Guide for the advertising of medicines for human consumption aimed at the public

From the Ministry of Health and Consumer Affairs and specifically the General Directorate of the Basic Portfolio of Pharmaceutical and SNS (the Spanish Health System) services. June 2019.

This is an unofficial and non-binding GRS translation of the key sections 2.1–2.3 and chapters 3 and 4 of the document described above. We have not translated the introduction/ presentation, definitions and legal framework, or the annexes. The original document in Spanish is linked immediately below.

https://www.sanidad.gob.es/areas/farmacia/publicaciones/guiaPublicidad/docs/Guia_Public_Mtos_Uso_Humano_Publico_junio_2019_2.pdf

2.2. GENERAL PRINCIPLES OF ADVERTISING REGULATION

a) Principle of legality. Advertising must respect current legislation and especially the values, rights and principles recognised in the Constitution.

b) Principle of social responsibility. The advertising message will not imply any form of discrimination, nor incite violence, nor will it encourage Illicit, illegal or socially irresponsible behaviours.

c) Principle of truthfulness. All the message content must be able to be properly substantiated and, in the case of medicines, comply with the competent authority's authorisations.

The design and presentation of the advertising execution must be clear and easy to understand by the consumer to whom it is directed. When written notes feature, they must appear in a font size sufficient to be easily legible.

d) Principle of honesty. The advertising message may not be conducted in terms that imply an abuse of consumer trust or exploitation of their lack of information, inexperience, fears or superstitions.

e) Principle of objectivity. Advertising must contain precise, balanced, honest and objective information and be sufficiently complete for the recipient to make the most appropriate choice for their needs.

2.3. SPECIFIC PRINCIPLES OF ADVERTISING MEDICINES FOR HUMAN USE DIRECTED TO THE PUBLIC

Medicine advertising must be governed by **all general principles** established in point 2.2. of this Guide, as well as others more specific that are included in the legislation currently in force on this matter, such as:

a) Appropriateness of the message content. All elements of the advertising of a medicine must comply with the information that appears in the technical sheet or, failing that, in the authorised leaflet.

b) Promotion of the rational use of medicines. Medicines advertising must in any event foster their rational use, presenting it objectively and without exaggerating their properties.

c) Principle of commitment to health: medicines advertising will respect the following rules:

- if it refers to components of other legally authorised preparations, it will not highlight their absence or imply that they are less safe.

- general characteristics that similar medicines meet or should meet will not be ascribed as exclusive.

- It will not be based on recommendations or testimonies from health professionals, nor will it encourage considering their consultation as superfluous.

- it will not contain statements or illustrations that ensure a cure, arouse apprehension or fear of suffering from a complaint of greater magnitude than the one suffered or of contracting it by not using the advertised preparation, nor will it imply that a normal state of health can be improved by using of the product.

- it will never be directed at children under 16 years of age, nor will it suggest or recommend that the product be administered to them, unless the marketing license of the product and its registration expressly authorise it.

- it will not suggest that the worth or safety of the product or preparation derives from being a natural product.

3. REQUIREMENTS FOR ADVERTISING MEDICINES FOR HUMAN USE ADDRESSED TO THE GENERAL PUBLIC

3.1. GENERAL REQUIREMENTS

All medicine advertising intended for the public must comply with the following general requirements:

a) Be conducted in such a way that the advertising nature of the message is evident and it is clearly specified that the product being advertised is a medicine.

b) Contain the identifying data and recommendations determined by the Ministry of Health, Consumer Affairs and Social Welfare to avoid their abuse and prevent risks derived from their normal use.

c) Include the information essential for the correct use of the medicine and, at minimum:

- the name of the medicine, as well as the Spanish Official Name (DOE) or, failing that, the International Common Name (INN), or the normal or scientific common name when the medicine contains a single active substance.

- an express and clearly visible request to read carefully the instructions that appear on the package leaflet or on the external packaging, as the case may be, and the recommendation to consult the pharmacist about its correct use.

d) Include in the advertising message, as a mandatory requirement, the following text: "Read the instructions for this medicine and consult the pharmacist." *(Lea las instrucciones de este medicamento y consulte al farmacéutico)*

e) All information included in medicine advertising must be legible and noticeable, paying special attention to the size of the font, its contrast with the background and the length of time the message lasts.

