RASCI

THE CODE ON THE INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

Adopted by the Romanian Association of the Self-Care Industry (RASCI) on 29.09.2020

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INTRODUCTION

The Romanian Association of the Self-Care Industry[1] was established in 2016 to promote the responsible personal care in Romania by creating a positive and sustainable environment for personal care products and becoming a reliable partner for the authorities.

We are the association that supports the common goals of manufacturers, importers and distributors of over-the-counter medicines, food supplements and medical devices for personal use (as defined by the Association of the European Self-Medication Industry "**AESGP**") which operates in Romania.

Since its creation in 2016, RASCI has been affiliated with AESGP, the association that officially represents the manufacturers of over-the-counter medicines, food supplements and medical devices for personal use in Europe. The association is made up of national associations and major multinational and local companies producing personal care products. In addition, there are a number of industry associations and companies that focus on specific areas directly related. The main mission of AESGP, and implicitly of RASCI, is to ensure the sustainable positive development of the personal care industry.

By disseminating scientific and educational information, the results of years of scientific activity and considerable investment in research and development will be made available to health professionals and the general public. In all healthcare-related activities, industry representatives believe that high standards need to be defined and observed, and they are convinced that self-discipline is the process that best serves the public interest. The ethical criteria for the promotion of personal care products are considered the basis for appropriate behavior, consistent with the search for truth and fairness.

In January 2007, Romania became a member of the EU. In order to apply the same high ethical standards for the promotion activities carried out by the pharmaceutical industry in the EU, it is recommended to implement in Romania a code of conduct aligned with that applied in the EU countries. In this regard, RASCI adopted the RASCI Code on September 28, 2018, revised on September 29, 2020.

The RASCI Code for Interaction with Healthcare Professionals and the General Public (hereinafter referred to as the "**RASCI Code**") is a voluntary set of standard practices that all RASCI member companies follow and which comply with the applicable laws, regulations and guidelines in Romania; The code will be a reference that should thus help to align with acceptable ethical standards and legal provisions regarding the promotional practices related to personal care products.

RASCI is committed to ensuring that all Member States are aware of the importance of providing accurate, correct and objective information about personal care products so that rational decisions can be made regarding the use thereof.

[1] For the purposes of the RASCI Code, references in the field of personal care or personal care products shall be construed as including references to over-the-counter medicines, dietary supplements and medical devices for personal use, in accordance with the purpose and objectives of RASCI.

The RASCI Code also reflects the principles contained in the requirements of the AESGP Code and complies with the requirements of the Council Directive 2001/83/EC of the European Union[2], as subsequently amended, on medicinal products for human use (the "**Directive**"). The RASCI Code is part of the general framework established by the Directive, which recognizes the role of voluntary standards for the control of medicines advertising practices by self-regulatory bodies and their application by the industry and the appeal of the government administration to these bodies when filing complaints.

RASCI encourages fair competition between personal care companies operating in Romania. The RASCI Code is not intended to restrict the proper promotion of personal care products or to impose legal and ethical limits on the interaction with healthcare professionals in a manner that infringes the law and practice of fair competition. Instead, it intends to ensure that promotional and other related activities are carried out in a fair and compliant manner, avoiding misleading practices and potential conflicts of interest with healthcare professionals and in accordance with the European and Romanian laws and regulations. Therefore, the RASCI Code aims to promote an environment in which the general public can be confident that the choices regarding recommended personal care products are made on the basis of the merits of each product and the health needs of each person.

THE RASCI CODE SCOPE

The RASCI Code regulates the promotion of personal care products and the interactions of RASCI member companies with health professionals and the general public. This includes interactions with a variety of healthcare professionals, including physicians, dentists, pharmacists, and nurses or pharmacy assistants. It also recognizes the dual interactions that manufacturers, importers, and distributors of personal care products may have with pharmacists, as healthcare professionals, and the retail store/pharmacy owners, to ensure that non-promotional and promotional materials are used in accordance with these interactions.

The RASCI Code applies to all RASCI member companies and their affiliates[3] and subsidiaries[4] in Romania.

The member companies are responsible for the obligations imposed under any applicable code (defined below in the "APPLICABILITY OF THE RASCI CODE"), even if they contract other parties (e.g. sales forces, consultants, market research companies, advertisers based on a contract) to design, implement or engage on their behalf in activities that fall under the applicable code.

[2]The Council Directive 2001/83/EC was amended in 2004 by the Council Directive 2004/27/EC.

