DECISION

no. 27/11.10.2013

on approval of amendment to the revised version of the Guideline on assessment of advertising of medicinal products for human use, as approved through SCD no. 18/08.08.2013

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health No. 158/18.02.2013, reunited on summons of the NAMMD President in the ordinary meeting of 11.10.2013, in accordance with Article 12 (5) of Emergency Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, hereby adopts the following

DECISION

Sole article. - The amendment of the revised version of the Guideline on assessment of advertising of medicinal products for human use, as approved through SCD no. 18/08.08.2013 is approved, in accordance with the fragments highlighted in blue in the Annex, which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,
Acad. Prof. Dr. Leonida Gherasim

ANNEX
(SCD no. 27/11.10.2013)

GUIDELINE
ON EVALUATION OF ADVERTISING OF MEDICINAL PRODUCTS FOR HUMAN USE

CHAPTER I
Introduction, definitions, scope, provisions

SECTION 1
Introduction

Article 1. - The mission of the National Agency for Medicines and Medical Devices (hereinafter, NAMMD) is to contribute to the protection and promotion of public health. The NAMMD is the competent authority in respect of approval of advertising material and any other forms of advertising related to medicinal products for human use, according to provisions of Law no. 95/2006 on healthcare reform, Title XVII – The Medicinal Product.

Article 2. – (1) In all activities regarding medicinal product advertising, standards and regulations shall be defined and observed which would organise and regulate this activity.

(2) The entire activity concerning advertising and promotion of medicinal products shall be carried out responsibly, ethically and at the highest standards in order to ensure safe use of medicinal products, both in self-medication and in case of medicinal products administered under medical guidance and supervision.

Article 3. – (1) Medicinal product advertising for human use is only accepted provided compliance with legislation in force.

(2) This guideline aims at facilitating application of regulations in force by clarifying certain detail aspects, so that advertising for any medicinal product, irrespective of its form (in order to arouse consumers' interest) be at a high standard and observe legal provisions.

(3) Medicinal product advertising not include anything offensive or misleading for the consumer.

SECTION 2
Definitions

Article 4. – For the purposes of this Guideline, the following terms and concepts shall have the following meaning:

1. Administrative staff – decision-making staff in public and private healthcare institutions and members or chairpersons of medicinal product therapeutic commissions;

2. Adverse reaction – a harmful and unwanted response to a medicinal product, and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological functions;

3. Advertising agent/agency – any person (physical or legal) appointed by a pharmaceutical company to provide advertising services of any kind to its benefit, on the grounds of an agreement;

4. Advertising (promotional) material – any means used for advertising (promotional) purposes as defined by the concept of "promotion";

5. Common Name – the international non-proprietary name recommended by the World Health Organisation (WHO) or, if one does not exist, the usual common name;

6. Comparative advertising – any form of advertising explicitly or implicitly identifying the competition and/or comparative description;

7. Competent authority – the National Agency for Medicines and Medical Devices;

8. Educational material

a) material targeting the general public and/or healthcare specialists, which aims at target audience information on a certain pathology or medicinal product, used for scientific/educational purposes and not encouraging prescription, delivery, sale, administration, recommendation or consumption of the respective medicinal product;

b) Material as part of consolidated risk management actions and not subject to this Guideline (except for the manner of application submission and fee) shall not be considered educational material.

9. Essential information in the SmPC: minimum information in the summary of product characteristics necessary for a correct use of the medicinal product. This will generally include information in sections 1-4 and 6-7 of the Summary of Product Characteristics: indications, doses and method of administration, contraindications, warnings and cautions, as well as adverse reactions. Abbreviation or removal of information deemed unessential of these sections may be acceptable;

10. Generic medicinal product – medicinal product with the same qualitative and quantitative composition as regards the active substances and the same pharmaceutical form as the reference medicinal product and whose bioequivalence with the reference medicinal product has been proved by proper bioavailability studies. Various salts, esters, ethers, isomers, mixtures of isomers, compounds or derivates of an active substance are considered as the same active substance, if they do not present significantly different properties with respect to safety and/or efficacy. The applicant does not have to provide bioavailability studies, if he/she can prove that the generic medicinal product meets the relevant criteria as defined in the proper detailed guidelines;

11. Healthcare professionals - physicians, dentists, pharmacists and nurses;

12. Healthcare services – the totality of medical or pharmaceutical services accomplished by healthcare professionals in order to treat or prevent disease in humans.

13. Homeopathic medicinal product - any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia; a homeopathic medicinal product can contain number of active principles;

14. Medical events – planned scientific events, organised for healthcare professionals, initiated and organised locally, regionally, nationally or internationally, such as: congresses, symposia, round tables, workshops, classes, Advisory Boards (expert meetings);

15. Medical prescription – any medicinal product prescription issued by a person qualified to this purpose.

16. Medical representative – a person paying visits to healthcare professionals and appropriate administrative staff regarding promotion of medicinal products, such as but not limited to assigned sale managers, product managers, marketing managers etc.;

17. Medicinal product/Medicine:

a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

18. Medicinal product advertising (trade) – any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:

a) medicinal product advertising to the general public;

b) medicinal product advertising to persons qualified to prescribe or supply them;

c) visits by medical sales representatives to persons qualified to prescribe medicinal products;

d) supply of samples;

e) sponsorship of promotional meetings with participation of persons qualified for medicinal product prescription or supply;

f) sponsorship of scientific congresses with participation of persons qualified for medicinal product prescription or supply and in particular payment of travelling and accommodation expenses in connection therewith;

19. Misleading advertising – any form of advertising which, under any form, presentation included misleads or is liable to mislead any person;

20. Name of the medicinal product – the name assigned to a medicinal product, which can be an invented name not leading to confusions with the common name or a common or scientific name, accompanied by the trademark of the marketing authorisation holder;

21. On prescription medicinal product – any medicinal product for which the consumer shall provide a medical prescription for release to be performed;

22. OTC (over-the-counter) medicinal product – any medicinal product that is available without a medical prescription;

23. Pharmaceutical company – any legal person undertaking and carrying out any sort of activities in the pharmaceutical industry, whether or not a parent-company (for instance main office, control or company office), company subsidiary, branch or any other form of enterprise or organisation;

24. Promotion – it relates to any organised activity encouraging prescription, delivery, sale, administration, recommendation or use of medicinal products;

25. Reference medicinal product - a medicinal product authorised according to Article 700 and 702 of Law no. 95/2006 or a medicinal product authorised in one of the Member States of the European Union or by centralised procedure;

26. Reminder – a short advert meant for the target audience, which by exception from the common law in the field, may include the name of the medicinal product or the international non-proprietary name only, if any, the trademark of the medicinal product, the name of the company or image of the medicinal product. Reminders may only be used within a campaign and via the same communication channel where the full advertising material is presented according to legislation in force;

27. Representative of the marketing authorisation holder – person, usually known as "local representative", appointed by the marketing authorisation holder (MAH) for representation in Romania;

28. Risks related to use of the medicinal product:

a) any risk for the patient's or public health, regarding the quality, safety or efficacy of the medicinal product; and/or

b*)* any risk of unwanted effects on the environment;

29. Sample – medicinal product supplied on free of charge to healthcare professionals in order to become accustomed with the product and acquire experience with its use;

30. Serious adverse reaction - an adverse reaction which results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect;

31. Strength of the medicinal product – the content of the active substances expressed quantitatively per dosage unit, per unit of volume or weight according to pharmaceutical form;

32. Subliminal advertising – advertising using adverts whose beneficiary is not aware thereof, for instance expressed with a low acoustic intensity or displayed on a screen for a short period of time, no longer than a second;

33. Unexpected adverse reaction - an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics.

SECTION 3
Scope

Article 5. – (1) This Guideline regulates advertising of medicinal products for human use (whether original or generic medicinal products, on prescription medicinal products to healthcare professionals or OTC medicinal products).

