



Advertising of nonprescription medicines to the public

A significant contributor to healthcare



WSMI

WORLD *self*-MEDICATION INDUSTRY

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Executive summary

Advertising creates awareness of nonprescription medicines, helps consumers in the search for products they need, and directs consumers to labeling that supplies details essential for safe and appropriate product use.


Nonprescription (or over-the-counter, OTC) medicines are medicines which are approved as safe and effective for use without a doctor's prescription. These and other self-care products are available without medical supervision and can be purchased by patients and consumers through pharmacies and, in many countries, from supermarkets or other retail outlets. As no health-care professional is necessarily involved in their use, advertising directly to the public of the availability of nonprescription medicines is essential and makes an important contribution to public health.

Advertising is suited to the transmission of simple, focused messages. Information on nonprescription medicines for patients and consumers comes in various forms and from various sources, including advertising and labeling, advice from pharmacists or other health professionals, the internet, and so on. Each of these information sources contributes in different ways to a patient's knowledge and understanding.

Advertising has a general role to play in modern healthcare, ranging from publicly-funded communication programs encouraging better health practices to industry communication programs describing the availability of nonprescription medicines in support of better health.

The emergence of chronic diseases such as cardiovascular disease, cancer and diabetes as the main future source of morbidity and mortality in most countries is also particularly significant. These are diseases which are caused by factors substantially within an individual's control – tobacco smoking, insufficient physical exercise and excess body weight for example. Government health promotion campaigns helps people to think more about their health and become more aware of their symptoms and condition. Nonprescription medicines' advertising reinforces this by showing the availability of medicines that can help.

Regulations should recognize the role, and limitation, of advertising. Basic standards will ensure that the information conveyed is truthful and not




misleading to consumers. Health departments, regulators and manufacturers should work together to ensure that consumers have the information they need about the benefits and risks of the medicine. A mix of government and self-regulatory tools that help ensure industry responsibility and accountability can be used effectively to oversee advertising. Nonprescription medicines manufacturers are committed to strict codes of practice, both as individual companies and through membership of country trade associations.

This monograph summarises the case for clear, ethical and efficient advertising of nonprescription medicines, recognizing its limitations but also demonstrating its special role in the new global public health context.

Scope of the monograph

The scope of this monograph is all self-care products available without a medical prescription. This includes herbal products and supplements, as well as nonprescription medicines or OTCs. Advertisements for all self-care products should be truthful and not misleading to consumers, and treated equally in the regulatory control processes for their advertisement.

It must also be emphasized that this monograph does not address the entirely separate issue of advertising of prescription drugs. The fundamental difference between prescription medicines and self-care products is that the latter can be purchased and used by the consumer of the medicine without the necessary intervention of a medical doctor. This has far-reaching consequences for supporting the appropriate use of nonprescription products by consumers and patients. Informing individuals about 'responsible' self-medication is appropriate ; entirely different controls are necessary than those on doctor prescribing of prescription medicines. For self-care products there is therefore a special place for the provision of consumer information, and in making patients aware of product choices. For self-care products, labels, leaflets and, not least, consumer advertising have a special importance.



WHAT IS IT?
The nature of
nonprescription
medicines advertising

Section I

The extent and purpose of advertising

Advertising materials which are aimed at consumers and those persons who may legitimately purchase medicines on behalf of another consumer (e.g. parents, who purchase medicines on behalf of their children) can come in a variety of forms, including :

- 1 Printed advertising material (e.g. newspapers, magazines, booklets, posters, direct mail materials etc.);
- 2 Electronic media advertising, such as websites, press releases intended for internet publication, and other on-line advertisements;
- 3 Audio and audiovisual advertising (e.g. cinema, television or radio commercial, videos);
- 4 'Other' – for example promotional scripts for use by telephone help lines, promotional text messages, aerial promotions such as hot air balloons, outdoor advertising, and so on.

Consumer-directed advertising has one principal purpose : “to alert consumers to the availability of products for conditions suitable for self-medication” (WSMI, 1999). To accomplish this, advertising must attract attention, stimulate interest and provide information to mass audiences of consumers about what a particular product might do. The focus is on informing consumers about the indications suited to self-care and the products available.