3.2. REMINDER ADVERTISING

a) Advertising of a medicine intended for the public may include only its name, or its INN or DOE, whenever it exists, or the trademark, when its sole objective is to remember said name.

b) Optionally, in addition to the name /trademark of the medicine, the name and logo of the laboratory, the logo of the medicine (colours, font type, symbols and/or elements that contribute to the identification of the brand) and a phrase such as "if in doubt, consult your pharmacist" or a similar expression.

c) Reminder advertising does not permit the inclusion of images, slogans or other advertising elements.

d) A medicine may be eligible for reminder advertising when it is sufficiently known by the public and has conducted promotional campaigns for at least two years, or if for less time, it can be demonstrated that it is sufficiently known by the public, based on the impact of campaigns.

e) Reminder advertising of several medicines in the same medium is permitted.

3.3. PROHIBITIONS

Advertising of a medicine intended for the public may not include any element that:

a) Attributes superfluity to medical consultation or surgical intervention, especially by offering a diagnosis or advising treatment by correspondence.

b) Suggests that its effect is assured, that it has no side effects or that it is superior to or equal to that of another treatment or another medicine.

c) Suggests that the user can improve his or her health through its use, or it may be affected if not used. This last prohibition will not apply to vaccination campaigns regulated in Royal Decree 1416/1994. In particular, suggesting that the use or non-use of the promoted medicine generally improves or deteriorates health is prohibited, but this prohibition does not extend to references to the effectiveness of the medicine in relation to the specific therapeutic indication for which it is authorised.

d) Suggests or indicates that its use enhances sports performance.

e) Is directed, exclusively or mainly, to children.

f) Refers to a recommendation made by scientists, health professionals or other people who may, due to their notoriety, encourage the consumption of medicines.

g) Equates the medicine to a food product, a cosmetic product or any other consumer product.

h) Suggests that the safety or effectiveness of the medicine is due to it being a natural substance.

i) Can encourage, via a detailed description or representation of the anamnesis (medical history), a false self-diagnosis.

j) Refers in a distressing, alarming or misleading manner to healing testimonies.

k) Uses in a distressing, alarming or misleading manner, visual representations of the alterations of the human body caused by diseases or injuries, or of the action of a medicine on the human body or parts thereof.

3.4. MANDATORY ELEMENTS THAT MUST APPEAR IN THE ADVERTISEMENT ITSELF

The following elements must always appear in the advertisement, in a legible font size and in a visible place:

a*) Name of the medicine*, and the active ingredient if it is a 'monodrug'.

b) *Name and/ or logo of the owning laboratory* (so long as it includes the name of the laboratory) the marketing authorisation for the medicine or its local representative in Spain.

c) *Authorised therapeutic indication*, including the age of the recipients if it is part of the indication.

d) *Contraindications, precautions and important warnings* incorporated until now and expanded hereinafter, as the case may be, and whose medicine contains:

- *Analgesics with acetylsalicylic acid (ASA), Ibuprofen, Naproxen and Diclofenac.* "Do not administer in case of gastroduodenal ulcer."

- *Analgesics for external use.* "Do not apply before "x" years, nor on wounds or mucous membranes" (the age will be specified as established in the medicine leaflet).

- *First generation antihistamines.* "Do not consume alcoholic beverages. If you feel drowsy, do not drive or undertake dangerous activities while taking this medicine."

- *Antihistamines for occasional insomnia.* "Do not administer to children under "x" years of age. Do not consume with alcoholic beverages. Take only before going to bed" (the age will be specified as established in the medicine leaflet).

- *Nasal decongestants administered nasally.* "Do not use in children under "x" years of age" and "Do not administer more than "x" days in a row without consulting your doctor" (the age and days will be specified, as established in the medicine's package insert).

- *Ocular decongestants administered via the eye.* "Do not administer in case of glaucoma", "Do not administer more than "x" days in a row without consulting your doctor" (the days will be specified as established in the medicine leaflet).

- *Drastic laxatives.* "Do not administer more than "x" days in a row without consulting your doctor" (the days will be specified as established in the medicine leaflet).

