



**Federal Agency for Medicines and Health Products
(FAMHP)**

**Regulations regarding advertising for medicinal products
for human use
General dispositions**

Regulation regarding advertising related to medicinal products

Specific regulation based on the European directive 2001/83/CE(articles 86 à 100) transposed in:

- the law of 25 March 1964 regarding medicinal products, articles 9, 10, 1,12, as amended on 16 December 2004 (art 10) and the 1 May 2006 (art 9)
- the Royal Decree of 7 April 1995 relating to the information and advertising concerning medicinal products for human use
- the Royal Decree of 11 January 1993 regarding the delivery of samples

What is an advertising?

See article 9 of the law of 25 March 1964

“Any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products”

In particular:

- *advertising to the general public*
- *advertising to persons qualified to prescribe or supply medicinal products*
- *visit by medical sales representatives to them*
- *supply of samples*

- *provision of inducements to prescribe or supply by means of gifts, special offers or promises of a benefit or bonus (see article 10 law 25.3.1964)*

- *sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products*
- *sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products, in particular payment of their travel and accommodation expenses incurred by the congress.*

What is an advertising ?

- **Attention to indirect advertising for a medicine !**
= material that does not bear the name of the medicine but refers to it by taking elements of a known advertising, packaging, slogan, logo, etc...

What is an advertising ?

The following are not covered :

- leaflet and labelling as such
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product (following the initiative of the person requesting)
- factual, informative announcements and reference material relating, for example, to pack changes, warnings about adverse reaction as part of general drug precautions, trade catalogues and price lists, provided they include no product claims
CONDITION: no other information about the medicine
- information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products

Information campaigns about health or illness

Public information campaigns

(art.9 §3 law 25.3.1964 - art.2 & 3 RD 7.4.1995)

- about human health or a human disease,
- which refer directly or indirectly to medicines

BUT which do not meet the definition of the advertising according to the law of 25 March 1964 on medicines

are nevertheless subject to some measures in common with advertising.
(except approved RMA and “official” campaigns)

- respect all the bans concerning public advertising
(especially article 7 of the Royal Decree of 7 April 1995)
- encourage the rational use of medicines
- can not be misleading

Information campaigns about health or illness

No promotional connotation:

- possibility of referring to a group of prescription medicines provided **all treatments**, including non-medicinal ones, are mentioned
- **no highlighting of a particular medicine**,
- **no fancy or molecule name**,
- **no indirect advertising** for a medicine by using colour, logo, slogan referring indirectly to a medicine

Information campaigns about health or illness

No promotional connotation:

- Differentiate between the groups of medicines, for example, by the administration route,
- **no information on the respective properties of the medicines**
-> return to the doctor for the diagnosis, the proposal and the monitoring of the treatment
- Written material : name of the **responsible editor must be mentioned discreetly**
- TV or radio spot : no name of the advertiser if it is a firm which sells medicines indicated for the treatment of the disease but mention « **PRIVATE INITIATIVE** » to avoid misunderstanding about the origin of the message

Information campaigns about health or illness

- For the radio or TV campaigns = prior visa after advice of the Control Commission of medicines advertising
- If the radio/TV campaign uses other media, information elements distributed by these media must also be attached to the visa application dossier and are be reviewed by the Control Commission of medicines advertising

Examples: website, brochure, posters, magazine notice...

Advertising : for what medicines, to whom?

Advertising always prohibited for:

- Unauthorised, banned or suspended medicines

Advertising prohibited to the general public for

- Medicines that can be obtained only with a medical prescription
- Narcotics and psychotropics

The general public is defined as those persons not qualified to prescribe or deliver medicines:

- physiotherapists, nurses and pharmacy assistants are placed in the same category as the general public for the enforcement of the advertising regulation

Advertising : for what medicines, to whom?

Medicines that may be advertised to the general public :
(art 6 Royal Decree 7/4/1995):

- Medicinal products according to their composition and purpose that are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary

Advertising to the public may be inappropriate for non-prescription medicines but not designed for treatment initiated by self-medication, without preliminary diagnosis by a doctor.

