Spain – AUTOCONTROL/ ANEFP Code 2020

La Asociación para el Autocuidado de la Salud (anefp). The Association for Personal Healthcare Code of ethical standards for the marketing, promotion and advertising of self-care medicines (authorised medicinal products that are non-prescription and not funded by the National Health System).

https://www.autocontrol.es/wp-content/uploads/2020/06/codigo-anefp-autocontrol_may2020.pdf

This is an unofficial, non-binding translation of the sections of the Code for non-prescription medicines advertising to the consumer. The code in its original form linked above also covers advertising in various forms to health professionals and some related processes etc; those provisions are not translated here.

INTRODUCTION

The Personal Healthcare Association *(anefp)* brings together and represents companies that manufacture or distribute different self-care products in the Spanish territory, including medicines - of synthetic or plant origin, and homeopathic – that are not dispensed or prescribed and are not within the pharmaceutical provision of the National Health System. These are medicines for which, in its different forms, advertising to the general public is permitted.

Similarly, *anefp* brings together, as signatories, those companies that provide services to the self-care pharmaceutical industry.

Anefp is a member of the European Self-Care Industry (AESGP), which in turn belongs to the World Federation of the Personal Healthcare Industry (WSMI), a non-governmental member of the World Health Organisation.

Anefp's statutory purposes include the formulating of recommendations and development of standards or guidelines to promote appropriate marketing, promotion and advertising of self-care products. In the exercise of these statutory powers of self-regulation, as well as the promotion of appropriate marketing of self-care products, *anefp* is aware of the need to have a truly effective Code of Ethical Standards, adjusted for current market circumstances, that provides the self-care industry with an essential tool for proper compliance with applicable regulations. *Anefp*, aware of the importance to its associates of responsible marketing and promotional activity, taking into account the nature of its products, and obligations to patients and consumers, has adopted this Code of Ethical Standards, which sets out general principles to ensure that the marketing, promotion and advertising activities of medicines not subject to medical prescription and not included in the pharmaceutical provision of the National Health System, which are aimed at both health professionals and the general public, are lawful and truthful.

Companies associated and affiliated with ANEFP, and signatories to this code, undertake to comply with ethical principles contained therein in their business activity, avoiding practices or initiatives that may be perceived as inappropriate, to safeguard both their image and that of the other associated companies.

The obligations undertaken by the members of ANEFP and by signatory companies, emanate from compliance with existing legislation that regulates non-prescription medicinal products, as well as general

regulation on advertising, consumer protection and competition.

In light of the above, the companies associated and affiliated with ANEFP, and signatories to the Code, undertake to promote and respect it.

1. PURPOSE OF THIS CODE

The Personal Healthcare Association (*anefp),* according to the articles of its association (its statutes), making use of its legal status and full capacity to act, and in its power of self-regulation, has adopted this code that i) constitutes a guide for the development of marketing activities and, in particular, in the field of the promotion and advertising of non-prescription and unsubsidised medicines ("MENOSREME"; *GRS note: Menosreme is an acronym for Medicamentos no sujetos a receta médica; non-prescription medicines)*; (ii) establishes a procedure for prior technical-health advice *("anefp seal"),* a joint procedure for granting the *anefp* seal and Copy Advice® (prior review) of the Association for the self-regulation of Commercial Communication (Autocontrol), (iii) establishes an internal mediation process for the resolution of conflicts that could arise between the affiliated companies; and (iv) establishes acceptance of the resolutions of the self-regulatory Jury in the event of a claim.

The provisions of this Code are fully adapted to and constitute a development from the applicable regulations, consisting, among others, of the following provisions and resolutions:

1) Treaty on the Functioning of the European Union.

2) Directive 89/552/EEC of the European Parliament and of the Council of 3 October 1989 on the coordination of certain laws, regulations and administrative provisions of the Member States relating to the provision of audiovisual communication services (as amended by Directive 2007/65/EC).

3) Directive 2006/114/EC of the European Parliament and of the Council of December 12, 2006, on misleading and comparative advertising.

4) Directive 2006/123/EC of the European Parliament and of the Council of December 12, 2006, relating to services in the internal market.

5) Law 14/1986 of April 26 on General Health.

6) Law 34/1988 of November 11 on General Advertising.

7) Law 3/1991 of January 10 on Unfair Competition.

8) Law 41/2002 of November 14 on basic regulation of patient autonomy and rights and obligations regarding clinical information and documentation.