[3]Affiliate means, in relation to any entity, any other entity that directly or indirectly controls, is controlled by, or is under the joint control of, individually or through several intermediaries of that entity; for the purposes of this definition, "control" (including "controlled" and "controlling") means the power to direct or dispose of the direction of that entity's policies, directly or indirectly, either by holding guarantees or partnerships or other proprietary rights, by contract or otherwise.

[4]An independent company that operates independently, autonomously, in its own headquarters, endowed with legal personality, constituted by and under the control of another company (known as the parent company) that holds the majority of the capital.

The common business practices with respect to commercial terms, including, but not limited to, sales promotions, discounts, margins and any other commercial terms, are subject to applicable laws and regulations and they are always established unilaterally and independently of each company member of RASCI in relation to its clients and do not fall within the scope of this RASCI Code.

The RASCI Code governs all methods of promotion described in this document and all other interactions with health professionals and organizations with health activities, with the exceptions listed below. The following materials are not subject to this RASCI Code, as they are governed by other provisions:

- The Summary of Product Characteristics ('SPC') and other full descriptive information documents, including information leaflets for patients /professionals included in medicine packaging;
- Labeling and instructions for use for food supplements and medical devices;
- The correspondence, possibly accompanied by non-promotional materials, in response to individual questions from health professionals or relevant decision-makers or in response to specific communications from them, whether questions or comments, including letters published in professional journals only if they relate to the subject of the letter or question and are not of a promotional nature;
- Factual, informative, and reference notices on authorized medical products that refer to, for example, packaging changes, adverse reaction warnings as part of general precautions, trade catalogs, and price lists, provided they do not include product promotional messages;
- Non-promotional information on human health or disease, provided that there is no direct or indirect reference to certain medical products;
- General non-promotional information about companies (such as information to investors/current/potential employees), including financial data, descriptions of research and development programs and discussions about regulatory approaches affecting the company and its products.

The following is attached to the RASCI Code:

- Annex A – “Rules of application and procedure”;
- Annex B – "Guide to the websites available to healthcare professionals, patients and the general public";
- Annex C – “Guide to commercial communication related to food supplements”;
- Annex D – “Medical Communication Guide for Medical Devices”.

APPLICABILITY OF THE RASCI CODE

The RASCI Code sets out the minimum standards that RASCI member companies have voluntarily undertaken to apply.

The provisions of the RASCI Code apply to all RASCI member companies, together with affiliates or subsidiaries that promote personal care products and each will be held responsible for the compliance with all provisions of the Code.

The RASCI member companies must comply with the RASCI Code and all the applicable European or national laws and regulations.

In the event of a conflict among the provisions of the applicable code, laws and regulations specified above, the more restrictive provisions, aligned with the legal provisions, shall apply.

RASCI also encourages the compliance with the letter and spirit of the provisions of the following laws and regulations, including, but not limited to:

- Law no. 95/2006 on the health care reform, with all subsequent amendments;
- Order of the Ministry of Health no. 194/2015 on the approval of the Norms for the evaluation and approval of advertising for medicines for human use;
- The Government Decision no. 54/2009 on the conditions for placing medical devices on the market;
- The Government Decision no. 798/2003 on establishing the conditions for the placing on the market and use of medical devices for in vitro diagnosis;
- The Law no. 491/2003 (as amended by Law no. 239/2010) on medicinal and aromatic plants, as well as on hive products;
- The Order of the Ministry of Health no. 1069/2007 for the approval of the Norms regarding food supplements;
- The Order of the Ministry of Agriculture and Regional Development no. 1946/2014 for the approval of the Procedure regarding the notification of the finished products based on medicinal plants, aromatics and hive products;
- The Joint Order of the Ministry of Agriculture and Regional Development and the Ministry of Health no. 244/2005 on the processing, processing and marketing of medicinal and aromatic plants used as such, partially processed or processed in the form of pre-dosed food supplements;
- The Regulation (EC) no. 1170/2009 of the Commission amending the Directive 2002/46/EC a European Parliament and of the Council and Regulation (EC) No Regulation (EC) no. 1925/2006 of the European Parliament and of the Council as regards the lists of vitamins and minerals and the forms in which they may be added to foods, including food supplements;
- The Regulation (EC) no. 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods;
- The Council Directive 92/28/EEC of March 31, 1992 on the advertising of medicinal products for human use;
- The Regulation (EU) no. 432/2012 of the Commission Regulation (EC) of 16 May 2012 establishing a list of permitted health claims on foodstuffs other than those relating to the reduction of the risk of disease and the development and health of children and the rectification of Regulation (EC) no. 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods;
- The Council Directive 93/42/EEC of June 14, 1993 on medical devices;