(2) By "advertising activity" or "promotion", one understands any activity carried out, organised or sponsored by a pharmaceutical company (or by an advertising agency on its behalf by authorisation) resulting in encouragement of prescription, release, sale, administration or use of a medicinal product.

(3) This Guideline relates to promotion and advertising aimed not only at physicians, but also at all other healthcare professionals who, within their professional activities, can prescribe, supply, administer a medicine or encourage its sale, distribution or use.

Article 6. - This Guideline relates to all promotion methods, namely to those mentioned under Article 4 (21), as well as to visits from medical representatives accompanied by delivery of promotional material, advertising in newspapers or magazines, scientific publications, direct e-mail advertising, and other means of electronic communication (sites, web-pages, blogs, forums), use of audio-visual systems (such as films, video recordings, data storage services).

Article 7. - This guideline does not seek to limit or restrict supply of medical or scientific information to healthcare professionals or the public.

Article 8. - This guideline does not cover the following fields:

a) summaries of product characteristics, as provided by relevant legislation, labelling and patient leaflets of medicinal products, if not promotional in nature;

b) mail exchanges, possibly accompanied by material of non-promotional nature, in response to individual questions of healthcare professionals, only if exclusively related to the letter or the question subject and if not promotional;

c) general, non-promotional information about companies (such as information for investors or current/prospective employees), including financial data, descriptions of research and development programs and discussions on regulation affecting the company and its products.

Article 9. - This Guideline has been developed according to provisions of the following documents:

(1) Law no. 95/2006 on healthcare reform, Title XVII – The medicinal product, published in the Official Gazette of Romania, Part I, no. 372 of 28/04/2006, as amended, transposing Directive 2001/83/EC on the Community code relating to medicinal products for human use, published in the Official Journal (OJ) of the European Union no. L 311 of 28 November 2001, as amended;

(2) Law no. 148/2000 regarding advertising, published in the Official Gazette of Romania, Part I, no. 359/2000, as amended;

(3) Law no. 158/2008 regarding misleading advertising and comparative advertising, published in the Official Gazette of Romania, Part I, no. 559/2008;

(4) The Law of audio-visual no. 504/2002, published in the Official Gazette of Romania, Part I, no. 534/2002, as amended;

(5) The Audiovisual Code – Decision no. 220/2011 concerning the regulation of audio-visual content, published in the Official Gazette of Romania, Part I, no. 174/2011, supplemented through National Audiovisual Council no. 459/2011, published in the Official Gazette of Romania, Part I, no. 534/2011;

(6) The European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice on promotion of prescription-only medicinal products to, and interactions with healthcare professionals], adopted in July 2007 and updated in June 2011.

Article 10. – This Guideline applies not only to pharmaceutical companies *per se*, to their affiliated companies or representatives, but to other partners as well (agents, agencies, MAH representatives) with whom agreements are in place for conduct of the respective pharmaceutical company's advertising of any type concerning medicinal products thereof.

Article 11. – (1) Pharmaceutical companies and their representatives are responsible for compliance with this Guideline, even for activities contracted out to third parties (e.g. marketing contractors, consultants, market research companies, advertising agencies), such as promotional, advertising or implementation activities as well as involvement, on their behalf, in advertising activities subject to this Guideline provisions.

(2) Pharmaceutical companies shall ensure that any of the third parties to whom medicinal product advertising activities have been contracted out are compliant with provisions of this Guideline.

(3) Pharmaceutical companies and their representatives shall not be considered liable for promotional activities initiated by third parties outside a contract with the MAH/their representative, clearly stating a promotional activity as an object of the contract.

SECTION 4
Provisions

Article 12. - Medicinal product advertising means any type of organised activity aiming to provide information by direct/indirect means, as well as any type of promotion meant to encourage prescription, distribution, sale, administration, recommendation or use of one or several medicinal products for human use.

Medicinal product advertising may target healthcare professionals or the general public.

Article 13. – (1) Medicinal product advertising shall:

a) be accurate, balanced, unbiased, objective and contain enough information to allow the target audience to form their own opinion concerning the therapeutic value of medicinal product concerned;

b) be based on updated evaluation of all relevant evidence and clearly reflect such evidence;

c) encourage reasonable use of the medicinal product, by objective presentation without undue exaggeration of its properties and therapeutic qualities;

d) not encourage self-medication or the irrational use of the medicinal product;

e) not be misleading, subliminal or misleading by distortion, overstatement, unjustified emphasis, omission or in any other way etc.;

f) not suggest that a medicinal product/active ingredient has any particular merit, quality or property, unless supported by scientific data;

g) not be detrimental to respect for human dignity and public morals;

h) not include any form of discrimination based on race, gender, language, origin, social background, ethnic identity or nationality;

i) not be detrimental to any person's image, honour, dignity and private life.

(2) All information included in medicinal product advertising material shall be compliant with the information stipulated in the SmPC.

Article 14. – (1) As a general rule, advertising to the public is prohibited for the following categories of medicinal products:

a) medicinal products without a marketing authorisation valid in Romania;

b) medicinal products released on medical prescription only.

(2) a) Exceptionally, manufacturing companies or their representatives in Romania may disseminate clearly specified information (e.g. data on new medicinal products or new methods of administration of already authorised medicinal products, with potentially substantial impact on associated costs) to healthcare authorities or authorities in Board of Directors of Healthcare Institutions, such as, for instance persons in charge of establishing institutional budgets required for medium- and long-term planning of estimated healthcare costs.

Distribution of such material is to be performed specifically to the budget decision-making staff.

b) Likewise, manufacturing companies and their representatives in Romania may distribute relevant information when specifically requested by healthcare authorities.

Article 15. – Responsible parties:

(1) The MAH or their representative is responsible for the content of advertising/promotional material developed by the former for a given medicinal product.

(2) The MAH is also responsible for the training and conduct of medical representatives concerning use and distribution of advertising/promotional material.

(3) Apart from an existing contract with a third party, the MAH bears no responsibility with regard to the manner of distribution and use of promotional material.

(4) Pharmaceutical companies set up, internal training systems related to promotional material manner of use by their representatives in promotional campaigns.

