Federal **A**gency for **M**edicines and **H**ealth **P**roducts
(FAMHP)

Advertising intended for healthcare professionals

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1. Introduction

Purpose of the presentation

To give general information about the regulation concerning advertising for health professionals but mainly focused on problems
currently or frequently encountered by the FAMHP during controls.

2. Legal context

- The Directive 2001/83/EC of the European Parliament and of the Council of 6.11.01 on the Community Code relating to Medicinal Products for Human Use, titles VIII and VIIIbis .
- The Law of 25.03.64 on the medicinal products, article 9.
- The Royal Decree of 7.04.95 related to the information and advertising concerning medicinal products for human use.
  In particular articles 9 to 11.
  But the general provisions of this decree concerning any advertising for medicinal products are also applicable to the advertising intended for healthcare professionals.
- NB: Circular 407 (26.04.01) available on http://www.fagg-afmps.be/fr/binaries/circulaire-407-2001-04-26_tcm291-27203.pdf (FR) and http://www.fagg-afmps.be/nl/binaries/ozb-407-2001-04-26_tcm290-27203.pdf (NL).

3. Generalities

3.1 Definition of «healthcare professionals»

- In the specific scope of this regulation, the persons qualified to prescribe or deliver medicinal products, that is to say:
  - Physicians.
  - Dentists.
  - Pharmacists.
  - Veterinarians (not concerned by this presentation).

- Advertising intended for nurses must respect the provisions concerning the advertising intended for general public.
  BUT nurses are well concerned by the regulation « premiums and advantages » in article 10 of the law of 25.03.64 on the medicinal products.

3. Generalities

3.2 Authorized promotional mediums

- Cfr document “Regulations regarding advertising for medicinal products for human use - General dispositions”.

- Nevertheless some differences with the advertising to the public:

  - Advertising by fax, e-mail and mailing is authorized if requested by the addressee. But e-mail concerning patients data may not be interrupted by advertising for medicinal product.
  - Advertising in prescription books is authorized.
  - Advertising in folders in publications is authorized.
  - Advertising in software is authorized.
  - Advertising in software processing patients medical files is forbidden.
  - Scientific studies and information by audiovisual or electronic ways without the intention of promoting the sale or prescription of medicinal products may not be interrupted by advertising for medicinal products.

4. Written advertising

4.1 Requirements about the content of a written advertising (1/3)

- All the elements of the advertising must comply with the SPC.
- The advertising must further the rational use of the medicinal product by an unbiased and not misleading presentation of the medicinal product.
- All the elements of the advertising must be exact, updated, verifiable and sufficiently complete. So must the professional be able to get a personal idea of the therapeutic value of the medicinal product.
- The advertising contains at least:
  - Some essential information about the medicinal product.
  - The status of delivery of the medicinal product.
  - The public selling price of each packaging.
  - Date of creation or of last revision of the advertising.

4. Written advertising

4.1 Requirements about the content of a written advertising (2/3)

Details of the “essential information” that must appear:

- Name of the medicinal product.
- Qualitative and quantitative composition in active substances.
- Pharmaceutical form.
- Section indications of the SPC.
- Section posology of the SPC.
- Section contraindications of the SPC.
- Section undesirable effects of the SPC (of the PIL/labelling if homeopathic medicinal product).
- Name of the MA holder.
- MA/Registration number.

4. Written advertising

4.1 Requirements about the content of a written advertising (3/3)

- Quotations, tables, … from medical journals or books should be exactly reproduced and the source mentioned.
- If reference is made to elements of a study which are approved in the scope of the MA/registration :
  - Either it concerns a study which appears in the MA/registration file.
  - Or it concerns a study which does not appear in the MA/registration file but which has been realized in accordance with the data contained in the approved SPC and confirms data already approved. In this case, the study has been published in a peer review magazine.
- The original text of the publication or study must be provided to the professional who has requested for it.
- Reference to publications, studies reporting data not approved during the MA/registration is forbidden (ex: not approved indication)

4. Written advertising

4.2 Requirements about the form of a written advertising (1/3)

- The advertising must form a whole.
  Ex: “teasing” advertising using several advertising inserts
  is not compatible with this provision.

- The “essential information” (see slide with point 4.1 (2/3)) must cover at least 50% of the total surface of the advertising.

- The public selling price of each marketed packaging must appear:
  - in bold against contrastive background
  - at the top right of the advertising
  - covers at least 0,50% of the total surface of the advertising.

- The “essential information”, the status of delivery of the medicinal product and the public selling price of each packaging must be perfectly readable.

4. Written advertising

4.2 Requirements about the form of a written advertising (2/3)

Importance of the readability of the mandatory content in advertising :

- cfr circular 407 of 26.04.2001.
- Recommendations:

  - Minimal character size: 9 points Didot.
  - Line spacing of at least 2 mm.
  - Characters against a contrastive background. Avoid a text's color with same component than in background's color (Ex: yellow ←→ orange).
  - To highlight the titles and subtitles.
  - To avoid to cut titles and subtitles.
  - To avoid to cut sentences by pictures, …
  - To respect the reading direction of the announcement.

