cases, excessive or non-medical use may be a problem. Reports have been received of OTC medicines being misused by drug addicts (2) and, according to a recent study in Northern Ireland, pharmacists admit that OTC drugs may be used in this way (3).

There are several critical issues involved before deciding if drugs should be authorized for self-medication. First and foremost, is the principle that no drug is absolutely safe — prescription drugs remain potent medications. Self-medication is, in the majority of cases, applied without medical supervision and, to a certain extent, is an uncharted area with regard to interactions, pregnancy, lactation, use in children and the elderly, driving, working conditions, alcohol, or food compared to the more controlled prescription-only environment. In many countries, the possibility of reporting adverse drug reactions (ADR) to self-medication products is not available since many conventional ADR reporting schemes operate through health care professionals. Only in a small number of countries with highly developed ADR systems are patients and consumers able to report ADRs directly to the authorities or through pharmacies. Moreover, clinical trial data for prescription use may not necessarily be valid for self-medication. This situation is beginning to improve within some countries that now demand OTC-environment studies to be undertaken before registration.

Special mention should be made of the heavy reliance placed on OTC analgesics. These have long been associated with chronic renal failure. Many earlier reports implicated phenacetin-containing analgesics as the risk factor. Since the early 1980s, several case-control studies have reported associations between chronic renal failure and use of other forms of analgesics, including paracetamol, aspirin, and other nonsteroidal anti-inflammatory drugs (NSAIDs). Although findings from these studies should be interpreted with caution, the use of OTC analgesics is widespread and the potential impact of these drugs on the development of chronic renal failure may be significant (4). Furthermore, the consumer may be unaware that several products with different brand names and for different indications may contain the same active ingredient.

Consumers need independent information to ensure the safe, effective and rational use of drugs in

self-medication. Advice to the consumer/patient should include a description of how to use the product without medical supervision and the circumstances in which referral for medical advice is necessary. In many cases, self-medication products are also understood to mean alternative medicines, food supplements, vitamins, herbs or other substances contained in commercially available products. Many are also sold in pharmacies or health food stores and have not been clinically tested and do not have a scientific basis for their recommended medicinal use. Moreover, certain products can cause severe safety problems. In highly regulated markets, pharmacists and other health care providers that recommend alternative medicines expose themselves to malpractice and liability claims if a patient is either injured or has treatment inappropriately delayed as a result of recommending such products.

In conclusion, self-medication can facilitate access to medicines and reduce health care costs. But more specific studies are needed to evaluate the impact and role of self-medication in the diversity of settings of different health care sectors. The combined efforts of industry and regulators must meet the expectations of consumers by providing products which are safe, effective, good value for money, and accompanied by complete and relevant information. High ethical standards should be applied to the provision of information, promotional practices and advertising. The content and quality of such information and its mode of communication remains a key element in educating consumers in responsible self-medication.

An abridged version of WHO's Guideline for the Regulatory Assessment of Medicinal Products for Use in Self-Medication is included on pages 18–26 of this journal.

#### References

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