(5) Within a company, final approval of all advertising/promotional material is delegated to a responsible person. Moreover, the NAMMD may request MAHs or their representatives to provide the names of the persons delegated for final approval of advertising/promotional material, as well as the names of their alternates.

(6) Although the main responsibility for ensuring compliance with regulations in force of all medicinal product advertising material lies with the MAH, other third parties may be responsible as well, who are involved in the manufacturing and distribution of non-compliant promotional material. This provision also enables sanctioning of third parties involved in the manufacturing and distribution process of non-compliant advertising material.

Article 16. Notification, submission for approval, evaluation and archiving of material:

(1) The MAH is required to submit for NAMMD approval all advertising material to the general public/patients and only place them on the market after grant of advertising approval.

(2) Advertising material for OTC medicinal products, as well as educational material for the general public/patients are subject to Article 16 (1).

(3) Advertising material is submitted together with the application form for assessment of the material and the payment form.

(4) Payment of evaluation fees is performed for each product and each communication channel for the respective advertising material.

(5) NAMMD assessment of advertising material is only commenced after confirmation of respective fee payment; assessment may result in either approval of advertising material submitted or request for their change.

(6) Requests for change or potential non-compliances are notified to the MAH or their appointed representatives, respectively, via e-mail.

(7) For compliance check reasons, when NAMMD approval is obtained for a changed proposal (from the one initially submitted), the MAH is required to submit a printed copy of the finally approved material (the actually marketed version) and another in unprintable electronic format.

(8) The NAMMD assesses advertising material for healthcare professionals, concerning on-prescription/non-prescription medicinal products after distribution, in a random manner or following complaints.

(9) MAH participation in medical events is notified to the NAMMD prior to the event.

(10) To check compliance, the NAMMD hereby establishes a 3-year period as a minimal mandatory period for archiving of advertising material by the MAH, for both printed material and electronic ones.

(11) The period mentioned under Article 16 (10) runs from date of the first use of the advertising material.

Article 17. – The main forms of advertising used in the pharmaceutical industry are as follows:

(1) Printed material (prints):

Such material is defined in Annex 1 to this Guideline.

a) scientific/promotional material for healthcare professionals;

b) advertising material for the general public;

c) educational material for patients and patient organisations/ associations;

d) posters, invitations;

e) reminding material (reminders);

(2) Audio-visual advertising (radio, television)

(3) Billboards or any other form of outdoor advertising or any other form of advertising using a different communication channel than pharmacies, medical practices, audiovisual media, written press, the internet;

(4) Advertising over the Internet (web pages, e-mail, forums, blogs or any other form of electronic support, except for social networks such as, for instance, Facebook and Twitter etc., or android mobile applications);

(5) Provision of samples;

(6) Promotional objects (relevant for medical practice).

CHAPTER II
Misleading and comparative advertising, encouragement of reasonable use, compliance with SmPC content

SECTION 1
Misleading advertising

Article 18. - (1) Misleading advertising means any form of advertising which, in any way, by presentation method includes, misleads or is likely to mislead any person it is intended for or makes contact with it.

(2) No form of advertising shall suggest that a medicinal product or an active ingredient has any special intrinsic worth, quality or property, if not scientifically documented. This is a general provision.

(3) In order to determine the misleading character of advertising, all its characteristics are considered, particularly such components as:

a) medicinal product characteristics (irrespective of their nature), the extent of their compliance with their intended purpose and outcomes expected from its use;

b) omission of essential information regarding identification and description of that medicine in order to mislead the target audience of the advertising in question.

c) accurately described information, likely to mislead because of the overall impression derived from their contradicting the respective therapeutic indications. Examples may include advertising material showing images related to driving when the respective medicinal product can affect the ability to drive vehicles.

SECTION 2
Comparative advertising

Article 19. - (1) Comparative advertising means any form of advertising explicitly or implicitly identifying a competitor by its comparative description. Any comparison between different medicinal products shall be based on relevant and comparable aspects.

(2) Comparative advertising for the general public is prohibited.

(3) Comparative advertising for healthcare professionals is prohibited if:

a) the comparison is misleading, according to the above-mentioned specifications;

b) the trademark of a competitor is used; only international non-proprietary names are allowed.

c) the comparison is made between/among medicinal products with different therapeutic indications or different pharmaceutical forms;

d) no objective comparison is made between/among essential, relevant, verifiable and representative characteristics of medicinal products, among which the price may also be included;

e) confusion arises in the market between the advertised company and a competitor thereof or between/among the various trademarks, international non-proprietary names or other distinctive marks of the advertised medicinal product and those belonging to a competitor;

f) a competitor's trademark, non-proprietary name, other distinctive marks, activities or any other characteristics are discredited or blamed;

g) a competitor's reputed trademark, international non-proprietary name, distinctive marks or any other characteristics are incorrectly taken advantage from, without evidence to support the advertiser's allegations.

SECTION 3
Encouragement of reasonable use

Article 20. - (1) Any advertising material shall encourage accurate and adequate use of the medicinal product. Therefore, it is compulsory that any advertising material include information regarding:

a) the recommended dose/administration pattern/specific administration instructions if any;

b) the exact indications of the medicinal product according to the SmPC;

c) special warnings and precautions according to the SmPC;

d) contraindications according to the SmPC.

(2) Any piece of information included in advertising material shall be supported by clear scientific reference, without exaggerations or extrapolations not scientifically substantiated. For instance:

a) advertising material for a medicine alleviating symptoms of a disease may not suggest that that medicine can cure the respective disease;

b) advertising material in which data of clinical trials results are not accurately presented or are taken out of context will be deemed as exaggerating the properties of that medicine.

SECTION 4
Compliance with SmPC content

Article 21. - (1) No advertising material shall promote use of the medicinal product outside the therapeutic indications listed in the SmPC approved for that medicine.

(2) No advertising material for a medicine shall promote its use by certain categories of patients for which there is no indication in the SmPC. (For instance, the presence of an infant's image in an advertising material for a medicine not recommended for infants represents a breach of this provision).

CHAPTER III
Advertising for healthcare professionals
General considerations, advertising forms

SECTION 1
General considerations

Article 22. – (1) Promotion of medicinal products is prohibited before grant of a marketing authorisation allowing for their sale or distribution.

(2) Promotion of medicinal products outside approved therapeutic indications is prohibited.

Article 23. – (1) Any form of advertising shall be in compliance with provisions listed in the approved SmPC as well with marketing authorisation terms as granted by the NAMMD or in compliance with the European Commission Decision, as appropriate,.

(2) Any form of medicinal product advertising not compliant with the marketing authorisation is prohibited.

(3) a) Information regarding certain indications of a medicinal product which are not specified in the marketing authorisation (MA) ("non-label indications") and may only be supplied in response to an appropriately documented request from a healthcare professional.

b**)** Use of such information in order to promote the respective medicinal product in unauthorised indications or promote its use under different conditions than included in the approved SmPC is prohibited.

c**)** In this case, the MAH ensures that the data provided are purely informative, non-promotional, clearly specifying that the respective information regards "non-label" use.