Overall, consumer-directed nonprescription medicines advertising can achieve a number of purposes. It can :

- increase awareness among patients and consumers about their condition and about the availability of suitable medicines for self treatment;
- alert consumers to new products and new indications and reinforces other forms of communication about a product and brand;
- develop brand recognition to provide the consumer with confidence in the brand and the company;
- facilitate product search and helps consumer make informed selections

- stimulate competition in the areas of product quality, product improvement and product development;
- help bring market forces into play, creating competitive product prices;
- reinforce good medicines use (“always read the label;” “if symptoms persist, consult a healthcare professional”).

Without advertising, consumers would be at a disadvantage. They would have less information on which to base their search for and selection of self-care health products.

The limitations of advertising

Advertising is a low involvement medium ill-suited and demonstrably ineffective for carrying detailed or highly specific information. Rather, detailed information is more relevant at a time a product is selected for purchase, and later when the product is used. This more detailed information can come from discussion with a healthcare professional and in particular in the case of nonprescription medicines, from the product label and leaflet.

Thus advertising alone cannot convey all of the information that a patient needs to practice responsible self-medication. Advertising is limited in how much information can be conveyed. It is well-known that the greater the volume of information in an advertisement, the smaller the likelihood of a particular item being remembered (box 1). Recognizing its limitations, advertising must then be reasonably focused on what it can do: attract the viewer, listener, or reader’s attention.

Summarizing a report by the International Advertising Association, the World Health Organization describes the purpose of advertising as: “Attract attention, offer choices, and provide limited general information to mass audiences of consumers. It must stimulate the interest of prospective buyers in a... product [and] inform them of what it may do for them... Therefore, advertising should not be overloaded with information to the point that the individual prospective buyer may fail to comprehend it or may even ignore it.”

Box 1 Consumers recall fewer than 3 messages from an advertisement

A major study in Britain by Taylor Nelson Research (1990) found that consumers usually recall fewer than 3 messages from an advertisement. Those in the study who viewed television commercials containing the full label text from a nonprescription medicine could not remember the details. In addition, detailed information significantly decreased recall of the main messages concerning the medicine's name and purpose. Viewers of full-text commercials were more likely to describe them as 'confusing', 'complicated', 'unclear' and 'having too much information'.

A consistent study in Germany (Kepplinger, 1990) showed that specific items of information in print advertisements are less likely to be remembered as the volume of information in the advertisement increases. The potential effectiveness of information is "inversely proportional to the amount of information presented". The study concluded that putting a lot of detailed information about contraindications and side effects into an advertisement has no substantial effect on consumer knowledge, even when such information is repeated. By contrast, the information on medicines labels does increase the knowledge of a large proportion of consumers, and reinforcement by health professionals such as pharmacists can also be very valuable.

Consistent with these results, it has been demonstrated specifically that the addition of warning messages to advertisements will not necessarily lead to increased compliance with label directions among consumers (Stewart and Martin, 1994)

In summary, detailed information about product use and risks decreases recall of the main messages in the advertisement. Advertising is especially suited to raise the awareness of patients and consumers on a particular public health concern or disease, or to communicate the availability of a medicine, but it cannot alone provide comprehensive instructions.

General messages in advertisements

Because an advertisement is not the appropriate place for detailed information, a general invitation to read carefully the instructions accompanying the medicine is more useful for conveying use information and any cautions.

In 1992, the European Union decided to free advertising of nonprescription medicines from including detailed information. In preference the EU developed a directive on medicine information on leaflets and labels which has to be written in consumer language and where appropriate should be tested with consumers to establish that it is readable and understandable. The European advertising directive requires references in advertising to the label and leaflet information to encourage consumers to read them. When appropriate, consumers could also be invited to discuss with a health professional for additional information and appropriate advice (for example in cases where a symptom persists, suggesting a more serious underlying condition).

Some examples of messages that have been adopted by some countries are :

- Portugal : "Read the information on the label or in the leaflet."
- Poland : "Read carefully the instructions on the package leaflet or on the outer packaging."
- Argentina & Australia : "Read the instructions for use carefully and consult a doctor in case of doubt."
- Brazil : "Ask for medical advice if symptoms do not disappear."
- Canada : "This product may not be right for you. Always read and follow the label."

Label and leaflet information

There are more effective communications means than advertisements to convey fuller information to consumers. Labels and leaflets are especially important in the nonprescription sector although these can still be supplemented by advice from pharmacists or other health professionals when needed. The role of the label is to allow consumers:

- to quickly and easily make a choice about the appropriateness of this medicine for their needs, at the point of sale;
- to find and appropriately use instructions for using the medicine safely and effectively, at the point of use;
- to access further information, if they want to know more about the medicine, at any point.