- *Antitussives, mucolytics and expectorants that include this contraindication in their technical specifications or leaflet.* "Do not take in case of respiratory failure or asthma."

e) *The message "Read the instructions for this medicine and consult the pharmacist"* in a legible font size. In media:

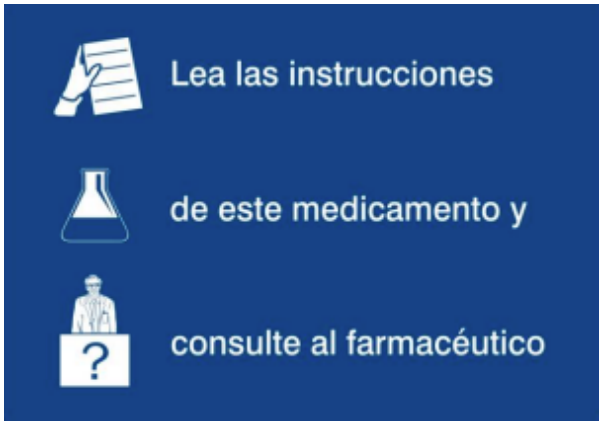
1) Print: it must be included in a visible place and in a font size legible and proportionate to the advertising text.

2) Audiovisual: 2a) Audiovisual commercials inserted in TV, cinema, internet and other videos: It will not be mandatory to express the contraindications, precautions and warnings defined in point 3.4.d), when the phrase "Read the instructions for this medicine and consult the pharmacist" *(Lea las instrucciones de este medicamento y consulte al farmacéutico) is* included. on a blue screen (figure 1) in line with the recommendations established in Circular 7/99 of the General Directorate of Pharmacy and Health Products of the Ministry of Health.

The screen will be inserted at the end of the advertisement. The phrase will be written and spoken and will remain on the screen long enough (at least 3 seconds) to be perceived by the recipient.

The printed characters will be written in Arial font, the measurement will be at least 34 points (pixels) for TV or its equivalent measurement in other audiovisual media, and the screen will have a blue background *Pantone Reflex Blue* and on it, and in the following order, the pictograms with their message will appear. During the blue screen display, no visual or audio advertising element that distracts the consumer's attention may be included.

Figure 1. Blue screen



2b) Radio. It will not be mandatory to express the contraindications, precautions and warnings defined in point 3.4.d), when the phrase "Read the instructions for this medicine and consult the pharmacist" *(Lea las instrucciones de este medicamento y consulte al farmacéutico)* is included at the end of the commercial. The voiceover duration will be at least 3 seconds and during its course no other audio advertising element that distracts the consumer's attention may be included.

2c) TV sponsorships: It will not be mandatory to express the contraindications, precautions and warnings defined in point 3.4.d), when the blue band (figure 2) is included at the bottom of all the scenes of the advertisement.

Figure 2. Blue band

3.5. SPECIFICATIONS FOR MEDIA / ADVERTISING EXECUTIONS

a) Television sponsorships: sponsorships in audiovisual communication services, linear and non-linear, conducted for medicines advertised to the public must ensure compliance with the legal requirements established for television sponsorships and for the advertising of medicines directed to the public:

1) Regarding sponsorships (Law 7/2010 of March 31 on General Audiovisual Communication and Royal Decree 1624/2011, approving the Regulation implementing General Act 7/2010 on Audiovisual Communication, in relation to television advertising;

- indicating the sponsorship at the beginning of the program, at the beginning of each resumption after intervals or at the end of it and
- identifying the sponsor verbally, visually or both
- the duration of the sponsorship may not exceed 10 seconds
- purchase should not be directly encouraged, in particular via specific promotional references to the products
- Advertising or promotional messages, telesales, excerpts from advertising or telesales messages, characteristics and presentation elements similar to advertising or telesales messages will not be permitted as sponsorships.

2) Regarding medicine advertising, it must include:

- the name of the medicine
- active ingredient (if it is a single drug)
- authorised therapeutic indication
- age (when it is part of the authorised indication)
- titular laboratory
- blue band with the message "Read the instructions for this medicine and consult the pharmacist"

If any of this information does not appear on the medicine's pack in the advertising execution or it is not legible, it will be

included in an overprint on the advertising execution in the smallest and least invasive way possible.

Compliance with these conditions and those established in article 12 of Royal Decree 1624/2011 means that sponsorship is excluded from the calculation of the 12 minutes per clock hour allocated to commercial communications.

b) Audiovisual media: Article 80.2.f) of Royal Decree 1/2015 establishes that advertising messages for medicines that are broadcast in audiovisual support must comply with the accessibility conditions for people with disabilities established in the legal system for institutional advertising.

c) Cubes (cubos): All mandatory elements must appear on two consecutive faces of the cube to ensure their visibility by the consumer. *Explanation of Cubos here*

d) Digital Media:

Given the interactivity and relationship of content that digital media allow, special attention must be paid to the context in which the advertising is placed, so that it is coherent and ethically correct and does not create confusion for the consumer about the true nature or purpose of the advertised product or about the advertiser.