Article 24. – (1) Any form medicinal product advertising for persons qualified to prescribe or supply such products shall include:

a) essential information compatible with the approved SmPC;

b) the classification for supply of the respective medicine;

c) mentions regarding the date of the latest set-up or revision of the documentation used for development of the advertising material or of any other form of advertising.

(2) All information included in the documentation under Article 24 (1) shall be accurate, updated, verifiable and comprehensive enough to allow the recipient to develop their own opinion regarding the therapeutic quality of the medicine concerned.

(3) Quotations as well as tables and other illustrative material taken from medical literature or other scientific works for use in the above-mentioned documentation shall be faithfully reproduced, with exact indication of the source (references).

(4) All illustrations in promotion material, including graphs, various images, photographs and tables, taken from published studies shall meet the following conditions:

a) clearly indicate their exact source/ sources;

b) be faithfully reproduced, except when adjustment or change is needed (for instance, to comply with any applicable code/codes), in which case any such adjustment/change shall be clearly specified.

c) Not be misleading regarding the nature of the medicine (for instance, concerning appropriateness use in children or not) or regarding a statement or comparison (for example, by use of incomplete, statistically irrelevant information or inappropriate comparisons).

Article 25. - Without appropriate scientific arguments, such words as "safe" or "risk-free" shall never be used to describe a medicinal product.

Article 26. - The word "new" shall be avoided to describe a product or presentation form generally available previously or a therapeutic indication generally promoted for longer than one year (in Romania).

Article 27. - No product may be presented as having no adverse reactions, toxicity or addiction risks, except for those cases mentioned in the SmPC.

Article 28. - The design and presentation of advertising shall allow clear and effortless understanding. When footnotes are used, these shall be obvious, be proper in size, be easily legible and have a duration which allows reading.

Article 29. - Advertising for persons qualified for medicinal product prescription or supply shall not promise gifts, advantages in cash or in kind.

SECTION 2
Advertising forms

Article 30. - Printed advertising material meant for healthcare professionals

(1) Advertising (promotional) material for on-prescription medicinal products shall be distributed to healthcare professionals only.

a) Display of such promotional material is prohibited in places accessible to the general public such as, but not limited to, pharmacies, waiting rooms of medical practices, hospital and clinic halls etc.

b) Liability for display of such promotional material, to the general public is presumed to lie with the pharmaceutical company, which may prove the contrary with documents.

(2) Any printed advertising material meant for healthcare professionals shall include at least the following information:

a) the name of the medicinal product and active substance (INN = international non-proprietary name);

b) the pharmaceutical form and strength;

c) the dosage for each administration route and each therapeutic indication, as appropriate;

d) the date of the first authorisation or of authorisation renewal;

e) the other essential information in the SmPC;

f) the date of the text revision (for the SmPC);

g) the mention: "This promotional material is meant for healthcare professionals."

h) the classification for release and the type of prescription required for release;

i) Information in the SmPC is printed using font size *10*, irrespective of the font type.

(3) Inclusion into printed advertising material of messages stating or suggesting that use of the respective medicine is risk-free is prohibited, except for the cases mentioned in the SmPC.

(4) Unless scientifically supported, all steps shall be taken for healthcare professionals not to be misled by allegations that a product is better or safer than another.

Article 31. – Posters, invitations to medical events:

(1) If not related to the therapeutic effects of a medicinal product, invitations to medical events organised for healthcare professionals can only include the name of the product or its international non-proprietary name, if any, or its trademark and, if necessary, a plain statement of the indications meant to designate the therapeutic category of the product or its route of administration. Otherwise, such material is subject to regulations provided in Article 30, **"**Printed advertising material meant for healthcare professionals".

(2) Posters as well as invitations aimed at promoting certain undertakings, activities, scientific medical events, educational programs, or meant to increase the recognition of a certain pathology and displayed in public places shall comply with regulations provided in Article 51 "Printed advertising material meant for the public".

Article 32. – Short trades (reminders):

By way of exemption from provisions of Article 30,"Printed advertising material meant for healthcare professionals", for short trades meant as reminders, medicinal product advertising for healthcare professionals may only include the name of the medicinal product or its International Non-proprietary Name, if any, or its trademark.

Article 33. - International literature for healthcare professionals

Promotional material included in international literature to be distributed by the MAH or their representatives in Romania shall be in compliance with regulations in force.

Article 34. – Advertising over the Internet

(1) Since advertising over the internet is normally accessible to the general public, Internet advertising of on-prescription medicinal products is only allowed if compliant with regulations in force.

a) In such cases, the MAH shall prove restriction of access to this information for all other persons except healthcare professionals, by a valid and verifiable system of password protection. A complete SmPC is mandatory for the information included.

b) Likewise, web-site providers shall ensure that the material posted on the site does not contain information non-compliant with national and international rules in force. As for other advertising forms, this channel for promotion to the general public of on-prescription medicinal products is prohibited.

(2) As for the other advertising material, medical information shall be endorsed by scientific references compatible with the approved SmPC.

(3) When links are included on certain web-sites that are meant for foreign users, Romanian users shall be specifically informed thereof.

(4) The following represent good practice rules for medicinal product advertising for human use:

a) Romanian users have to be provided direct access to any web-page containing medicinal product related information (SmPC – for web-sites intended for healthcare professionals, leaflet – for web-sites intended for the general public);

b) the web-site shall mention the category of targeted users;

c) any information about web-sites targeting healthcare professionals representing an advertising form be compliant with legal provisions regulating the content and format of the trades, as well as the manner of medicinal product advertising.

Article 35. – **Hospitality**

Hospitality to healthcare professionals is allowed at scientific/professional events only and under the terms provided by regulations in force. Therefore, it shall be limited to the main objective of the meeting and may not be extended to other people outside healthcare professionals or for whom the scientific field of the event has no professional relevance.

Article 36. – Sponsorship

(1) Any type of sponsorship provided to healthcare professionals shall not be correlated with the name of a medicinal product, regardless of its status for release (on- or non-medical prescription).

(2) Sponsorship activities shall not involve use of direct/indirect promotional messages for medicinal products, regardless of their release status for release (on- or non-medical prescription).

Article 37. - Facilitation of access to educational programs, scientific material, medical goods or services

(1) Programs initiated by the MAH or their legal representatives, which are aimed at providing sponsorship for scientific research activities, study visits etc. are allowed provided that:

a) they do not include promotional elements regarding a medicine;

b) they are not provided on condition of prescription or stimulation of a prescription of a medicine.

(2) Supply of goods and services to hospitals or other healthcare institutions:

a) shall have as a sole aim the welfare of the patients;

b) shall not be provided on condition of prescription, stimulation of a prescription or distribution of a medicine;

c) shall not in general be related to a medicinal product.