Consumer behaviors should be taken into account when elaborating the wording to be placed on advertisements or outer packaging of products. Much effort goes into the design and wording of the labels and leaflets of nonprescription medicines. High percentages of populations have said that they always read the label or package insert completely before taking a nonprescription medicine for the first time: from 97% in the UK through 91% in Latin America to 83% only in Spain. This confirms that the place for detailed information is in labels and leaflets or package inserts, not in advertisements.

Conclusion of Section I

The specific objective of advertising is to alert the public to their condition and the availability of personal treatments. Because advertising of consumer products is limited by the amount of information that can be conveyed, its role resides simply in attracting attention and raising awareness. Other communication channels such as product labels and leaflets are more important for presenting larger amounts of detailed information.

Advertising of nonprescription medicines has a number of positive benefits for public health in general, the marketplace, and the individual patient.



WHY IS IT VALUABLE?
The benefits of
nonprescription
medicines advertising

Section II

Public health benefits

Advertising is well-suited and efficient in raising awareness on health matters; research carried out on the effects of direct-to-consumer advertising of prescription drugs suggest that health advertisements motivate people to seek out more information about either a drug or their own condition.

Advertising of nonprescription medicines can play a similar role in public awareness. By addressing the public's instinct for taking care of themselves, nonprescription medicine advertisements can in some circumstances reinforce a public health awareness prevention or self-care program (Box 2).

Box 2 The role of advertising in public health – the example of smoking cessation

In estimating the impact of allowing nonprescription sales of nicotine replacement therapy (NRT) in the United-States on increasing the numbers of smokers quitting, Shiffman et al (1997) found :

"The ability to sustain smokers' interest in quitting with NRT may be attributable, in part, to the intensive advertising and promotional campaigns that have characterized the OTC market in NRT...Although many promotional activities promote particular products, this marketing and outreach effort also brings smoking cessation messages before the public in unparalleled intensity. This makes it particularly plausible that many of the quit efforts involving OTC NRTs are incremental efforts that would not otherwise have occurred.... The middle-ground estimates of approximately 225 000 incremental quits – an increase of almost 20% – are probably quite realistic."

Advertising may also have a positive effect on compliance : Wosinska (2005) reported for prescription drugs that "patients that started a medicine following...advertising are found to be more compliant possibly because they initiate the process and thus are more motivated to continue their therapy".

A different but no less important public health benefit of nonprescription medicines advertising is in encouraging people to look after themselves

when they can and should do so, and not simply go to the doctor on every occasion. Many surveys have shown how much time is wasted by doctors in general practice treating patients with common illnesses that could have been self-managed. Relieving doctors from unnecessary involvement in patient self-care allows them to focus on other priorities, to the general benefit of public health. Advertising of nonprescription medicines may thereby assist in supporting the proper contribution of self-medication to a country's healthcare system.

In summary it is clear that expenditure on nonprescription medicines advertising is a hidden asset of the healthcare system and makes an important (but largely unappreciated) contribution to public health objectives.

Benefits of market competition

Positive and informed consumer behavior is the foundation for a dynamic and well-functioning marketplace. In response, manufacturers compete to provide new, better and different choices for consumers. Manufacturers focus on the development of brands and the freedom to advertise those brands is a key requirement for investment in their development. The resulting dynamic, competitive market delivers consumer choice and helps keep prices down.

Advertising is thus an effective structural tool of an efficient and effective market economy. It brings market forces into play, feeding competition between companies, leading to more medicines being made available, and to improvement in brands, giving as a direct result more choice for patients and consumers.

Brands have a particular significance to the nonprescription medicines sector since it is always a brand that is the object of the advertising¹ – generic manufacturers rarely advertise generic names.

1 A brand is a collection of images and ideas – the name (product and company), a trademark or logo, a slogan, a design scheme, etc. Companies seek to differentiate their brands by brand name, colour scheme, trademark, packaging, shape, company name, intangibles, after sales service etc. The use of the same brand name or trademark for prescription and nonprescription products also helps with consumer confidence when a medicine is switched from prescription to nonprescription use.

Brands began (in the 19th century and before) as a form of consumer protection. This remains true today, with the brand being a statement by the company of its offering, its guarantee, to customers.

Companies invest in developing brands; in the nonprescription sector not only through new products but also through product developments such as improvements in taste, ease of use, clearer patient information, improved formulation, novel presentations, packaging technology, novel administration forms and child-friendly & child-proof technology. For these reasons consumers trust a brand and may therefore be more willing to try new products, encouraging appropriate use of relevant medicines.