- The Directive 98/79/EC of the European Parliament and of the Council of October 27, 1998 on the in vitro diagnostic medical devices;
- The Directive 2001/83/EC of the European Parliament and of the Council on medicinal products for human use, as amended by the Council Directive 2004/27/EC and the Directive 2010/84/EC;
- The Laws, Decisions, guidelines, provisions of the Romanian National Agency for Medicines and Medical Devices ("ANMDMR") which regulate the activity of promoting over-the-counter medicines and medical devices;
- The Guide "Food Supplements" (2013 edition) issued by the National Institute of Public Health;
- The "Guide of Food Supplements based on Medicinal Plants, Aromatic and Hive Products" (2018 edition) issued by the National Research-Development Institute for Food Bioresources - IBA Bucharest;
- The Law no. 160/2018 for the amendment and completion of the Pharmacy Law no. 266/2008 and the Order of the Ministry of Health no. 444/2019 for the approval of the Norms regarding the establishment, organization and operation of pharmaceutical units (especially the regulations regarding the conduct of online trade activities for OTC medicines).

The above laws and regulations are a non-exhaustive list and may be amended from time to time, in which case RASCI member companies must comply with and observe all applicable laws and regulations at the time of application.

This RASCI Code covers the advertising and promotion of personal care products for the general public and the healthcare professionals.

The personal care industry explicitly confirms that promotional practices provide a legitimate benefit to both the healthcare industry and healthcare professionals. By clarifying this, the personal care industry is taking a proactive step towards the collective recognition of its legitimate and beneficial interests, as well as that of health professionals and the general public.

All materials, regardless of the media used (conventional and electronic media) developed by or on behalf of the company to support or encourage the release, sale, administration or consumption of products are considered promotional materials, in particular:

- Any kind of advertising (product brochures, visuals, non-scientific posters, announcements, files, correspondence, gifts, etc.);
- Product monographs;
- Educational materials, if used for external audiences;
- Educational websites that support related products or diseases;
- Informational (or similar) social networks written by or sponsored by member companies.

The RASCI member companies must comply in good faith with the requirements set out in the RASCI Code and must comply with it in relation to their direct and indirect actions when operating through third party contractors (e.g. distributors, agents, foundations, etc.)).

PROVISIONS OF THE RASCI CODE

Article 1. The marketing

Section 1.01. The advertising for personal care products is only allowed for:

- Over-the-counter medicines that have a marketing authorization issued by the NATIONAL AGENCY OF MEDICINE AND MEDICAL DEVICES IN ROMANIA / EUROPEAN COMMISSION;
- Food supplements containing only vitamins and minerals that have a notification issued by the MINISTRY OF HEALTH;
- Herbal food supplements or mixtures that have a Notification issued by:
  NATIONAL SERVICE FOR AROMATIC MEDICINAL PLANTS AND HIVE PRODUCTS within the National Research and Development Institute for Food Bioresources (SNPMAPS - IBA) or the PUBLIC HEALTH DIRECTORIES (DSP);
- Medical devices holding an EU Manufacturer's Declaration of Conformity and / or an EC Certification from a Notified Body in accordance with applicable European legislation.
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Section 1.02. The personal care products should not be promoted outside the scope of approved/notified indications/purposes.

Article 2. Promotion and substantiation

Section 2.01. The RASCI member companies hereby express their commitment to comply with the provisions of European and Romanian legislation applicable to promotion methods in all marketing and promotional activities carried out in relation to personal care products. The promotion must always be in accordance with applicable laws and regulations, as well as with this RASCI Code.

Section 2.02. The promotion must not discredit or reduce the confidence in personal care products and must always recognize the special nature of personal care products and protect the public health. The promotion must be appropriate and encourage the responsible use of personal care products.

Section 2.03. All interactions with healthcare professionals must take place in a highly professional and ethical manner, by respecting the independence of healthcare professionals and the general public in decision-making.

Section 2.04. The promotion must never be disguised, as detailed in Article 3.

Section 2.05. The advertising and promotion must be accurate, balanced, decent, fair, objective and sufficiently comprehensive to enable the recipient to form their own opinion on the therapeutic value of, for instance, the personal care products in question.