1) Web pages

Pages or tabs where only medicines appear may include the blue band with the message "Read the instructions for this medicine and consult the pharmacist."

In addition, it must be understood as intended for the public in Spanish territory, for example, using the .es domain, or including some reference to the fact that the page is in Spanish or that these are medicines authorised in Spain and/ or that the advertising is directed to the public resident in Spain.

2) Mobile applications

The application screens in which only medicines appear may include the message "Read the instructions for this medicine and consult the pharmacist" placed in the blue band or screen.

3) *Banners, posts,* ads on social networks, and other ads in digital media

These may include the message "Read the instructions for this medicine and consult the pharmacist" in the last bullet of the sequence inserted in the blue screen or band or, alternatively, the message in the blue band may be placed in all the bullets.

The transition between the scenes must be such that it allows the readability of the contents of the advertisement, while at the same time not discouraging the reading of the complete advertisement, preventing the user from giving up reading.

4) Advertisements in digital media with limited space *(microbanners, tweets,* SEM, etc.)

As stated in Law 3/1991 on Unfair Competition, in the event that there is a limit of space or time to include all the mandatory information in advertising, the measures adopted by the advertiser to convey the information by other means will be considered and to this end, in the case of medicine advertising aimed at the public, the advertisement may include only:

- the name of the medicine
- the authorised indication
- the message "Read the instructions for this medicine here and consult the pharmacist" *(Lea aquí las instrucciones de este medicamento y consulte al farmacéutico)* in which the word 'here'/ aqui will include a direct link (with a single click) to the medicine's leaflet where you can consult the rest of the mandatory information in advertising of medicines aimed at the public (laboratory owner, age if it is part of the indication and active ingredient if the medicine is a single drug) or to a medicine's advertising in which all the information appears. This message will be inserted on the screen or blue band whenever the format permits.

Users must clearly understand that the rest of the mandatory information related to the medicine is included in said link.

In the case of SEM (search engine) ads, since the advertising is identified with the word "Ad" and there is an obvious character limitation, the following only may be included:

- the name of the medicine
- the authorised indication
- a statement that the advertised product is a medicine
- direct link (with just one click) to the drug leaflet where you can consult the rest of the mandatory information in drug

advertising aimed at the public (owner laboratory, age if it is part of the indication and active ingredient if the drug is a single drug) or to an advertisement for the medicine in which all this information appears, for example, the medicine's website.

Users must clearly understand that the rest of the mandatory information related to the medicine is included in said link.

4. INFORMATION ON ADVERTISING ACTIVITIES

In accordance with the provisions of article 21.b) of Royal Decree 1416/1994, of June 25, which regulates the advertising of medicines for human use, obligations of the laboratory that holds the marketing authorisation for a medicine are:

- Sent to the Ministry of Health, Consumer Affairs and Social Welfare, General Directorate of the Basic Portfolio of SNS Services and Pharmacies, Information Area for Professionals and Advertising of Medicines, an annual table of all the advertising activity carried out in the year (see annex 1). The submission of the annual activity table must be made during the month of January following the reference period.

II. CODE OF GOOD PRACTICE ON ADVERTISING MEDICINES AIMED AT THE PUBLIC

1. OBJECTIVES

The code of good practices on advertising of medicines aimed at the general public intends to establish principles, criteria and recommendations in order to be an instrument that facilitates and encourages compliance with best practices in advertising for these non-prescription medicines aimed at the public.

For its development, both the general principles of advertising and the specific principles on medicines indicated in different sections of the first part of this Guide have been taken into account.

On the other hand, this code aims to ensure that the information transmitted about the type of medicines that qualify for advertising aimed at the public, contributes to the citizen's rational and appropriate use of them, while attempting to facilitate truthful and efficient communication of the attributes and characteristics of these medicines.

2. ADVERTISING MESSAGES

The transmission of information on medicines must be precise, balanced, honest and objective, being complete enough to allow the citizen to judge for himself/ herself the therapeutic value of the medicine in a language understandable to him/ her, and must not create confusion by distortion and omission.

For a better understanding of this point, the recommendations to be taken into account from different approaches to advertising executions have been segmented.