In brief, with brands, companies will invest in disease area and brand development. This can benefit patients by:

- increasing choice, and increasing choice widens access;
- raising patient's awareness of their condition and their treatment options;
- improving understanding of how to use the medicine;
- providing guarantees of efficacy and safety;
- providing guarantees of quality, reliability and consistency;
- helping with recognition where there is a multiplicity of choice.

With a branded medicine, and the freedom to advertise, the brand owner has interest in improving medicines, guaranteeing medicine quality, and promoting healthy practices. Without brands, or without the freedom to advertise, the government has to take greater responsibility guaranteeing public drug quality, improving medicines, and for educating patients and consumers in healthy practices such as their possible need for treatment and appropriate use of a medicine.

Advertising does not promote inappropriate consumption

Advertising alerts consumers to the availability of medicines suitable for self-care and self-medication, but it is not the prime factor affecting the consumer's choice of product. For example, television advertising appears to have a limited impact with respect to overall nonprescription medicine use: in Brazil (1997), 81% of consumers disagreed with the statement: "I customarily purchase medicines advertised on TV".

In Italy, between 1977 and 1987 – a period known in Europe for its large increase in television advertising and in the use of healthcare services, the use of nonprescription medicines increased by only 2%.

Similar results may be found across Europe. Quaeyhagens (1990) gathered data on consumer advertising in the print and electronic media in seven European countries. Total advertising expenditures and sales figures were analyzed for three markets: pain relievers, laxatives and cough and cold remedies, together constituting more than 55% of the overall nonprescription market. Over a five-year period, no correlation was found between overall advertising expenditures, and overall sales. In fact, the French analgesic market showed a reverse trend for advertising and sales. The study concluded that increasing advertising expenditures does not result in a growth in overall consumption, and that effective advertising can only increase the market share of one brand at the expense of another.

The underlying reasons for this are clear. Nonprescription medicines are not "aspirational" goods – people do not choose to buy medicines if they have no need for them. Advertising cannot force people to buy and use a medicine they do not want or need. Thus it is generally accepted that consumer behaviour with respect to the purchase and use of medicines differs greatly from other common items of commerce. For example, clothing and even automobiles are often influenced not by need but by want or desire. They can be impulse items even when very large sums of money are involved.

Self-care health problems on the other hand are clearly dealt with differently by consumers. Nonprescription medicines in particular are not impulse purchase items as the need for a medicine is identified always by the pre-

existence of a health concern. When faced with such a concern, there is a clear search process used by consumers that is different from other common items of commerce. In the first step of the decision process, the consumer experiences the symptoms of an illness, evaluates them and decides whether or not to treat them. Next they activate a search process that depends upon their experience with this condition in the past. Where they have had the condition before, they usually can move directly into the product selection process. Where they have had no previous experience they begin a search for information on available treatment options. The resources for this search are numerous and typically consumers avail themselves of several sources including doctors, pharmacists and the Internet. Medicine advertising plays a role in awareness of products suited for treating health conditions. Either through recall of advertising seen when no problem existed (lowest likelihood of recall) or advertising seen at the time a need is identified, the consumer can add this information to the search process. If a medicine for the specific condition is recalled, the next step is to select a product from the retail environment. Studies show that for first time experiences with self-treatable illness, the consumer will typically go to a pharmacy and seek further information either through the advice of a pharmacist or by comparing medicine labels. When the consumer has a recurrence of a particular condition often they will go straight to product selection and then either choose a medicine that has worked for them before or seek a different product if they are not satisfied with their former selection.