The advertising and promotion must be consistent in terms of content and the interpretation from a medical / scientific viewpoint and the product information must not be misleading in any way.

The statements must be no stronger than the arguments by scientific evidence, as the case may be, and every effort must be made to avoid ambiguity. Important information will not be omitted in order not to mislead the advertisement recipients.

The promotion must be based on an up-to-date assessment of all relevant evidence and it must clearly reflect this evidence. It must not be misleading by misrepresentation, exaggeration and exaggerated highlighting, omission or otherwise.

Section 2.06. The comparative advertising must comply with the legislation in force (for example Law no. 363/2007, Law no. 158/2008, with all subsequent amendments). Any comparison between different personal care products should be based upon relevant and comparable aspects of the products. The comparative advertising must not be misleading or derogatory.

The comparative advertising does not allow:

a) The denigration of the products of another company;

b) The use of the brand name (trademark) of another company;

c) The comparison of products with different indications / destinations or which cannot be compared in another way;

d) Carrying out a non-objective comparison of one or more essential, relevant, verifiable and representative characteristics of the products, including the price;

e) Creating a confusion on the market between the advertiser and a competitor or among the various trademarks or other distinctive signs of the advertiser and those belonging to a competitor;

f) Discrediting or denigrating the trademark, other distinctive signs, activities or any other characteristics of a competitor;

g) Improperly exploiting the reputation of a trademark, the distinctive signs of a competitor or any other characteristic of a competitor without having evidence in support of the assertions.

Section 2.07. All illustrations, including graphics, diagrams, photographs, and tables taken from published studies included in the promotional materials, must clearly indicate the source (s) of the illustrations and information.

Section 2.08. The wording “safe”, “risk-free” or similar wordings should not be used to describe a personal care product without proper justification.

Section 2.09. It should not be mentioned that a product does not cause side effects, toxicity or risk of addiction.

Article 3. The transparency of promotion

Section 3.01. The promotion must not be disguised.

Section 3.02. The post-market surveillance studies or any other data collection should not be used to mask promotion. Such assessments, programs and studies must be carried out primarily for scientific or educational purposes.

Section 3.03. When promotional materials are published in the press as a result of services contracted by a RASCI member company, a subsidiary or an affiliated company (e.g. the PR company of the RASCI member company), these promotional materials must clearly disclose the RASCI member company which is the beneficiary of the publishing service. This article should not resemble an independent editorial issue.

Section 3.04. Each RASCI member company is responsible for all advertising and educational materials related to its products. Where such materials are disseminated by public relations agencies under contract, the RASCI member companies shall be responsible for the design, distribution and use of the materials.

Article 4. No advice on personal health issues

Section 4.01. In the event of requests from the general public for advice on personal health issues, the applicant should be advised to consult a healthcare professional.

Article 5. Promotional items, informational and / or educational materials and medical articles

Section 5.01. The transmission of promotional items, informative/educational articles and articles of medical utility to health professionals is allowed, provided that the following are met simultaneously:

a) to be of "moderate value", a recommended value of maximum 150 RON, including VAT, before personalization,

b) to be relevant to the practice of the profession of health professionals and

c) to be beneficial for patient care.

Section 5.02. The medical promotional items / items intended directly for the education of health and care professionals may be provided if they are of modest value and do not compensate for the recipient's routine business practices.

Section 5.03. The purpose of the informational and educational materials and articles of medical utility in question may not be to circumvent the prohibition of gifts, as defined in Article 6 of this Code.

Section 5.04. The transmission of such materials or articles should not be an incentive to recommend, prescribe, purchase, release, sell or administer a personal care product.

Article 6. The prohibition of gifts

Section 6.01. No gift, pecuniary benefit or other benefit of any kind may be provided, offered or promised to a healthcare professional. The payments in cash or cash equivalents (such as certificates or gift certificates) are prohibited.

Article 7. Events and hospitality

Section 7.01. All promotional, scientific or professional meetings, congresses, conferences, symposia and other similar events (each of which is an "event"), including, but not limited to, visits

to production sites or research laboratories, meetings of advisory committees, planning meetings, educational meetings (courses) or investigators' meetings for clinical or non-interventional studies organized or sponsored by a RASCI member company must be held in a suitable location, which promotes the main purpose of the event and provides hospitality only then when the hospitality is adequate and complies with the provisions of the RASCI Code.