This section is divided into the following headers

2.1. Medicine related

2.2. Text related

23. Related to childhood and gender

2.4. Related images and musical elements

2.1. MEDICINE RELATED

a) Adhere to the technical specifications of the medicine authorised by the Spanish Agency for Medicines and Health Products, avoiding technical terms incomprehensible to the average consumer, and, where appropriate, to the authorised leaflet.

b) When graphic information about the dosage is included in the advertising execution, the amount of medicine corresponding to the dose per intake unit stated in the package insert must be shown or, by exaggeration, the complete primary packaging (e.g. 1 tablet, if the dosage is 1 tablet/ 8 hours, or the entire blister).

c) In the case of general indications (never specific), the activity may be stated (as long as it is understandable by the consumer) instead of the indication, as long as it is short texts or advertising executions with limited space and exclusively adjusted to authorised indications (e.g. antiseptic, anaesthetic).

d) Highlight the occasional occurrence of certain conditions that can occur chronically: insomnia, occasional constipation

(e.g. including phrases such as “sometimes”, “when I have”, “if you have” ...).

e) Possibility of including references to the speed of action of the medicine in the case of those medicines whose speed is calculated from the technical sheet, or failing that, from the authorised leaflet. The time of onset of action or that they have been galenically formulated to obtain a faster effect may also be referenced as long as it is stated in the technical sheet or leaflet.

f) The place of action of the medicine must correspond to reality. It is appropriate to use phrases such as “acts at the focus of pain” (for topical analgesics, *i.e. those applied to body surfaces*), “action at the centre of pain” (for oral analgesics) or in both cases “relieves at the point of pain/ relieves where it hurts.”

g) Reference to the specific properties of the active ingredient is permitted, as long as they are related to the authorised indication. advertising of the medicine and are specified in its leaflet or technical sheet, and as long as they are understandable to the consumer.

h) Characteristics of the medicine related to the pharmaceutical form, the galenic form or the presence of any excipient *(inactive substance)* may be mentioned, as long as they are duly justified (e.g. viscous, soft, cold effect, heat effect, etc.).

i) Possibility of mentioning the popular name of a certain active ingredient, provided that the DOE is included in the message and this name contributes to a better understanding of the advertising message by citizens (e.g. “vitamin C” in instead of ascorbic acid, “glycerine” instead of glycerol).

j) The advertising message can be focused on one of the authorised indications for the medicine and/ or on one of the target groups for the treatment (e.g. “analgesic for back pain or menstrual pain in women"). In the case of associations, the symptoms relieved by each active ingredient in the association must be mentioned (e.g. e.g. "flu shot for fever/pain, nasal congestion and cough").

k) Advertising materials that consist of a reproduction of the medicine packaging (the “dummy medicine packaging”) must represent the packaging as authorised. Furthermore, in cases where the authorised packaging does not contain all of the mandatory information, the fictitious packaging must include a tab or similar in a visible area that contains the rest of the mandatory information, as well as the message "Read the instructions on this medicine and consult the pharmacist.”

l) Comparative advertising between medicines will be admitted as long as the comparison is carried out objectively between one or more essential, relevant, verifiable and representative characteristics of the same. As an example, and depending on the particular circumstances of each case, comparisons between the composition, dose, indication, dissolution, means of administration etc. could meet the requirements set out above.

m) Advertising may under no circumstances suggest that the effect of the medicine is superior to or equal to that of another treatment or other medicine.

n) Self-comparison made between medicines from the same company will not be considered comparative advertising for the purposes of the point under l).

o) In advertising executions for nicotine replacement treatment to help quit smoking, willpower must always be included legibly.

p) Only advertising with the appearance of a game that is not likely to trivialise the use of a medicine (e.g., making it similar to a consumer product) will be permitted and provided (i) that it is not directed, exclusively or primarily, to children and (ii) it is justified in a context that supports health education, or contributes to better knowledge of the condition or the medicine itself.

q) In combined advertising of medicines and other laboratory products, the nature (specifying the type of product: medicine, health product, cosmetic, food supplement, etc.) and purpose of each of the advertised products must be clearly identified. In the case of the medicine, the blue band/ screen will be understood to be information that concerns only it and, depending on the medium, it can be done in the following way:

- Audiovisual/TV: The medicine commercial will end with the blue screen; the other products may appear after it.
- Radio: The medicine commercial will end with the mandatory phrase and the other products may appear after it.
- Print media: the medicine information will appear boxed and on a different background. The blue band will appear at the base of the medicine box.
- Website/ mobile apps: different products may appear in different tabs, the tabs in which the medicine appears will have the blue band at the base.