9) Royal Legislative Decree 1/2007 of November 16, which approves the consolidated text of the General Law for the Defence of Consumers and Users and other complementary laws.

10) Law 7/2010 of March 31, General Audiovisual Communication.

11) Royal Legislative Decree 1/2015, of July 24, which approves the consolidated text of the Law on guarantees and rational use of medicines and health products.

12) Royal Decree 1907/1996 of August 2 on advertising and commercial promotion of products, activities or services with intended health purposes.

13) Directive 2001/83/EEC, of the European Parliament and of the Council, of November 6, 2001, establishing a community code on medicinal products for human use.

14) Royal Decree 1416/1994 of June 25, which regulates the advertising of medicines for human use.

15) Royal Decree 1345/2007 of October 11, which regulates the authorisation procedure, registration and dispensing conditions of industrially manufactured medicines for human use.

16) Royal Decree 870/2013 of November 8, which regulates the distance sale to the public via websites, of non-prescription medicines for human use.

17) Royal Decree 544/2016 of November 25, which regulates the distance sale to the public of veterinary medicines not subject to veterinary prescription.

18) Order of December 10, 1985 of the Ministry of Health and Consumer Affairs, which regulates advertising messages referring to medicines and certain health products.

19) Circular 6/1995, from the General Directorate of Pharmacy and Health Products of the Ministry of Health and Consumer Affairs, on clarifications to Royal Decree 1416/1994, of June 25, which regulates the advertising of medicines for human use. Amended by Circular 7/1999, of May 27, of the General Directorate of Pharmacy and Health Products.

20) Guide of the National Health System for the advertising of medicines for human use aimed at the public. General Directorate of Basic Portfolio of SNS Services and Pharmacy. Ministry of Health, Consumer Affairs & Social Welfare. Second edition. June 2019

21) Similar documents approved by the autonomous communities, such as the 'Guide for the advertising of medicines for human use from the Government of Catalonia'.

2. SCOPE OF APPLICATION OF THIS CODE

2.1.- This Code is applicable to all marketing, promotional and advertising activity of companies, in relation to MENOSREME *(Menosreme is an acronym for Medicamentos no sujetos a receta médica; non-prescription medicines)* or, in the case of affiliated companies, the services they provide in relation to such products

In particular, the provisions of this Code are applicable:

1) Subjectively:

a) to the laboratories and associated companies that in Spanish territory manufacture or distribute medicines – of synthetic or plant origin and homeopathic – non-prescription and not within the pharmaceutical provision of the National Health System (MENOSREME); such organisations are referred to as "associated companies."

b. to the entities or companies affiliated to the Association, which are referred to as "affiliated companies";

c. To companies and entities that, without being associated or affiliated to *anefp,* voluntarily decide to observe this Code, which organisations are referred to as "signatory companies".

For associated companies and those affiliated to *anefp,* observation of this Code will derive from the company's status of associate or affiliated member of *anefp.* For companies that are Code signatories, a specific act of affiliation signed by their legal representatives and those of *anefp* will be required.

From now on, the references contained in this Code to companies or organisations will be understood to include the three categories of associates, affiliates or signatories.

2) Objectively, to all marketing, promotion and advertising activities of the MENOSREME.

Membership of anefp, or affiliation and signatory to the Code, implies acceptance of its entire content; partial acceptance of its provisions or exclusion of any part of the Code is not possible.

The representative associations associated with *anefp* are excluded from the scope of application of this Code and, for their part, have mandatory Codes that for their associates or members.

2.2.- Companies that belong, directly or through their membership of a group of companies, to other associations or self-regulation systems, whose purposes or objectives coincide with any of the purposes provided for in the Anefp Statutes will be obliged in all cases to respect the provisions of this Code, even when they may conflict with those related to other self-regulation systems that may be applicable.

The companies associated or affiliated with *anefp,* and those who are signatories to the Code, with respect to the MENOSREME, will individually be responsible for potential breaches of the Code committed by third parties acting on their behalf, representing them or under their control, or in the context of a signed agreement (without limitation: external sales networks, market research companies, travel agencies, advertising agencies, etc.).

The companies affiliated to the Code will contribute to the operating and application expenses of the Self-Regulation System, via the established financial contribution.

2.3.- Companies may ask questions about the scope and applicability of this Code, or about a certain activity or commercial practice's applicability to the Code. Queries regarding the content of specific promotional material are excluded when these are governed by the *"anefp seal"* regulation.