Section 7.02. It is recommended that no RASCI member company organizes or sponsors an event that takes place outside Romania, with the following exceptions:

a) The majority of the guests are from outside Romania and, considering their countries of origin, from a logistical viewpoint, the organization of the event in another country is justified, or
b) Given the location of the relevant resources or expertise that is the subject of the event, logistically it is justified to organize the event in another country (an "international event").

Section 7.03. The promotional information that appears on exhibition stands or is distributed to participants in international events may relate, unless otherwise prohibited or regulated by local laws and regulations, to personal care products (or uses) that are not registered in the country where the event takes place, or which are registered under different conditions, as long as:

a) An appropriate statement shall be attached to all such promotional material (except promotional material) indicating the countries in which the product is registered and specifying that the product or use has not been registered locally, and
b) An explanatory statement indicating the conditions of registration must be attached to all such promotional material relating to prescription information (indications, warnings, etc.) authorized in a country or countries where the personal care product is registered differs internationally, if any.

Section 7.04. The hospitality offered in connection with promotional, professional or scientific events must be limited to travel, meals, accommodation and actual registration fees.

The sponsorship of the participation of health professionals in fashion-related events, independent sporting or cultural events or in the context of congresses is not allowed.

Section 7.05. The RASCI member companies must not provide or offer meals (food and beverages) and accommodation to healthcare professionals unless, depending on the situation, the value of such meals (food and beverages) does not exceed the financial threshold set out below. The financial threshold set in the country where the event takes place by the relevant applicable code (e.g. "host country") prevails.

Section 7.06. Any kind of hospitality can only be offered to people who qualify as participants as such.

Section 7.07. All forms of hospitality offered to healthcare professionals must be reasonable in level and strictly limited to the duration of the event.

Section 7.08. In order not to influence the health professionals, the RASCI member companies should avoid using venues that are famous for their entertainment or sports facilities or for their "extravagance" or "luxury".

Section 7.9. The recommended maximum limits for hospitality expenses are:

a) The travel by plane (domestically and abroad): at economy class. The business class or over is not allowed.

b) The accommodation is recommended for hotels classified with a maximum of 4*;

c) The meals: for the internal meals, the maximum limit is 300 RON (VAT included) per day, for each person, when the hospitality includes two meals and 150 RON (VAT included) per person, when the hospitality includes only one main meal;

d) For "coffee breaks", the maximum limit is 35 RON (VAT included) for each person. For all-day events, no more than 2 "coffee breaks" are accepted for each day of the event.

e) In the countries - hosting countries - where local regulations do not set a limit for meals, the maximum limit is EUR 150 per day (or equivalent) for lunch and dinner. This limit does not apply to "*official dinners*" held at international conventions (as described in the event documentation).

The RASCI member companies should not provide or offer meals (food and beverages) to healthcare professionals unless the value of such meals (food and beverages) meets the financial threshold set out herein.

Article 8. Sponsorships / Donations / Grants / Free Rentals Supporting Medical Care or Research

Section 8.01. The Sponsorships/Donations/Grants (in cash, in-kind or otherwise) and/or free rentals to/from public institutions, organizations or associations which comprise healthcare professionals and/or which provide or carry out healthcare research activities (which are not otherwise regulated by the RASCI Code) are allowed only if, cumulatively:

a) It is performed in order to support medical care or medical research;

b) It is documented and kept in the records by the donor/supplier;

c) To recommend, prescribe, purchase, release, sell or administer specific personal care products does not represent an incentive; and

d) It is specifically based upon a request from that organization/association/institution.

The donations and grants for individual health professionals are not allowed under this section. The sponsorship of health professionals by companies to participate in international events is governed by the Article 10. The beneficiary companies are encouraged to make available to the public the information about donations and grants (in cash or in-kind or otherwise) received by them, and which are the subject of this Section 8.01, if the legal provisions so provide.

The RASCI member companies have the responsibility (i) to include in the sponsorship contracts a ban on the use of the equipment for personal gain or to obtain material benefits from the beneficiary's employees, (ii) to ensure that the beneficiary uses the object obtained through this donation or sponsorship exclusively for the free benefit of patients and (iii) to request the beneficiary to prepare a complete presentation of these activities, in accordance with the provisions of the legislation in force.