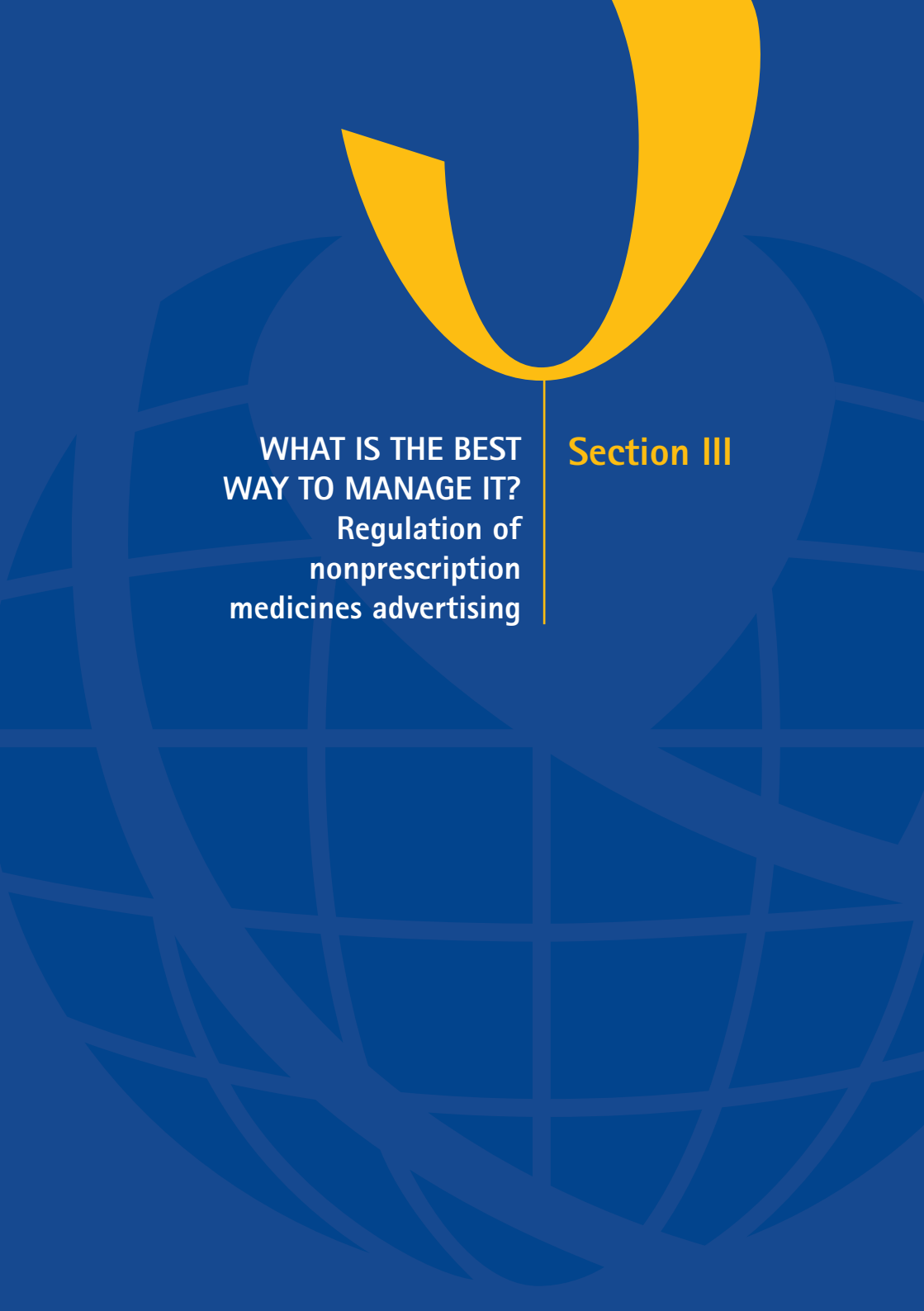
While there is more to consumer health behaviour than outlined here, it is clear that when it comes to nonprescription health products consumers do treat them differently than other consumer goods. To put it plainly, even if a consumer doesn't need a new pair of designer jeans they may still buy them. But if they don't have athlete's foot there is no amount of advertising that will get them to buy an antifungal medicine.

As advertising of nonprescription medicines is not a general consumption incentive, the manufacturer's purpose in advertising their brands is worth understanding. The answer is that manufacturers are competing with each other in a 'zero-sum game' to encourage patients and consumers to use their product, rather than a competitor's. This is one reason the market of the nonprescription medicines sector has grown so slowly for many years

because there is competition between products for market share, rather than growth in overall market size.

Conclusion of Section II

Advertising facilitates the rational use of nonprescription medicines for the benefit of public health, and in this way represents a hidden asset in healthcare. Advertising of nonprescription medicine brands stimulates competition in the area of medicines quality, product improvement and product development, and helps keep prices down. Research shows that advertising of nonprescription medicines does not lead to growth in consumption.



WHAT IS THE BEST
WAY TO MANAGE IT?
Regulation of
nonprescription
medicines advertising

Section III

Background

Nonprescription medicines are especially designed and labeled for use without medical supervision, and are approved as safe and effective for such use. There would be little point in approving a medicine for nonprescription use, and then preventing or unnecessarily restricting the advertising of the product. This is not to say that there should be no regulation – indeed high standards should be applied as described in this section – but the underlying approach should be supportive to advertising rather than restrictive.