Queries of general interest for the entire sector may be published at the discretion of the *Anefp* Board of Directors, with full respect for the confidentiality of the data of the consulting company or third parties.

3. BASIC PRINCIPLES OF THE CONDUCT OF *ANEFP* ASSOCIATED COMPANIES OR THOSE WHO ARE SIGNATORIES TO THE CODE

3.1. Promotion and advertising of MENOSREME products shall comply with the legislation in force at any given time regardless of its content, medium or form it takes. Specifically, promotion & advertising of non-prescription & unsubsidised medicinal products must contribute to the health education of consumers via dissemination of truthful, clear, appropriate, reliable information on the correct method of use, characteristics and therapeutic indications of the product.

3.2. The promotion and advertising of medicines will comply with the requirements of good faith and good commercial practice, regardless of its content, medium or form it takes.

3.3. With regard to the Code's provisions, companies must support and respect the guidelines and agreements reached mainly by the governing bodies of *anefp*.

3.4. All companies must comply with the priority objectives of *anefp*, among which is promoting and strengthening the market for authorised non-prescription medicines.

3.5. All companies must collaborate and ensure the defense of the interests of *anefp* in circumstances when it is necessary.

3.6. *Anefp* wishes to provide maximum collaboration to the health authorities, so all companies must collaborate with the Health Administration in the actions that arise from the agreements reached between it and *anefp*.

3.7. *Anefp* will ensure that the content of this Code is observed by all members of the Association and by

all signatory members, and will be responsible for ensuring that actions arising from non-compliance are resolved internally.

3.8. All companies undertake that in the event of disagreement with the actions of any other associate or adherent to the Code, all possibilities of resolution via internal mediation will be exhausted before resorting to other dispute mechanisms or systems.

3.9. For its part, *anefp* will ensure confidentiality in the treatment of matters that affect individual companies. In particular, *anefp* and mediating companies undertake to preserve the confidentiality of the processing of claims, their content and their outcome, avoiding disseminating any information without the express consent. of all parties involved.

3.10. Companies undertake that authorised non-prescription, unsubsidised medicines will not be used as a means to promote medicines that require a prescription.

3.11. Compliance with the provisions of this Code is understood to be without prejudice to the obligation of companies to comply with the applicable general and sectoral regulations. Companies will be solely responsible for its correct application and for observance and compliance with applicable regulations, without *Anefp* assuming any responsibility for the approval of this Code or its content.

4. GENERAL PRINCIPLES RELATING TO THE COMMERCIAL COMMUNICATION OF AUTHORISED NON-PRESCRIPTION AND UNSUBSIDISED MEDICINES

All commercial communications will take into account the following principles:

4.1. The principle of respect for citizens' fundamental rights

The advertising message may not violate the dignity of the person or violate the values and rights recognized in the Constitution.

Furthermore, no commercial communication may be made that abuses human dignity or encourages discrimination based on sex, race, ethnic origin, nationality, religion, belief, disability, age or sexual orientation, or that uses the image of the person in a distressing or discriminatory manner.

Similarly, commercial communication in any form that encourages behaviour harmful to people's health or safety is not permitted.

4.2. Principle of truthful commercial information and the prohibition of misleading advertising

In addition to compliance with general legal requirements in advertising matters, the recipients of the Code undertake:

1) Not to issue advertising messages that may mislead or deceive their recipients.

2) Not to omit fundamental data about products, activities or services in advertising when such omission misleads its recipients.

3) To hold sufficient substantiation, if required by the competent authorities or by *anefp,* of the content of the disseminated advertising messages.

4) To present advertising that is clearly identifiable as such for the consumer to whom it is directed. To this end, undertake that written notes are in an appropriate font size so as to be easily legible.

4.3. Principle of competitive integrity of advertising

Companies will carry out their advertising activities in accordance with the requirements of good faith and business integrity. To this end, they commit not to undertake the following unfair competitive

practices:

1) Practices that fail to deliver the requirements of good faith.

The behaviour of a company that does not display professional diligence, understood to be a standard of competence and particular care that may be expected of a business conducting itself according to honest market practices, that distorts or may distort significantly the economic behaviour of the average consumer or the average member of the practice's target group, if it is a commercial practice directed at a specific group of consumers, will be understood to be at odds with good faith requirements.

2) Deceptive acts

Any conduct that includes false information or information that due to its content, even if true, misleads or may mislead recipients and is likely to alter their behaviour, is considered unfair.