Article 9. Service charges

Section 9.01. The contracts concluded between the RASCI member companies and institutions, organizations or associations of health professionals under which institutions, organizations or associations provide any kind of service to RASCI member companies (or any other type of funding not covered by Article 8 or not otherwise subject to the RASCI Code) are allowed only if such services (or other funding):

a) They are provided for the purpose of supporting medical care or research; and

b) To recommend, prescribe, buy, deliver, sell or administer specific personal care products does not represent an incentive.

Article 10. The sponsorship of health professionals

Section 10.01. The RASCI member companies must comply with the criteria governing the selection and sponsorship of healthcare professionals to participate in training courses or events, as set out in, or in connection with, any applicable code (s). The funding will not be provided to compensate for the time spent by health professionals in attending events. In the case of international events for which a RASCI member company sponsors the participation of a healthcare professional, if such funding is granted to such healthcare professionals in accordance with the provisions of this Section 10.01, such funding is subject to the rules of health jurisdiction in which such healthcare professionals operate, not the rules applicable in the jurisdiction in which the international event takes place. For the avoidance of doubt, this Section 10.01 is not intended to prohibit the provision of hospitality to healthcare professionals in accordance with Article 7 of this Code.

Article 11. The use of consultants

Section 11.01. The RASCI member companies are allowed to employ health professionals for services such as, but not limited to, lectures, consultancy and/or counseling (participation in, but not limited to, meetings of advisory committees) and involvement in medical activities/ scientific studies, training services, as well as the participation in market research, in groups or individually.

The arrangements covering such consultancy or other services must meet, to the extent relevant to that arrangement, all of the following criteria:

a) A written contract or agreement shall be agreed upon before the start of the provision of the services specifying the nature of the services to be provided and, subject to clause (g) below, the basis for payment for such services;

b) A legitimate need for services has been clearly identified before requesting services and concluding arrangements with potential consultants;

c) The criteria for selecting consultants are directly related to the identified need, and the persons responsible for selecting consultants have the necessary expertise to assess whether the health professionals concerned meet these criteria;

d) The number of contracted health professionals does not exceed the number reasonably required to meet the identified needs;

e) The contracting company keeps records of the services provided by the consultants and uses them accordingly;

f) The hiring of health professionals to provide the relevant service is not an incentive to recommend, prescribe, buy, deliver, sell or administer a particular personal care product; and

g) The compensation for services is reasonable and reflects the fair market value of the services provided.

Section 11.02. For the services provided, the external consultants will be offered reasonable compensation, including reimbursement of reasonable travel, subsistence and accommodation expenses (if applicable). The limits considered reasonable (gross hourly rates) are described below and are recommended to be followed by RASCI member companies.

Section 11.03. Based upon the public information related to the activities carried out by health professionals in private clinics or pharmacies, the RASCI member companies recommend as fair market value for health professionals in Romania the following gross amounts (hourly rates), excluding VAT:

a) Up to 450 RON (four hundred and fifty RON)/hour for healthcare professionals, who find themselves in the following situations: primary care physician with or without a university degree;

b) Up to 370 RON (three hundred and seventy RON)/hour for healthcare professionals, who find themselves in the following situations: medical specialist with or without a university degree;

c) Up to RON 285 (two hundred and eighty-five RON) hour for healthcare professionals, who find themselves in the following situations: pharmacists;

d) Up to 150 RON (one hundred and fifty RON)/hour for health professionals, who find themselves in the following situations: resident physician;

e) Up to 70 RON (seventy RON)/hour for healthcare professionals, who find themselves in the following situations: nurses.

For other categories of specialists associated with the health field, such as, but not limited to – psychologist; health economist; specialist in medical devices – the above hourly fees may be applied depending on their expertise and level of training, without exceeding the maximum limits per activity.

Section 11.04. A total gross amount (excluding VAT) of the fees of RON 2,700 (two thousand seven hundred) per activity for event services will be taken into account, for example, but not limited to conferencing and moderation, and 5,400 (five thousand four hundred) RON per activity for services provided at events, for example, but not limited to advisory boards and trainings. The total amount of service fees includes preparation and performance time. There are no maximum limits for NON-event-related consulting services (non-event-related services, which may take a considerable amount of time to prepare and/or perform).

Section 11.05. The transparent communication to the audience of the speaker's affiliation with a RASCI member company as a recipient of the service must be made explicit. The RASCI member

companies will internally define reasonable limits for such services, which can be paid to a healthcare professional within one year.