Article 38. – Advertising in medical events

(1) Local, regional, national or international medical events are subject to this provision. These are forms of advertising intended for healthcare professionals only and therefore the MAH or their representatives shall notify the NAMMD with respect to the following aspects:

a) the type of event in which the MAH participates;

b) The material to be distributed during or after the event (must be listed, not presented as such);

c) The medical information supplied during these events – the set of slides only with reference to product characteristics and not the entire presentation;

d) Romanian specialists participating in international events, who provide medical information on certain product characteristics in the event, shall only submit the set of slides referring on product characteristics as such and, not to the entire presentation;

e) the promotional objects distributed (to be listed);

f) Specialisation of healthcare professionals for whom the information is intended.

(2) Irrespective of the information support, none of the advertising material used in this context shall go against regulations in force. The MAH or their representatives shall ensure that all advertising material contains all recommended information.

(3) Should a single set of studies be used during a medicinal product advertising campaign, a single notification will suffice, submitted at the beginning of the campaign and accompanied by a plan of all events in the campaign.

(4) Should prizes be offered in such events, these shall be of no significant value and not be provided on condition of medicinal product prescription. Notification is to be made 10 days prior to the event.

Article 39. – The granting of samples

Exceptionally, free samples are only offered to persons qualified for prescription of such products and under the terms imposed by the legislation and regulations in force.

Article 40. – Promotional objects

(1) Healthcare professionals may not be supplied with, offered or promised any gifts, financial advantages or in kind benefits as stimulant for the prescription, purchase, supply, sale or administration of a medicinal product.

(2) a) When medicinal products are promoted to healthcare professionals, such promotional objects may be supplied or offered if only not costly (not exceeding RON 150, VAT included, before personalisation) and relevant for the practice of medicine and pharmacy.

b) Objects of general use, used as promotional objects, may include pens, notebooks, calendars, watches or other similar stationary items (parasols, bath towels etc. are excluded).

(3) Promotional objects may only bear:

a) the name and logo of the pharmaceutical company;

b) the name of the medicine, or its international non-proprietary name, if any, or the trademark;

c) The strength, pharmaceutical form and a simple statement of the indications meant to designate the product therapeutic category;

(4) Imprinting of the trade name of medicinal products under promotion on gowns offered to healthcare professionals as promotional objects is prohibited.

CHAPTER IV
Advertising to the general public
General considerations, recommendations related to statements contained in the advertising material for the general public, advertising forms

SECTION 1
General considerations

Article 41. - Advertisement to the general public is only allowed for those medicinal products, which, by their composition and purpose, are meant for use without a physician's intervention in diagnosis, prescription or treatment monitoring, a pharmacist's advice being sufficient in case of need.

Pharmacies are allowed to present trade catalogues and lists of prices to the general public provided that such material does not contain promotional offers whatsoever, and it is only displayed in pharmacies and medical practices.

Article 42. – (1) Advertisement to the general public is prohibited for medicinal products which:

a) are released on medical prescription only;

b) contain substances defined as narcotic or psychotropic within the meaning established by the United Nations Organisation conventions of 1961 and 1971, as well as the national legislation.

(2) Advertisement to the general public is prohibited in Romania for medicinal products prescribed and dispensed within the health insurance system. Such prohibition does not apply to vaccination campaigns carried out by the pharmaceutical industry and approved by the Ministry of Health.

(3) Manufacturers are not allowed to directly distribute medicinal products to the population for promotional purposes.

(4) Advertising to the general public by means of social networks such as, for instance, Facebook and Twitter etc., or android mobile applications is prohibited.

Article 43. – Advertisement for the general public performed by the MAHs and contracted third parties acting on their behalf is prohibited for medicinal products containing promotional offers (e.g.: "buy one and get .....", or "buy X + Y" and get a gift, discount etc.) or references to discounts, price cuts, special prices.

Trade companies (authorised pharmacies or third parties) are also prohibited from such advertising to the public.

Article 44. – Any form of public medicinal product advertising shall:

(1) be designed in such a way as to clearly outline the advertising character of its message and allow unambiguous identification of the product as a medicinal product;

(2) include at least the following information:

a) the name of the medicinal product, and the non-proprietary name should the medicine contain a single active substance;

b) all necessary information for correct medicinal product use (therapeutic indication(s), recommended dose according to therapeutic indication(s) it refers to);

c) an explicit and legible invitation to careful reading of instructions in the patient leaflet or the outer packaging, worded as follows: *"This medicinal product is available without medical prescription. Careful reading of the patient leaflet or the information on the package is recommended. In case of any unpleasant manifestations, please contact your physician or pharmacist."*

d) 'reminder' material shall include the name of the medicinal product and the invitation to read the instructions in the patient leaflet or the outer package, as appropriate.

3) be submitted to the NAMMD for approval; the NAMMD grants an approval valid for a 6 month/1 year period, depending on the applicant's request; the number of the approval and the date of its grant shall be imprinted and displayed. Further to grant of approval for advertising visa maintenance, the inscription of the visa number needs no changing.

Small advertising material such as change trays, wobbler etc. (as detailed in Annex 1 to this Guideline) are exempted from mandatory visa number inscription.

4) shall not contain any element, material, date or information which:

a) leaves the impression that no medical advice, medical intervention or surgical procedure is necessary, especially by offering diagnosis suggestions or remote treatment;

b) suggests that treatment with the medicine in question has *guaranteed* effect or is free from occurrence of adverse reactions (e.g.: *"rids one from……"*);

c) suggests that the effect of the respective medicinal product is better or equivalents to that of a different treatment or active substance, unless scientifically grounds are provided for such statements;

d) suggests that the patient's health can only be improved by use of the respective medicinal product;

e) suggests that the patient's health may be harmed unless the respective medicinal product is used; such prohibition does not apply to immunisation campaigns;

f) targets children exclusively or especially;

g) relates to a recommendation by scientists, healthcare professionals or persons not part of these categories, but whose celebrity may encourage consumption of medicinal products;

h) suggests that the medicinal product is a food, cosmetic or other product for consumption;

i) suggests that medicinal product safety or efficacy is owed to its being non-synthetic;

j) by detailed description or representation of a case, be likely to induce inaccurate self-diagnosis;

k) provide, in inadequate or misleading terms, insurance regarding healing;

l) inaccurately, alarmingly or misleadingly use visual representations of disease or lesion induced changes or medicinal product action on the human body as a whole or in part;

m) allege that a marketing authorisation has been granted for that medicinal product;

n) expresses violence (even if not explicitly).

o) uses diminutives or other words (phrases) meant to trigger users' emotional response;

p) represents messages, images from campaigns related to other types of products (cosmetics, food supplements, medical devices etc.).

SECTION 2

Recommendations regarding statements in advertising material meant for the general public

Article 45. - Statements suggesting the product is the most efficient (e.g. *"No other medicine acts as fast as ……"*) are prohibited because of their capacity to mislead consumers with respect to therapeutic benefits of the medicinal product as compared to those associated to other medicinal products in the same category.

Article 46. – (1) Such terms as "safe" or "risk-free" shall never be used to describe a medicinal product, unless appropriate scientific arguments are given.

(2) The word "new" shall never be used to describe a product or a presentation form generally available or a therapeutic indication generally promoted for longer than one year on the Romanian market.

Article 47. – (1) The advertising material shall not suggest that the medicinal product is completely free from adverse reactions.