Advertising of nonprescription medicines is allowed in most countries. The 2002 report of the European G10 Medicines Group illustrates a common government view: "Industry has a legitimate right to advertise products that are available over-the-counter to the public just as the public has a legitimate expectation to know about nonprescription medicines that are available to treat illnesses. There should be no restrictions on advertising of nonprescription medicines, which are not reimbursed, in line with existing requirements for advertising to encourage the rational use of the product and not to be misleading".

General ethical criteria for nonprescription medicine advertising

The ethical criteria for drug promotion which are particularly relevant for self-medication products are highlighted in WHO's Regulatory Assessment of Medicinal Products for use in Self-Medication (2000):

- "While advertisements to the general public should take account of people's legitimate desire for information regarding their health, they should not take undue advantage of people's concern for their health".
- "While health education aimed at children is highly desirable, drug advertisements should not be directed at children".
- "Advertisements may claim that a drug can cure, prevent, or relieve an ailment only if this can be substantiated."
- "They should also indicate, where applicable, appropriate limitations to the use of drugs".

- “When lay language is used, the information should be consistent with the approved scientific data sheet or other legally determined scientific basis for approval. Language which brings about fear or distress should not be used”.

In short, advertising should contain only approved indications, it should not be directed to children, and it should not create fear or apprehension. Basic standards of advertising should ensure that the information conveyed is truthful and not misleading to consumers.

Mechanisms for regulation of advertising of nonprescription medicines

Different mechanisms can be used to ensure that nonprescription medicine advertisements are truthful and not misleading to consumers. Two dimensions are of importance. Firstly, whether a pre-release or post-publication system for advertisements is in place. For a pre-release system, advertisements are formally approved before they are released to the public.

A post-publication system relies on a complaints procedure being applied after the event. The second dimension is who undertakes the task of applying the regulatory process – a government or independent body, industry, or some combination of each of the interested parties. Of course even systems that rely solely on industry oversight procedures will usually have some government oversight or monitoring process remaining in place.

Systems where the government has a strict pre-control over advertising are gradually disappearing because they tend to impair the efficiency and effectiveness of advertising in its role of stimulator of the market competition. Substantial delays meant higher operating costs for the companies and also imposed an unnecessary workload on regulatory agencies' staff. It is also difficult for government authorities to assess and judge proposed advertisements with technical consistency. The global trend is now towards self-regulatory or co-regulatory methods with government post-publication surveillance (i.e., taking action against violations rather than pre-clearing the advertisements).

In practice national laws, voluntary industry codes on a national level, and responsible individual company action are effective in maintaining high standards of advertising.

Pre- or post-publication approval

A pre-clearance system for advertisements is carried out before they can be released. The pre-clearance may be carried out by the government, by the industry or by independent bodies. The pre-clearance may be required by the Law, or may be an industry voluntary procedure, as part of their codes of practice. For cultural and historical reasons different, but equally effective, approaches have evolved in different countries regarding pre- and post-publication controls on nonprescription medicines advertising.

In Australia, it is a legal requirement that all advertisements for therapeutic goods directed to consumers, published or broadcast in mainstream (designated) media must be approved before publication or broadcast.

The Ministry for Health and Ageing has the responsibility for approving advertisements, but the responsibility has been delegated to industry trade associations (the Australia Self-Medication Industry, ASMI and Complementary Healthcare Council, CHC) as part of a co-regulatory arrangement.