Banned advertising materials and medias

It is forbidden to make advertising for a medicinal product

- by means of aircraft, boats or panels on public highways (for example door or window displays in a pharmacy!)
- by means of luminous signboards
- by means of oral recommendations in public,
- by phone, SMS, fax, e-mail or direct mail advertising
- in publications intended for children
- by the organisation of publicity contests
- by means of objects of any kind intended to be used, partially or totally, for other purposes than communicating the information
- by the insertion of detachable supplements and flyers in publications
- software
- compensation in the case of patient dissatisfaction

Banned advertising materials and media : exemptions

- Derogations for medicinal nicotine-based products intended for the treatment of nicotine dependence:
 - panels on public highways
 - objects of any kind
 - fax, phone, SMS, e-mail, mailing of advertising in reply to a specific request spontaneously expressed by the addressee
 - oral recommendation in public in order to answer a question during information meetings as part of an awareness campaign and coaching programme (= leaflet)

Banned advertising materials and media : exemptions

- Exemptions for persons qualified to prescribe or deliver:
 - faxes, e-mails, mailing shots if people have so requested
 - ! information containing medical data concerning patients transmitted via e-mail cannot be interrupted by advertising
 - prescription books
 - leaflets
 - computer programmes except those for the management of the patient's medical dossiers

Content of the advertising in general

- Must comply with the particulars listed in the summary of product characteristics
- Shall encourage the rational use of the medicinal product,
 - by presenting it objectively,
 - without exaggerating its properties
 - without being misleading
- Accurate, up-to-date, verifiable

Content of advertising for the public

- Don't give the impression that the medical consultation or surgical intervention is unnecessary, in particular
 - by offering a diagnosis
 - by suggesting treatment by mail
- Don't suggest that the effects of the medicine,
 - are guaranteed
 - are not accompanied by adverse reactions
 - are better than, or equivalent to, those of another treatment or medicinal product (no comparative or superlative)

Content of advertising for the public

- Don't suggest that the health of the subject can be enhanced by taking the medicine
- Don't suggest that health could be affected by not taking the medicine (except vaccinations)
- Is not directed exclusively or principally at children
- Don't refer to a recommendation by
 - health professionals
 - scientists,
 - persons who, because of their celebrity, could encourage the consumption of medicinal products

Content of advertising for the public

- Don't suggest that the medicinal product is a foodstuff, cosmetic or other consumer product
 - Clear distinction between advertising for medicines and other products
- Don't suggest that the safety or efficacy is due to the fact that it is natural
- No description or detailed account of a case history that could lead to erroneous self-diagnosis

Content of advertising for the public

- Don't refer, in improper, alarming or misleading terms to claims of recovery
- Don't use, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or the action of a medicinal product on the human body
- Do not use pictures, drawings, photographs, representations affecting
 - the essentially informative character
 - the sobriety

Content of advertising for the public

- Do not play on a motivation other than that of rationally persuading the public to use the medicine in order to treat or prevent a disease
- The advertising character of the message must be evident
- The product must be clearly identified as a medicine
- Mention of a website if the site is notified or belongs to an official organism

Legal mentions advertising general public

1. In writing or voice-over

- Name of the medicine
- Name of the active substance (if only one)
- “this is a medicine, no prolonged use without medical advice”
- For traditional herbal medicinal products : “traditional herbal medicinal product for use for indication(s) specified on an exclusive basis for long-term use”
- Essential mentions for proper use of the medicine

Essential comments for a proper use

NON-EXHAUSTIVE LIST of EXAMPLES:

1. **All medicines:** “ask the advice of your pharmacist”

Always according to the SPC:

2. **AINS for internal use,**
 - contraindication for children
 - contraindication in case of allergy to salicylates et other NSAIDs
 - contraindication in case of gastro-duodenal ulcers
 - contraindication during pregnancy
3. **Acetylsalicylic acid,**
idem + warning “do not use without medical advice for children with fever”
4. **Nicotine**
 - keep out of reach of children
5. **Nasal vasoconstrictor**
 - contraindication for children

Essential mentions for proper use

6. Sympathomimetic for oral use

- contraindication in case of hypertension

7. NAIDS for external use

- contraindication for children
- contraindication in case of allergy to salicylates or other NAIDS
- ketoprofen: no sun exposure
- contraindication during pregnancy

8. Medicines in aromatic form

- keep out reach of children

9. Local anaesthetic for mouth-pharyngeal use

- contraindication for children

10. Antitussive medicines

- do not give to children under 2 years old
- limited use for children from 2 to 6 years old

Essential mentions for a proper use

11. Anti-louses

- carefully observe the warnings about use
- contraindicated in young children

12. St John's wort

- contact your doctor or pharmacist if you also take other medicines

Etc, etc, ...

Legal mentions advertising general public

2. In writing

- “Read carefully the patient information leaflet”
- Marketing authorisation holder name
(address, mail and phone **only as a “contact”, without any direct or indirect proposal for additional information**)
- Visa number (if applicable)

Legal mentions advertising general public

BE SURE to make the written legal mentions perfectly readable

- Size and clarity of characters
- Contrast
- Position on the advertising (in front, in the direction that one reads, easy to see,)
- TV advertising: circular no. 441, 2 March 2004

Logo pharmasmile

Authorised but not a substitute for the legal indications



This is a medicine;
Ask for advice from your pharmacist;
Read carefully the patient information leaflet;
No prolonged use without medical advice.

Reminder advertising

- Only the name of the medicine, the active substance and the MA holder (+ logo of the MA holder)
- No other words or figurative drawings

Advertising content for prescribers and pharmacists

- Advertising and/or scientific claims and mandatory mentions must be **a cohesive unit**
 - **The advertising must contain:**
 - name, qualitative and quantitative composition of active ingredients, pharmaceutical form
 - all elements of the indications, dosage contraindications, undesirable effects columns of the SPC (or of the leaflet for homeopathic medicines)
 - name of the MA or registration holder
 - MA or registration number
 - delivery mode
 - public sales price of each pack
 - date that the advertising was established or last revised
 - **Price in bold type** on contrasting background, at the top, on the right of the advertising (0,5% of the total area)
 - The legal mentions cover at least **50% of the total area** of the advertising
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Advertising content for prescribers and pharmacists

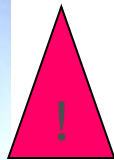
- All the information provided as part of the promotion of a medicinal product shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the medicinal product.
- Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works shall be faithfully reproduced and the precise source indicated. The original text should be made available to doctors on request.
- The scientific studies and the information distributed by audiovisual or electronic means without the intention of promoting the sale or the prescription can in no way be interrupted by an advertising for a medicine
- The SPC must be supplied to any person authorised to prescribe or deliver medicines who so requests

The medical sales representatives

- Shall be given adequate training by the firm which employs them (responsibility of the person responsible for pharmaceutical information)
- Shall have sufficient scientific knowledge to be able to provide information which is as precise and as complete as possible about the medicinal products which they promote
- Have available for the persons who are visited the SPC of each medicinal product presented, together with details of the public price of each marketed pack .

The medical sales representatives

- All information must be based on the data that was accepted when granting the MA. If the data goes beyond the SPC, it is put in a technical dossier signed and dated by the person responsible for information, that is given to visited practitioners, at his request. A copy of this dossier is kept available for inspection.
- Medical sales representatives shall transmit to the person responsible for pharmaceutical information any information about the use of the medicinal product they advertise, with particular reference to any adverse reactions reported to them by the persons they visit = RD 7.4.1995



Reminder of the current rule: any adverse reaction must be sent within 24 hours max by mail, phone or fax to the pharmacovigilance department of the firm, either directly by the delegate or by the responsible for information