(2) Moreover, allegations on medicinal product manufacturing resulting in lower residual content or higher quality than a similar product shall not be misleading as regards its therapeutic benefits.

Article 48. - The medicinal product's high action or absorption rate are characteristics resulting from the product's SmPC (e.g. action setting in less than 30 minutes).

Article 49. - The NAMMD does not encourage use of advertising material promoting medicinal products together with others with similar trade names, marketed by the same company. Such reference to other products in the advertising material can be misleading.

Article 50. - Manufacturing companies or their representatives in Romania shall not directly or indirectly communicate the idea that their product is better than others for having been granted a marketing authorisation.

SECTION 3

Advertising forms

Article 51. – Printed advertising material for the general public

Printed advertising material for the general public:

(1) may mention the name of the pharmaceutical company supporting development of the material without other reference but its identification data;

(2) may contain non-promotional information regarding human health or diseases, provided there is no direct or indirect reference to specific medicinal products (educational material);

(3) may contain advice (recommendations) for a better life quality of patients, however without referring to any medicinal product (educational material);

(4) does not encourage self-medication or unreasonable use of medicinal products;

(5) if medicinal products are concerned, the presentation is objective, realistic, supported by arguments, without exaggerating their properties and curative effects;

(6) the design and presentation of advertising shall allow for clear and straightforward understanding; when footnotes are used, these shall be obvious, of sufficient size, in order to be easily legible;

(7) shall be subject to NAMMD approval;

(8) shall contain the approval visa number and date of its release, in the following form: *"advertising approval no. /date*….".

Article 52. - Posters, invitations, catalogues

(1) Posters and invitations are compliant with recommendations for advertising material to the general public, including the recommendation regarding inscription of the approval number and date of release, in the following form: *"advertising approval no. /date*….".

(2) Catalogues in pharmacies:

a) may only mention non-prescription medicinal products;

b) may include the shelf price of the products, without mentioning promotional offers (e.g. ”buy one, get .....”, or ” buy X + Y and get a gift, discount” etc.), or reference to price, discounts, price reductions.

c) shall be submitted for NAMMD approval; the approval is valid for 6 months;

d) shall contain the approval number and the date of its release, in the following form: *”advertising approval no. /date*….”.

Article 53. Audio-visual advertising

Medicinal product advertising broadcast on radio and television programmes, by radio-electric means, cable or any other assimilated technical system is subject to legal provisions regarding audiovisual advertising.

(2) Audiovisual medicinal product and medical treatment advertising refers to any form of promotion performed in the frame of program services, meant to stimulate their distribution, consumption or sale.

(3) Advertising is only allowed for medicinal products not requiring medical prescription.

(4) Medicinal product advertising shall encourage their rational use, present them objectively, without exaggerating their therapeutic qualities.

(5) Promotion of medicinal products in audiovisual programs will necessarily include the following:

a) the name of the medicinal product;

b) the non-proprietary name if the medicinal product contains a single active ingredient;

c) the therapeutic indication (conditions in which the medicinal product is used);

d) an express, legible invitation to careful reading of instructions in the patient leaflet or on the packaging;

e) verbal warning: *“This is a medicinal product. Careful reading of the patient leaflet is recommended”;*

f) approval number and date of its grant, in the following form: *”advertising approval no. /date*….”, printed at the end of the spot, with mandatory update after each advertising visa renewal.

(6) By exemption from provisions of the previous paragraph, medicinal product advertising broadcast in a short form (reminders) shall include the warning: *“Careful reading of the patient leaflet is recommended.”*

(7) Warnings mentioned under paragraph (5) e) and (6) shall be broadcast under the following terms:

a) where the main TV advertisement is concerned, the warning text is presented at the end of the TV advertisement, visually, for a time long enough to ensure clear perception;

b) for reminders, the warning text is presented during the broadcast of the TV advertisement, in terms allowing for clear perception of the message.

(8) Broadcast of medicinal product advertising presented or recommended by public figures, cultural, scientific, sports figures or other people who, on account of their fame, can encourage the use of these products or treatments is prohibited.

(9) Likewise, no broadcast of advertising and teleshopping is allowed showing physicians, pharmacists or nurses recommending or expressing approval for medicinal products.

(10) No broadcast of medicinal product advertising during children’s shows or advertising breaks before or after such shows is allowed.

(11) Medicinal product manufacturers and distributors may not be sponsors of children’s programs or shows .

(12) Broadcast of advertising is prohibited suggesting the necessity that any person supplement their diet with vitamins and minerals and that such supplements can improve otherwise regularly good physical or mental functions.

(13) Advertising for any kind of medicinal product or treatment for weight loss or maintenance will observe the following conditions:

a) it shall not address people under 18 years of age and shall warn the public thereof in writing and / or sound;

b) it may not be broadcast in children's shows or advertising breaks before or after such shows;

c) it shall not be directed towards obese people, will not include examples of cases with reference to or appearance of formerly obese people before using the products or services advertised for;

d) it shall not suggest or assert that being underweight is adequate or desired.

(14) The design and presentation of advertising shall allow for clear and easy understanding, and include the transposition, understandable by patients/final consumers, of SmPC indications in the advertising material (e.g. varicose syndrome, pain, swelling, sensation of weight etc., if proven that these are the symptoms of the reference action).

Article 54. - Billboards or any other form of outdoor advertising or any type of advertising provided using any other communication channels than pharmacies, medical practices, audiovisual, the written press, the internet;

(1) For the above forms of advertising, special attention shall be given to their presentation manner and placement, to avoid misleading advertising because of various associations with other surrounding promotional elements.

(2) This type of advertising material is assessed within the NAMMD scientific council.

(3) The NAMMD does not encourage outdoor advertising **or any other form of advertising provided using any other communication channels than pharmacies, medical practices, audiovisual, the written press, the internet.**

Article 55. – Short trades *(reminders):*

(1) Reminder material shall include:

a) the name of the medicinal product;

b) an express, legible invitation to careful reading of instructions in the patient leaflet or on the packaging, worded as follows: *"Careful reading of the patient leaflet or information on the package is recommended".*

(2) For TV advertisement, a reminder means that an advertising clip cumulatively meeting the following conditions:

a) it is a part, sequel and/or supplementation of the same advertising campaign for a certain medicinal product, carried out at the same time and within the same audiovisual media service;

b) it reminds the audience of elements in the message broadcast in the main advertisement of the campaign;

c) is no more than 10 seconds in length;

d) it conveys the same information and messages as the whole trade;

e) it contains the approval visa number and its date of its release, as "*advertising approval no. /date*….".

Article 56. – **Advertising over the Internet**

As any other form of advertising, irrespective of its form, advertising over the Internet shall be subject to NAMMD evaluation and approval.

(1) **Web pages:**

a) Each web page shall clearly establish:

- the identity and material and electronic address of the sponsor (sponsors) for the web-page;

- the source(s) of all information on the web-page;

- the target audience of the web-page (for instance, healthcare professionals, patients and the general public, or a combination thereof);

- approval visa number and date of its release, as *"advertising approval no. /date ….*"

b) Webpage content:

- Information provided on the web-page will be updated with any significant changes in MA and/or medical practice and be subject to NAMMD approval; for each page and/or subject, as applicable, the date of the most recent update shall is will clearly displayed.