Section 11.06. In the written contracts with consultants, the RASCI member companies are encouraged to include provisions on the consultant's obligation to declare that he is a consultant to the company whenever he writes or speaks in public on a matter which is the subject of the agreement or any other matter relating to that company. The provisions of this Section 11.06 apply even if the RASCI Code does not otherwise regulate the general non-promotional information about companies (as specified in the "Scope of the RASCI Code" Section).

Section 11.07. If a healthcare professional participates in an event (an international event or other event) as a consultant, the relevant provisions of Article 8 shall apply.

Article 12. Samples

Section 12.01. Samples may be distributed in accordance with the applicable national regulations.

Section 12.02. Each sample must be appropriately marked, for example, with the label "free sample - not for sale", and must be accompanied by a copy of the Summary of Product Characteristics (SPC), leaflet, package leaflet, instructions or label, as appropriate, in accordance with the relevant legal requirements.

Article 13. The staff of RASCI member companies

Section 13.01. Each RASCI member company must ensure that its representatives, including the staff contracted under a third-party contract, as well as any other representatives of RASCI member companies who call on healthcare professionals, pharmacies, hospitals or other related healthcare institutions with the promotion of personal care products (each being a "representative") are familiar with the relevant requirements of the RASCI Code and all relevant laws and regulations in Romania and Europe and are properly trained and have sufficient scientific knowledge to be able to provide accurate and complete information about the personal care products they promote.

a) The representatives must comply with all the requirements of the RASCI Code and all the relevant laws and regulations in Romania and in Europe and each RASCI member company is responsible for ensuring the compliance by them.

b) The representatives must approach their duties responsibly and ethically.

c) The representatives must immediately send to the relevant department of their companies (medical, pharmacovigilance, quality assurance, promotion) any information they receive regarding the use of over-the-counter medicines outside the indications approved in Romania or regarding their use during pregnancy, as well as reports of side effects or reports of quality deficiencies of over-the-counter medicines marketed by their company.

Section 13.02. All the staff of the RASCI member companies and all the staff employed under contract with third parties who prepare or approve promotional materials or activities must be fully familiar with the requirements of the RASCI Code and relevant laws and regulations in Romania and Europe.

Each RASCI member company must implement a training program for all the relevant employees, which will be repeated whenever there are significant changes to the RASCI Code or to the laws

and regulations in force in Romania and Europe, in accordance with the internal policies of each RASCI member company.

Article 14. Market studies

Section 14.1. The market research means any organized effort to gather information about the market and consumers of personal care products.

Section 14.2. The market research is a valid method for recording data and characteristics of the market and consumers of personal care products.

Section 14.3. The market research can be performed:

a) Either by questionnaires to which the subjective answers are given by a representative sample for the reference population (e.g. health professionals);

b) Either through questionnaires administered to groups comprising a sample representative of the analyzed population (target groups - qualitative market studies) (e.g. health professionals), in order to obtain a summary of the answers.

Section 14.4. The market research must be impartial; it must not focus on the sales promotion, and it must not be intended to influence the opinion of the participants.

Section 14.5. Within each market study, attention should be paid to the random and representative selection of participants.

Section 14.6. The market study can be retrospective / prospective; or instantaneous-type.

Section 14.7. The information and statistical results obtained from market research may be used for promotional purposes, provided that the information on the studies (who, when, where, what sample) is clearly mentioned. In any case, the collection and use of data obtained from studies must be separate processes.

Section 14.8. The market research must be conducted in a manner that does not affect the credibility and reputation of the personal care industry.

Section 14.9. The market research must be carried out by certified companies in the field of market research, which must comply with the principles of ESOMAR/EphMRA (European Market Research Society, http://www.ephmra.org).

Section 14.10. Any communication between a patient and his family and market research companies dealing with the marketing / allocation / promotion of a personal care product is prohibited in these market research activities - as described above.

Section 14.11. The staff of RASCI member companies must not carry out market research or carry out such activities directly.

Section 14.12. If the RASCI member companies enter into contracts with market research companies, they may provide reasonable compensation to healthcare professionals, which may in no case exceed the fees - as listed in Section 11.

Article 15. Resolving complaints

Section 15.01. Receiving notifications

Any interested person / entity may submit a notification to RASCI by e-mail to office@rasci.ro (www.rasci.ro) for the attention of the RASCI Executive Director.

Section 15.02. Notification requirements

The issues related to the interpretation, compliance, application and / or violation of the Code may be subject to notification. The notifications are analyzed and evaluated by the RASCI Ethics and Compliance Task Force, through its designated representatives.