If the products appear in the same tab, the medicine information will appear boxed and on a different background. The

blue band will appear at the base of the medicine box.

- *Banner:* if it is a sequential ad, the medicine ad will end with the blue screen and the remainder of the products may appear after it. If it is a static ad, the medicine information will appear boxed and on a different background. The blue band will appear at the base of the medicine box.

2.2. TEXT RELATED

All elements of the advertising of a medicine must comply with the information contained in its authorised technical information sheet and, if necessary, its authorised leaflet. The text of the advertising execution will be related to the authorised indication of the medicine and must not exaggerate its properties.

Some recommendations on the use of terms are set out below:

a) For the promotion of a medicine, the terms "safety" and "quality" may not be used alone or in combination; In any event, it is advisable to use the word "efficacy" *(eficacia),* provided that in the context it is understood to be linked to the condition for which the promoted medicine is effective.

b) Adjectives or absolute terms "maximum", "optimal", "perfect", "total" or similar should be avoided when they may exaggerate the properties of the product. *(máxima, óptima, perfecta, total)*

c) The terms "unique", "exclusive" *(único, exclusivo)* or similar may only be used when the advertiser can justify that it is a true and demonstrable fact and provided that it is not misleading or denigrating. Furthermore, the advertiser must remove said term from the advertising executions if it is no longer accurate. On the other hand, it is permitted to use the expression "the first", so long as it is true and demonstrable.

d) Testimonial statements can be made as long as they are not exaggerated. In them, a person (except health professionals or people of notable popularity) declares that the medicine is effective, they are doing well, etc.

e) The concept "new" can be included for a maximum period of two years from the newness date. To do this, the date on which newness was authorised will be taken into account and, in cases where it is justified, the moment when the consumer has had access to it (effective date of marketing of the new name, the new packaging, of the new medicine).

f) The use of the term "safe" *(seguro)* is not permitted, nor is it permitted to suggest that the medicine has no side effects. On the other hand, expressions such as "I trust in" or "it is effective for" may be used. *(confío en, es eficaz para.)*

g) A phrase referring to the clinical demonstration of the medicine's effectiveness may be included: "Like all medicines, xxxx® is clinically proven", or similar.

h) It is not recommended to use the term "pleasant taste" in isolation as a central element of advertising or in such a way that it is likely to mislead its recipients in relation to the nature of the promoted medicine (so that, for example, the medicine can be equated with a consumer product). It is more appropriate to use terms such as "pleasant strawberry flavour", "mint", etc., as long as it reflects the reality and does not constitute the central promotional claim.

i) It is permitted to include phrases such as "sugar-free", "lactose-free", "gluten- free" or "alcohol-free" in the advertising execution, as long as it is true, verifiable and relevant to the type of medicine being advertised and this information. does not represent the main point of communication.

j) Advertising may refer to the natural origin of the active ingredients of medicines as long as it is not suggested that the safety or effectiveness of the medicine is due to the fact that it is a natural substance.

k) Advertising of traditional herbal medicines will contain the following mention: "Traditional herbal medicine for use in specific indication or indications based exclusively on a long-standing use", or something else of similar meaning.

l) Colloquial phrases may be used to express a certain situation ("my whole body hurts", "I'm knackered", "I can't sleep a wink", "I'm sleeping like a log/ baby", etc.), as long as they are not misleading or rude. Advertising exaggeration is therefore permitted when it is understood by the consumer as such and always refers to the situation and not the effect of the medicine.

m) The phrases "don't forget", "have on hand", "carry", "try", etc., are appropriate in the case of medicines, which, due to their indication and dosage, make it necessary or advisable to have them available.

n) Advertising phrases or corporate slogans referring to pharmaceutical companies may appear in the advertising execution, provided that the slogan does not contravene the principles of medicine advertising.

o) Corporate advertising conducted by laboratories is not subject to the requirements of medicine advertising, as long as

it does not introduce elements that, directly or indirectly, can be considered advertising for specific medicines (e.g. elements that an average consumer identifies with specific medicine advertising campaigns).