- Information that may be included on a single website or on multiple sites is as follows:

1. General information about the company:

- The webpages may contain information of interest for investors, news media and the general public, including financial data, descriptions of research and development programs, discussions of regulatory developments concerning the company and its products, information for prospective employees etc.

- The content of this information falls out of the scope of this guideline or legal provisions on medicinal products advertising.

2. Information regarding health education

- Webpages may contain non-promotional information regarding health education, characteristics of diseases, prevention methods, screening and treatment methods and other information aimed at promoting public health. These can relate to medicinal products, provided the discussion is balanced and accurate.

- Relevant information may be provided on therapeutic alternatives, including, if necessary, surgical procedures, diet, behavioural change and other interventions not requiring use of medicinal products.

- Web-pages containing information on health education shall always recommend visitors to require further information from healthcare professionals.

3. Promotional information for the patients and the general public

- Any information on web-sites for patients and the general public, which constitute a form of promotion shall be compliant with provisions of this Guideline, particularly with those mentioned under Article 53, "Audio-visual advertising", with regulatory provisions in force and with other codes of practice of the industry, regulating the content and format of trades and the manner of medicinal product promotion.

- Such information shall be clearly labelled as advertising information for the general public.

- Such promotional information shall always recommend visitors to seek further information from healthcare professionals and include an express, legible invitation to carefully read the instruction in the leaflet or on the package, as follows: *„This medicinal product can be released without medical prescription. Careful reading of the patient leaflet or information on the package is recommended. In case of any unpleasant manifestations, please contact your physician or pharmacist."*

4. (1) Non-promotional information for the patients and the general public

- According to Romanian laws and regulations in force, web-sites may include non-promotional information for patients and the general public, regarding products in the pharmaceutical company's OTC portfolio (including information on indications, adverse reactions, interactions with other medicinal products, correct use, clinical research reports etc.) provided that the information is balanced, accurate and in line with the approved summary of product characteristics.

- For each product discussed, the web-page shall contain complete, unchanged examples of the currently approved summary of product characteristics and patient leaflet. These documents shall be posted in conjunction with other product information or connected to the respective discussion by a visible link recommending reference for readers.

- Additionally, the web-page may supply a link to a full, unchanged copy of any public evaluation report issued by the Committee for Medicinal Products of Human Use (CHMP) of the European Medicines Agency (EMA) or a relevant competent national authority.

- Trademarks shall be accompanied by non-proprietary international names.

- The web-page may include links to other web pages containing reliable medicinal product information, including web-pages of governmental authorities, medical research entities, patient organisations etc.

- The web-page shall always recommend visitors to seek further information from healthcare professionals.

(2) Advertising by electronic mail (e-mail) or text messages (SMS):

Advertising of medicinal products for human use (SMS) is not recommended.

(3) Links from other web-sites:

- Links can be created to a web-site sponsored by a pharmaceutical company from web-sites sponsored by other people; however, pharmaceutical companies shall not create links from web-sites meant for the general public to company sponsored web-sites, meant for healthcare professionals.

- In the same way, links may be created to separate web-sites, including web-sites sponsored by pharmaceutical companies or other people.

- Links shall direct to the initial page (homepage) of the intended web-page or be treated in such to ensure reader awareness as to the web-page sponsor's identity.

(4) **Revision of scientific information**

- Pharmaceutical companies and/or their representatives shall provide revision of scientific and medical information prepared for posting on the web-site, compliant with this guideline provisions.

- This function shall be accomplished by the scientific department in charge of information related to MAH marketed medicinal products, set up in accordance with legal provisions.

(5) **Confidentiality**

Web-sites shall be compliant with legislation and applicable codes of conduct regulating the private character, security and confidentiality of personal information.

Article 57. – Awareness raising and prevention campaigns concerning certain diseases

(1) Campaigns classified as 'medical education' are encouraged (campaigns targeting general public health education, awareness raising and prevention of certain diseases).

(2) MAH shall ensure that the material included in the respective campaign does not contain advertising messages for on-prescription medicinal products and does not encourage abusive or excessive use of the given medicinal products.

(3) Promotion of messages which restricting the therapeutic range of a given disease is prohibited.

(4) MAH shall also ensure that patients and the general public clearly understand that the therapeutic decision lies with the physician.

Article 58. - Sponsorship

(1) Sponsorship of any kind concerning the general public may not be related to the name of any medicinal product available without medical prescription.

(2) Moreover, sponsorship actions shall not contain direct or indirect promotional messages concerning the medicinal products available without medical prescription.

(3) Mutual aid or charity programs may not be performed in the name of a specific medicinal product.

Article 59. - Provision of samples

(1) MAHs and contracted persons/entities acting on their behalf are prohibited to provide the public with samples for advertising purposes.

(2) Trade companies (authorised pharmacies or third parties) are not allowed to provide samples to the public for advertising purposes.

(3) Supply of samples by means of publications delivered directly or by mail or addition of samples in the publication packaging, as well as distribution of vouchers or tickets for access to free medicinal products or discounted medicinal products are prohibited.

Article 60. – Promotional objects

(1) Promotional objects given to the public shall be inexpensive and promote health and wellbeing.

(2) May only be offered for promoting non-prescription medicinal products.

Article 61. – **Promotion of medical and pharmaceutical services**

(1) Clinics, medical practices, pharmacies or other organisations providing healthcare services shall strictly limit themselves to provision thereof and may not include activities related to advertising of on-prescription products. The appropriate therapeutic approach of disease is the result of physician-patient cooperation.

(2) An example illustrating Article 61 (1) is beauty salons, which may promote "treatments against wrinkles", which is a non-specific, neutral indication, while not referring to a certain product however (botox or the botulinum toxin).

Article 61[1]. – Co-funding discount programs. All co-funding discount programs shall comply with the principles mentioned under Annex 2 to this Guideline.

Cards will be imprinted with information about the manner of adverse reaction reporting to the NAMMD.

CHAPTER V

Supervision and penalties
General considerations, notifications and potential non-compliances with the norms on the advertisement of medicinal products

SECTION 1
General considerations

Article 62. - The NAMMD is the authority entitled to take adequate and efficient steps for evaluation and monitoring of all forms of medicinal product advertising, as follows:

(1) a) for non-prescription medicinal products, **advertising material meant for the general public** is subject to prior NAMMD approval;

b) **Educational material intended for patients** is subject to prior NAMMD approval.

(2) a) **Advertising material intended for healthcare professionals**, promoting both on- and non- prescription medicinal products is reviewed by the NAMMD further to dissemination, randomly or following complaints.

b) **Educational material intended for healthcare professionals** are submitted for NAMMD prior approval.

(3) On applicant request, the NAMMD may grant advertising approval visa, valid for 6/12 months for advertising/educational material intended for the general public and for educational material meant for healthcare professionals, for fees in line with regulations.