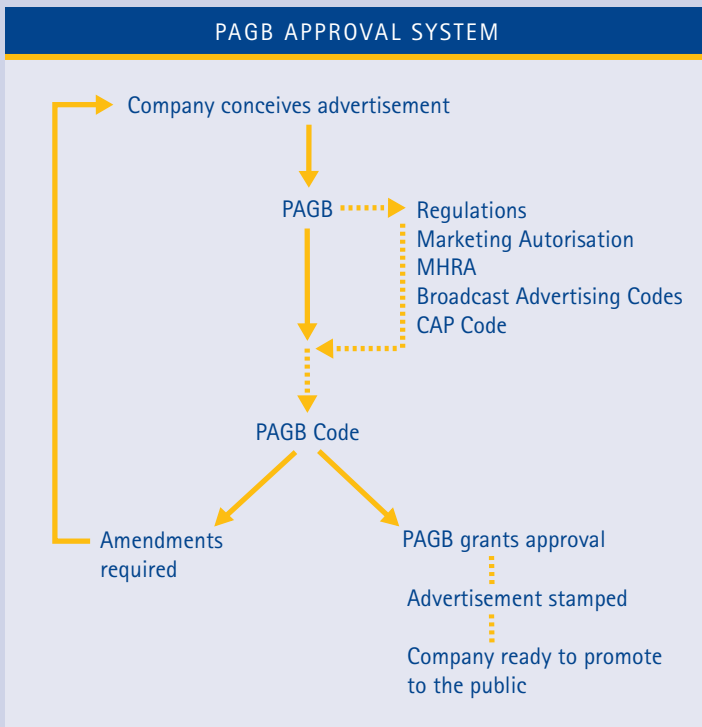
In the USA, the approval of the advertising material is given prior to publication by the major broadcast TV networks who have legal clearance departments.

In Canada, drug advertisements are reviewed and pre-cleared by Independent Agencies. Consumer-directed advertising for self-care products are pre-cleared by Advertising Standards Canada (ASC) and Broadcast Clearance Advisory (BCA).

In some self-regulatory systems, such as in Britain, the manufacturer association PAGB (the Proprietary Association of Great Britain) pre-approves the advertisements. While member companies are always legally responsible for their advertising, the pre-publication approval system aims to help members ensure that their consumer advertising complies with the legal and voluntary requirements. The review process usually also involves representatives of the advertising industry and others (Box 4).

Box 4 The pre-approval system of advertising material in Britain

- 3.4.1 PAGB's pre-publication approval of advertising materials has helped members achieve a high level of compliance with both statutory and self-regulatory requirements.
- 3.4.2 Specialist staff carry out the pre-publication approval of advertising materials. PAGB has access to independent medical and legal expertise to advise on evidence and matters of interpretation under the PAGB Consumer Code.
- 3.4.3 The system of pre-publication approval is as follows:



- the member company, or agents working on behalf of the member company, conceive the advertising.
- the member company, or agents working on behalf of the member company, submit the advertising to PAGB for approval.
- PAGB checks the advertisement against the rules in the PAGB Consumer Code, the Marketing Authorisation and any other regulation or code of practice which applies to the specific medium for which the advertisement is intended. Any queries over medical or legal claims are referred to PAGB's medical and/or legal advisers.
- PAGB notifies the member company or agents working on behalf of the member company of any changes required, or evidence which is needed, before the advertisement can be approved.
- once PAGB is satisfied that the advertisement complies with the PAGB Consumer Code, it is approved, subject to 'PAGB's Terms of Approval for Advertising' and the company is notified.
- the advertisement can now be seen by the public.

Source: PAGB's advertising codes, summary version, page 7:

<http://www.pagb.co.uk/pagb/downloads/advertisingregulations/PAGB%20Summary%20Medicines%20Advertising%20Codes.pdf>

Mexico is an example of a post-publication control system. Since April 2003, members of AFAMELA, the self-care trade association, have been exempted from pre-clearance of advertising. This agreement with the Mexican Regulatory Agency (COFEPRIS) was based on the principle that, by adhering to AFAMELA, members comply with the association's Codes which were found by COFEPRIS to exceed the requirements expressed in the legal provisions. Other country examples of post-event surveillance are Argentina, Germany, Japan, Croatia and the USA.

Post-event controls & complaints procedures

Whichever system is in place, there is always in addition a post-publication oversight of the advertising. Companies are in competition and are the first to point out and complain about a competitor should an unethical, misleading or unfair advertisement be broadcast to the public.

Complaints by consumers and health professionals also play a role in making these systems work. There are also government post-controls, as well as independent Advertising Standards Authorities which carry out surveys separate from complaints.

In Europe, article 97 of the Community Code states that "member states shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. Such methods shall in any event include legal provisions under which persons or organizations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Directive may take legal action against such advertisement, or bring such advertisement before an administrative authority competent either to decide on complaints or to initiate appropriate legal proceedings".

In the USA, the Federal Trade Commission (FTC) controls the advertisements after their publication. In addition, the Council of Better Business Bureau, National Advertising Division, runs a non-governmental advertising complaint system which reviews advertising complaints from consumers, competitors, or on its own initiative. Germany, Japan and Mexico are other examples of industry self-regulation with government post-publication controls and ample enforcement tools against violative advertisements. In fact, most industry self-regulated systems have governmental post-controls of advertising. However, experience has shown that punishments against violations of advertising rules are usually not needed in a self- or co-regulatory system.