The advertisement may include for information purposes an image or still with products from the laboratory, provided that it does not imply advertising of such products. So, for example, and among other measures, you must ensure that such images:

- have a secondary role in advertising
- are configured in such a way that an average consumer perceives them as a precise representation of the wide variety of products marketed by the laboratory (without being particularly identifiable or highlighted specific products or specific product ranges)
- and never include products that cannot be advertised to the general public

p) Statistical health-related data may be included in an advertising execution only if they are substantiated and duly documented by robust studies. The source and date of completion of said studies must be included in the advertising execution, and their results must be up to date at the time of the advertising.

q) The inclusion of market share data is acceptable, as long as it is accurate and verifiable. The data must appear referenced to the source and date of the study, be up to date, representative and from a reliable source (e.g. *"medicine xxxx number 1 in sales"*. [Name of the company carrying out the study] sales data in units of non-prescription antihistamines in Spain July 2017-July 2018*). ("medicamento xxxx nº1 en ventas". Datos [nombre de la empresa que realiza el estudio] ventas en unidades de antihistamínicos tópicos sin receta en España julio 2017-julio 2018).* This reference will appear in a visible place in the advertising execution and in a clearly legible size.

r) Medicines advertising will never suggest that the promoted medicine is not available in all pharmacies. Therefore, advertising may only contain references to specific pharmacy offices when it is via an exhaustive commercial listing and updated with all pharmacies in the area to which the advertising refers and the information source is specified, which must be reliable.

2.3. CHILDHOOD AND GENDER RELATED

a) Advertising executions for medicines (including those for paediatric use) must always be directed to the adult, who is the person who administers the medicine to the child.

b) In advertising executions in which children appear, the advertiser must take extreme care so that (i) either they belong to the age group for which the medicine is indicated, or (ii) the advertising never suggests that the child can consume the promoted medicine.

c) The content of advertising messages will not make reference to violent treatment, gender violence, aggressive attitudes, etc.

d) To avoid sexism or discrimination in the content of an advertising execution, the provisions of article 3a of the applicable Law 34/1988 General Advertising Law, will be observed.

In particular, it will be prohibited to present women in a humiliating or discriminatory manner through the following assumptions:

i. Using specifically and directly the woman's body or parts of it as a mere object unrelated to the product that is intended to be promoted.

ii. Using images of women associated with stereotypical behaviours that undermine the foundations of our legal system, helping to generate the violence referenced in Organic Law 1/2004, of December 28, on Comprehensive Protection Measures against Gender Violence.

iii. Trivialise or justify, in any way, behaviours or attitudes that imply any form of violence against women.

iv. Ridiculing, undervaluing or presenting women in any kind of professional capacity in a humiliating manner.

2.4. RELATED TO IMAGES and MUSICAL ELEMENTS

a) In medicines whose active ingredient is of plant origin, photographs, images or drawings of the plant species in question that contains said active ingredient may be shown.

b) Advertising exaggeration is permitted as long as it is understood by the consumer as such and always refers to the situation and not to the effect of the medicine (e.g. brazier on the seat of a chair depicting haemorrhoids or cactus outer

depicting itching of the skin, etc.).

c) The image of a pharmacist, or other health or scientific professionals, may be used, but the advertising execution may never suggest the recommendation of the advertised medicine by these professionals. This will be assessed on a case-by-case basis.

d) The image of people who, due to their profile, may encourage the consumption of the medicine, may not be used.

e) The image of the exterior of a pharmacy office may be featured, and if its interior or content appears, it must be shown blurred.

f) In images, the medicine cannot be compared to food or any other consumer product.

g) It is permitted to use the image of fruits (strawberry, orange) or leaves to represent the flavour/aroma of the medicine, as long as it is clear in the advertising that said images refer exclusively to the flavour/aroma of the medicine.

h) Images of organs may only appear illustrated or animated, but they can never be real.

i) Images must not refer to violence of any kind, humiliating treatment, dangerous behaviour or attitudes, etc.

j) The advertising execution will always suggest that there has been or there is a need to use the medicine for the condition for which the medicine is indicated, even in the case of medicines that are administered preventatively [e.g. vitamins (person who is toned and energetic), prevention of dizziness (happy child on a trip)].

k) People will decide to take/use the medicine of their own free will and may ask another person for it. In the case of children, it will be the adult who will decide whether it is appropriate to administer the medicine.

l) Musical pieces can be incorporated as background sound in audiovisual messages as long as their lyrics respect the criteria permissible in advertising and set out in this Guide.

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