4. Written advertising

4.2 Requirements about the form of a written advertising (3/3)

Importance of the readability of the mandatory content in advertising :

- Recommendations (especially on newspaper):

  - Characters should never be condensed if :
    - the original character's type is condensed (Ex: condensed Futura)
    - the original character's type is light (Ex: Futura light).
  - A character's type 'medium' could be condensed, but maximum 80%.
  - Color used should be a 100% color.
  - To avoid a background with color's gradation.
  - Color of a picture in the background should be toned down (at least 50 %).
  - To avoid the reduction of the size of an announcement (Ex: to avoid reduction A3 ➔ A4).

5. Reminder advertising

Defined as an advertising with the exclusive aim to remind the name of a medicinal product.

- Besides the name of the medicinal product, the eventual mention of:
  - the INN of the medicinal product;
  - the name and logo of the MA holder;

  is also acceptable.

- Other mentions as well as elements (EX: photo, pictogram, sign) giving information about the properties and indications of the medicinal product are forbidden.

6. Advertising by medical delegates (1/2)

The medical delegates:

- Are appropriately trained by the company.
  - Training at the time of first appointment.
  - Periodic updates of the knowledges.

  ! Think about the registration of the trainings for eventual control by the FAMHP!

- Have sufficient scientific knowledge to give the correct and as full as possible information about the medicinal products that they promote.

- Hand over to the visited professional (or put at his disposal) the SPC of the presented medicinal products.

- Hand over to the visited professional (or put at his disposal) the public selling price of each marketed packaging of the presented medicinal products.

6. Advertising by medical delegates (2/2)

The medical delegates:

- Hand over the technical dossier to the practitioner who has requested for it.
  The technical dossier contains promotional elements used orally by the delegates, other than the SPC and the price, but which have been approved during the MA/registration.

- Report to the responsible for information any data collected from the practitioners concerning the use of the medicinal products that they promote (ex: data pharmacovigilance).

7. Advertising on booths (Ex: congress for professionals)

- Advertising for medicinal products made on booths must be in accordance with the regulation.
- The breach sometimes encountered by the FAMHP during controls on congress is the lack for the mandatory essential information from the SPC of the promoted medicinal products (see slide with point 4.1 (2/3))
  - Promotional materials (Ex: leave behind, folder) that the participants can take away on the booth must contain this essential information.
  - For practical reasons, it may be accepted that advertising on boards, posters or screens on the booth does not directly mention this essential information. BUT in this case, the essential information is nevertheless available on an other medium on the booth (Ex: folder, sheet of paper).
- Reminder advertising is authorized (see slide with point 5).
- On request of participants, the SPC of the medicinal products must be handed over.

8. Control and sanctions

8.1 Types of control (advertising for professionals and general public/ information campaigns / samples)

- Internal control inside the company by the responsible for information concerning all advertising and information campaigns spread by the company and concerning the supply of samples.
- "A priori" control by the FAMHP concerning:
  - Advertising and information campaigns intended to the general public, on TV and radio : by the visa procedure.
  - Advertising intended to the general public, on other medium than TV and radio : by the notification procedure.
- Other controls performed by the FAMHP:
  - Follow-up of complaints.
  - Planned controls of advertising spread in retailed pharmacies and in the general press.
  - Planned controls of advertising in the professional press.
  - Planned controls of advertising on booths during congress.
  - Planned inspections in companies.

8. Control and sanctions

8.2 Sanctions (advertising for professionals and general public/ information campaigns / samples)

- The enforcement authority (FAMHP) may :
  - Give warnings.
  - Fix delays to the offender to straighten him out.
  - Make reports leading to either administrative fine or transmission to the judicial authorities.

- Amount of an administrative fine:
  - Infringement of article 9 of the law of 25.03.64 and RD 7.04.95 : Minimum 1.100€ and maximum 82.500€.
  - Infringement of article 12 of the law of 25.03.64 and RD 11.01.93 : Minimum 550€ and maximum 5.500€.

8. Control and sanctions

8.3 Other sanctions (1/2)

- The Minister or his representative may:
  - Order the discontinuation of an illicit advertising / information campaign.
  - Forbid the diffusion of an illicit advertising / information campaign (if not yet diffused).
- In case of an illicit advertising / information campaign persistance in spite of ban, the Minister or his representative may:
  - Require the publication of the decision banning the advertising / information campaign.
  - Require the publication of a rectification.

If it concerns an advertising / information campaign spread on TV or radio, the Minister or his representative takes these measures following the advice of the Commission of Control of Advertising of Medicinal Products.

8. Control and sanctions

8.3 Other sanctions (2/2)

- In case of an illicit advertising / information campaign spread on TV or radio, the Minister may withdraw the visa following the advice of the Commission of Control of Advertising of Medicinal Products.

  In case of emergency, the Minister may suspend the visa for 3 months without prior consulting of the Commission of Control of Advertising of Medicinal Products.

- The Minister may suspend the inscription of the responsible for information on the list of authorised responsibles following advice of the Commission of Control of Advertising of Medicinal Products.