Article 63. – (1) Generally, the deadline for review of all medicinal product advertising forms submitted for NAMMD approval in accordance with Article 62 (1) and (2) b) provisions or requested by the NAMMD in accordance with provisions of Article 62 (2) a) is 30 days from confirmation of payment/submission to the NAMMD (excluding the time used by the MAH to respond to potential NAMMD questions).

The MAH is notified on evaluation requirements.

(2) The 30-day deadline may be brought forward or extended, depending on the quality and/or complexity of the advertising material originally submitted for evaluation.

If data submitted for assessment of the various forms of advertising are substantial and evaluation is not possible to perform within the specified deadline, the NAMMD provides an estimate of the time necessary to complete the evaluation, however not exceeding 60 days.

(3) Responses to NAMMD requests shall be provided in no longer than 30 days, the *stop-clock* period. Otherwise, material submitted shall be deemed as rejected and the assessment fee shall not be returned.

(4) For advertising material submitted for reapproval, if NAMMD response/approval is not granted in 30 days, they shall be deemed as implicitly approval and continued on the market.

(5) Following reapproval, advertising material already printed need not be reprinted to include the approval visa number and date; assessment of compliance is performed based on the new approval granted by the NAMMD.

(6) As regards advertising material requiring reapproval, the application and fee shall be undertaken at least 30 days prior to expiry of approval.

Article 64. – In addition to the advertising form submitted for evaluation, the MAH shall indicate its target audience.

Article 65. – All advertising forms shall have already been submitted for evaluation by the internal scientific service responsible for monitoring of information concerning medicinal products marketed by the MAH.

Article 66. – When receipt of any type of advertising material, all units involved in medicinal product distribution are required to ascertain inclusion of the given product advertising NAMMD approval or its notification with the NAMMD.

Article 67. – The NAMMD may request counselling from other bodies responsible for evaluation of various advertising forms, concerning advertising type/form, target audience, as well as the date and duration foreseen for presentation/broadcast/transmission of each advertising form submitted for evaluation.

Article 68. - Natural and legal persons with legitimate interest in prohibiting any medicinal products advertising form noncompliant with legal provisions and regulations in force may notify the NAMMD in this respect, who shall answer in 60 days.

SECTION 2
Complaints and penalties for potential non-compliance with medicinal product advertising rules

Article 69. – To ensure implementation of proper, correct, unexaggerated advertising for medicinal products for human use marketed in Romania, in accordance with the legal provisions and regulations in force, for the general public as well as healthcare professionals, the NAMMD takes all required measures to insure compliance with the legal framework in that respect. Therefore:

(1) NAMMD qualified staff carries out inspections in units undertaking distribution of medicinal products for human use (community pharmacies, hospital pharmacies, druggist's shops, wholesale distributors), as well as MAH sites, for assessment of promotional material they hold or provide.

(2) NAMMD qualified staff also evaluates compliance with legal provisions of advertisement for healthcare professionals as displayed in scientific events (symposia, conference, congresses) attended by healthcare professionals.

(3) In case of non-compliance with legal provisions and regulations in force related to advertisement of medicinal products for human use, after responsible parts involved have been determined, the NAMMD applies penalties in accordance with provisions of Article 836 c) of Law no. 95/2006 on healthcare reform – Title XVII – The medicinal product.

Article 70. – (1) Any natural/legal person with legitimate interest in prohibition of any advertising form non-compliant with legal dispositions may submit a complaint to the NAMMD on breach of regulations for medicinal product advertising.

(2) The complaint may be in writing, according to the following requirements:

a) inclusion of the claimant's contact data (for easy identification and contact by the competent authorities for communication of the investigation status and results);

b) clear and comprehensive presentation of details regarding the type, moment and place where form of advertising in question has been encountered;

c) clear and specific presentation of the claimant's underlying reasons for concern;

d) if possible, a copy of the form of advertising (trade) making the subject of the inquiry;

e) copies of any documents as proof of possible prior contact with the MAH or advertising agent for amiable resolution of the disagreement.

Article 71. – (1) Although all inquiries submitted are deemed similarly important, the NAMMD is particularly concerned for complaints regarding cases of possible negative impact of advertising upon public health.

(2) Alternatively, a complaint may be submitted to any other regulatory body.

Article 72. – (1) The NAMMD records all complaints received and notifies the claimant thereof.

(2) Over the entire the investigation, the claimant's identity is unknown to the defendant (whether pharmaceutical company or advertising agent).

(3) The NAMMD shall respond to the complaint received within 60 days as of its registration.

(4) If, after evaluation, the NAMMD ascertains that legal provisions have been breached with respect to medicinal product advertising, considering the interests of all parties involved, but particularly taking public interests into account, the NAMMD may take all the necessary steps for the law to be observed, including by ruling termination of the advertising and withdrawal of the advertising material.

Article 73. - (1) In case the misleading or illegal advertising material has not been published yet, but the publication is impending, the NAMMD may rule that this advertising be prohibited.

(2) In case of serious violation of public health, the measure provided for in Article 73 (1) can be instituted by expedited procedure and may be temporary or permanent.

Article 74. - (1) When the NAMMD ascertains that a form of advertising is based on inconclusive or false evidence (clinical trials, epidemiological studies or any other scientific arguments), it shall be ruled that the broadcasting of that form of advertising and the incriminated evidence and arguments be prohibited.

(2) Moreover, in order to remove the effects of misleading advertising whose termination has been ruled by the NAMMD, the latter may request:

a) full or partial publication of the final decision under the form considered adequate;

b) publication of a corrective statement.

CHAPTER VI

Final provisions, emergency restrictions or variations to MA terms for safety reasons

SECTION 1

Final provisions

Article 75. – MAHs have the following obligations:

(1) keep available for or provide to the NAMMD a sample of all advertising material they have initiated, together with a statement as to its intended audience, the manner of notification and the date of the first notification;

(2) ensures that the advertising material drafted for its medicinal products are in compliance with legal provisions for public information, provide clear and legible information, in sufficient detail to allow readers a correct opinion as regards the efficacy, safety and manner of administration of a medicinal product;

(3) check whether their legal representatives have been appropriately trained and whether they fulfil their legal obligations;

(4) provide the NAMMD with the information and assistance necessary to accomplish its responsibilities;

(5) ensure that NAMMD decisions are enforced immediately and fully.

Article 76. **-** The NAMMD takes adequate steps to ensure application of legal provisions and regulations in force on advertising of medicinal product for human use and, in case of breach thereof, applies penalties in accordance with the law.

SECTION 2

Urgent restrictions or variations to MA terms for safety reasons

Article 77. – (1) The MAH or its legal representatives have to ensure that prescribers are immediately and fully informed on any important or relevant change of available product information as used in promotional campaigns.

(2) As a result of an urgent restriction required by changes in the safety profile or following a variation to MA terms for similar reasons, persons in charge of advertising campaigns shall take all necessary steps for advertising material subsequent to such change to reflect the new form and, where necessary, reflect possible differences in a relevant and clear manner.