Nevertheless, penalties for breaching advertising laws and / or self-regulatory codes can be substantial and include: discontinuation of the advertisement, circulation of a retraction statement, imposition of fines (high enough to be discouraging), formal publication of the decision, referral to the Ministry of Health, withdrawal of association membership, withdrawal

of right to advertise, and withdrawal of marketing authority for the product.

Industry self-regulation works well for a number of reasons, not simply because the penalties for transgression are substantial. Companies know that the alternative – direct government control – is undesirable, being slower and more costly.

Self-regulatory systems of advertising control

Self-regulation in the nonprescription medicine industry is the voluntary use of agreed Codes of Practice by pharmaceutical companies regarding promotion and advertising of medicines to the public. These codes are written and adopted by national associations of nonprescription medicine and self-care manufacturers. Codes contain procedures for judging complaints along with measures for non-compliance. Self-regulation works because companies in competition with each other are likely to be the most expert and sensitive critics of their competitor's advertising.

In some cases the Self-Regulatory Codes are underpinned by the law. This is then called Co-Regulation as both the government and the industry share the role, with the industry sometimes doing the pre-clearance.

Britain's positive experience with a self-regulatory system (described in Box 4) is reflected in the European Legislation which recognizes "the role of voluntary control of advertising of medicinal preparations by self regulatory bodies and recourse to such bodies" (Article 97, Paragraph 5 of Directive 2001/83/EC).

In Japan, a voluntary Code of Advertising Practice was issued in 1955 jointly by the Federation of Pharmaceutical Manufacturers Associations (FPMAJ) and the Japan Self-Medication Industry (JSMI). The code voluntarily subscribes to the content and spirit of both the Japanese Pharmaceutical Affairs Law and the 'Standards for Appropriate Advertisements of Pharmaceuticals' as edited by MHLW, the Japanese Health Ministry. The industry voluntary code has been adopted as the tool of reference by the regulatory authorities in view of its "comprehensiveness and reliability".

Many other countries around the world have written and adopted voluntary Codes of Practice. Argentina, Australia, Austria, Brazil, Canada, Croatia, Denmark, the Czech Republic, Finland, Ireland, Poland, Portugal, the Russian Federation, the Slovak Republic, Slovenia, Sweden, Switzerland, the USA are some examples. The positive experiences in self-regulation in Mexico are summarized in Box 5.

Box 5 Self-regulatory systems with government post-controls work well. The example of Mexico.

From April 2003, COFEPRIS, the Mexican regulatory agency (Comisión Federal Para la Protección Contra Riesgos Sanitarios) signed with AFAMELA, the Mexican self-care industry association, an agreement according to which members of the Association are exempted from the pre-clearance of their advertisements. This agreement was based on the understanding that companies comply with AFAMELA's Codes of Ethics. These Codes of Ethics were found by COFEPRIS to exceed the requirements expressed in the agency's Regulation of Advertising.

Controls may be carried out by COFEPRIS after the publication of the advertisements. Violators of the Code and/or Regulation would have to pay a fine and the advertisement would be subject to modification or withdrawal.

Because COFEPRIS has found the system to be working well, it decided in 2005 to extend the system to other healthcare products such as medical devices, diagnostics, and others.

A positive side effect of the implementation of the post-publication control system in Mexico has been a clear reduction of the regulatory agency's workload. And a growing number of healthcare companies are henceforth more responsive to the market, with their advertisements complying with the highest ethical standards of advertising practices.

Conclusion of Section III

Different mechanisms can be used to ensure that nonprescription medicine advertisements are truthful and not misleading. Two dimensions are of importance. Firstly, whether a pre-release or post-publication system for advertisements is in place. For a pre-release system, advertisements are formally approved before they are released to the public. A post-publication system relies on a complaints procedure being applied after the event. Either approach can work well depending upon individual country conditions. Experience also shows that the system of self-regulation works well. There are relatively few complaints and even fewer are upheld by the various bodies reviewing them, both governmental and non-governmental. The strengths of self-regulation are its efficiency and effectiveness when the structure exists to oversee it adequately. It does not use government resource which can be better deployed elsewhere, and it is much faster than government pre-control. This is very important for industry as advertising is frequently season-related. It also reinforces a responsible attitude on the part of companies. In a number of developing countries self-regulatory schemes are being developed with the authorities.

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