The omission or concealment of information necessary for the recipient to make or be competent to make a decision related to their behaviour, with due knowledge of the facts, is also considered unfair.

3) Acts of confusion

Any behaviour that is likely to create confusion with the products, product categories, services or advertising of third parties is considered unfair.

4) Acts of denigration

It is considered unfair to make or disseminate statements about the activity, performance, establishment or commercial relationships of a third party that are likely to undermine their status in the market, unless they are accurate, true and relevant.

5) Acts of misleading comparative advertising

Comparative advertising must meet the following requirements:

a. It may not suggest that effect is guaranteed or that it is greater than or equal to that of another treatment or other medicinal product.

b. The compared goods must have the same purpose or satisfy the same needs.

c. The comparison will be made objectively between one or more material, relevant, verifiable and representative characteristics of the goods, which may include the price.

d. The comparison may not be misleading, denigratory or exploit another's reputation.

e. The comparison will not be based on the information that a given product does not contain a component that is used in competitive products, creating the impression that said component is unsafe or harmful.

6) Acts of exploitation of another's reputation

The improper use, for one's own or another's benefit, of the rewards of the industrial, commercial or professional reputation garnered by another company in the market is considered unfair. Undue use may refer to advertising activity or any other commercial practice (e.g.: copies of packaging, other acts of imitation, etc.).

7) Acts of inducing contractual infringement

Any advertising aimed at inducing workers, suppliers, clients and others obliged to infringe the basic contractual duties contracted with competitors is considered unfair.

4.4. Principle of prohibition of subliminal and covert advertising

Advertising will not be undertaken or disseminated using techniques that produce stimuli that border with senses' thresholds or equivalent, which may have an effect on the target audience without being consciously perceived. (This is from the legal definition of subliminal advertising and is expressed in the original as *Publicidad que, mediante técnicas de producción de estímulos de intensidades fronterizas con los umbrales de los sentidos o análogas, puede actuar sobre el público destinatario sin ser conscientemente percibida.)*

Similarly, communications whose advertising nature is not recognisable may not be disseminated.

4.5. Principle of environmental protection

Advertising will not approve of or encourage behavior contrary to the existing laws and codes for the protection of the environment, nor to the basic rules governing responsible behaviour towards the environment.

5.- RULES FOR CONSUMER ADVERTISING FOR NON-PRESCRIPTION AND UNSUBSIDISED MEDICINES

5.1. General requirements

In line with regulatory provisions, advertising can only be undertaken for medicines that, having the relevant marketing authorisation:

1) are unsubsidised;

2) due to their composition and role, they are intended and designed for use without the intervention of a doctor carrying out the diagnosis, prescription or monitoring of the treatment, even if they require the intervention of a pharmacist, except in the case of vaccination campaigns approved by the competent health authorities;

3) do not constitute psychotropic or narcotic substances in accordance with those defined in international agreements.

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

1) Medicine advertising elements must be consistent with the information in the authorised technical sheet and, failing that, in the authorised leaflet.

2) Advertising of medicines must in any event highlight their rational use, presenting products objectively and without exaggerating their properties.

3) The advertising of medicines must be conducted such that the advertising nature of the message is evident and it is clearly articulated that the product being advertised is a medicine.

4) The advertising of medicines must contain the identifying data and recommendations established by the Ministry of Health to avoid their abuse and prevent risks arising from their normal use.

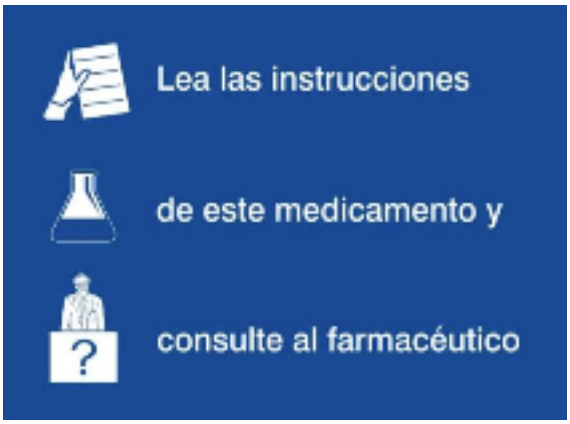
5) Medicines advertising must include the information essential for promotion of their rational use and, at minimum:

a. The name of the medication and the active ingredient, in the case of *a single drug.*
b. The name and/or logo of the laboratory that holds the authorisation of marketing or its representative in Spain.
c. Authorised therapeutic indication of the medication.
d. The *"Blue screen or band",* with the following text: *"Read the instructions of this medicine and consult the*

pharmacist." (*«Lea las instrucciones de este medicamento y consulte al farmacéutico»)*

This message must be adapted to the chosen medium, under the following terms:

- Audiovisual media: included on a blue screen with the recommendations established in current regulations. In the case of television, the message will be inserted at the end of the commercial, verbally and in writing, and will remain on the screen long enough (at least 3 seconds) to be perceived by the recipient.



- Internet (web *pages):* included in a blue band placed at the base of each of the screens on which the medicine's advertising information is displayed.

- Radio media. The voiced message will be inserted at the end of the commercial.
- Rest of the media: the phrase *"Read the instructions for this medication and consult the pharmacist"* must be included and placed at the base of the advertisement, presented in a font size proportional to the rest of the text of the message and the supporting information, in order to ensure its legibility.
- Print media: warnings must be included based on the active ingredients included in the SNS guide for advertising directed to the public of such medicines.
- If applicable, having the *"anefp seal"* respecting the graphic representation and dimensions defined in its internal regulations (see Annex IV to this Code), and its reference number.

6) Reminder advertising: when the sole objective is that the medicine is remembered, only the name or medicine trademark should be included. However, optionally a reference may be included to the name and/ or logo of the owner and logo of the medicine, as well as a phrase such as *"consult your pharmacist" ("consulte a su farmacéutico")* or similar.

It is considered that a medicine can carry out reminder advertising when it is sufficiently well known and has conducted promotional campaigns for at least two years or, in the event that it has been advertised for less than two years, it can be ensured that there is sufficient public knowledge of the medicine.

Reminder advertising may include several medicines in the same medium, as well as a reference to the commercial laboratory and the brand logo.

7) Sponsorship on television: must comply with requirements set out in Law 7/2010 on audiovisual communication; specifically:

a. That this is a sponsorship must be stated at the beginning of the programme, at the beginning of each resumption or at the end of the programme;

b. The identity of the sponsor must be stated verbally, visually or both;

c. It should not encourage purchase via product promotional references or selling messages;

d. It must not exceed the maximum permitted duration.

Advertising legislation requirements for non-prescription medicines must also be met; specifically:

a. The name of the medicine, active ingredient (single-drug), indication, age of the recipients, laboratory owner must be included in the advertising. This information must be included in an overprint, in the least invasive way, as long as it is not legible on the packaging;

b. The 'blue band' must be included in a clearly visible place.

c. If the sponsorship is in the form of reminder advertising, the advertising will only include the brand and, optionally, the laboratory and the blue band.

5.2. Prohibitions

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

1) Ascribes a superfluous quality to medical consultation or surgical intervention, in particular by offering a diagnosis or advising treatment by correspondence.

2) Leads to confusion regarding its administration and correct use.

3) Suggest 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. To this end, advertising will not offer a money-back guarantee on the product.

4) Suggests that the user can improve his or her health through its use, or that they may be affected by non-use; this last prohibition will not apply to vaccination campaigns. The communication will not include information that deliberately induces fear or apprehension of the suffering from a medical condition greater than that which is actually the case, or that suggests that such is experienced when the product in question isn't used.

5) Is directed, exclusively or mainly, to children, or may encourage use of the medicine by children without the supervision of parents, guardians or legal representatives. To this end, it will be presumed that advertising is directed mainly at children when it may capture the attention of minors in a significant way or is made for appearance in spaces, venues or places where the public audience is made up mainly in good measure by children.

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

7) Equate the medicine to a food product, a cosmetic product or any other consumer product.

8) Suggests that the safety or effectiveness of the medicine is because it is a natural substance.

9) May lead to, via a detailed description or representation of medical history, a false self-diagnosis.

10) Refers in an abusive, alarming or misleading manner to healing testimonies.

11) Uses in an offensive, 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.

5.3. Specific guidelines and recommendations for carrying out advertising aimed at the public

Advertising communications, in addition to meeting the requirements described in the previous sections, must observe the recommendations (those that refer to medicines, advertising copy, childhood and gender, images and musical pieces and media), included in the Medicines Advertising Guide. *(La Guía de publicidad de medicamentos; we assume that's the Ministry of Health document here):*

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

7.2. Direct promotion to the public

In accordance with existing regulations, the giving of gifts, premiums, bonuses, awards, discounts, competitions, or similar as methods linked to promotion to the public of these products, is not permitted.

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