A valid notification must be made in writing and it must contain:

a) The identification data of the person / entity making the notification;

b) The relevant details on which the notification is based;

c) The proposed / requested corrective measures, if applicable.

The RASCI Ethics and Compliance Task Force is composed of the designated representatives of each RASCI member company.

Section 15.03. Notification processing

Within a maximum of 10 (ten) working days from the receipt of the complaint, the Executive Director of RASCI will notify the RASCI Ethics and Compliance Task Force.

Within a maximum of 10 (ten) working days, the RASCI Ethics and Compliance Task Force will set up the ad hoc Assessment Commission. The Ethics and Compliance Task Force of RASCI will delegate from among its members to be part of the Evaluation Commission 3 representatives from different RASCI member companies, except the parties involved, for a preliminary evaluation of the documents based on the regulations of the RASCI Code.

In order to delegate the 3 representatives who will be part of the Evaluation Commission, the potential incompatibilities and conflicts of interest will be considered in order to ensure impartiality in the evaluation of the notifications.

The decisions within the Evaluation Committee are taken by consensus.

The Evaluation Committee has the following powers:

a) To analyze the notification from the viewpoint of the compliance with the provisions of this Code and to issue decisions, evaluation reports and proposals for solutions;

b) If the Committee considers the complaint to be unfounded or if it considers that it does not have the competence to solve the problem, it can reject the complaint in a motivated manner;

c) To initiate an evaluation procedure when there is a reasonable indication of a violation of the RASCI Code and to resolve the complaint through an evaluation report that includes the proposed solution;

d) To communicate any decisions, evaluation reports, proposals for solutions to the RASCI Ethics and Compliance Task Force and to the Executive Director.

Section 15.05. Carrying out the notification evaluation procedure

As part of the procedure for assessing the referral, if the case may be, the Evaluation Committee will be able to request the views of the parties involved on the subject matter of the referral. The persons/entities involved will be able to prepare and communicate to the Evaluation Committee the point of view and supporting documents, if necessary, within a maximum of 10 (ten) working days from the request.

A hearing/viewpoint of the persons/entities involved may be requested before the Evaluation Committee, which will take place/be submitted within a maximum of 10 (ten) working days from the request.

Section 15.06. The settlement

Upon completion of the evaluation procedure, the Evaluation Commission will prepare an Evaluation Report, through which:

a) It can establish that the violation did not take place and dismiss the case; or

b) It can establish that the violation has taken place and issue proposals for settlement.

The communication of the Evaluation Report is made by the Executive Director of RASCI within a maximum of 10 (ten) working days, by e-mail, to the person/entity that filed the complaint, to other parties involved, if applicable, and to the members of the Steering Committee.

Implementing the proposed solutions, if applicable remains the responsibility of the notified person/entity.

Section 15.07. Privacy

RASCI will ensure the privacy of the information obtained as a result of any procedure described in this Article.

Neither the persons/entities involved nor RASCI can publish the decisions, evaluation reports, proposals for solutions of the Evaluation Commission.

The deliberations of the Evaluation Committee, as well as any documents, information and views analyzed by the Evaluation Committee, are strictly private.

Article 16. Changes to the RASCI Code

Section 16.01. The RASCI Ethics and Compliance Task Force will regularly review this Code as well as any recommendations issued regarding the compliance with this Code.

The proposed amendments to this Code will be reviewed by the RASCI Ethics and Compliance Task Force after consultation with the RASCI member companies and the relevant RASCI committees. Any proposed amendments to the Code will be submitted for evaluation by the RASCI Management Board and the ratification by the RASCI General Assembly.

ANNEX A – RULES OF APPLICATION AND PROCEDURE

Article 1. Definitions

1. "**promotion**" means all the activities of the representatives of a company, as well as any activity organized or sponsored by any RASCI member company, or carried out under the authority of one of the RASCI member companies, which promotes the prescribing, issuance, sale, administration, recommendation or consumption of a personal care product. The term includes, but is not limited to:

   a) oral, written, online, radio and TV advertising and communication to the general public and / or qualified persons to prescribe, recommend or release personal care products;

   b) advertising in newspapers and by direct mail to the general public and / or qualified persons to prescribe, recommend or deliver personal care products; c) providing samples;

   d) providing relevant objects for medical and pharmaceutical practice;

   e) sponsorship of scientific or promotional meetings, including payment of expenses associated with the participation in such meetings;

   f) providing information to the general public directly or indirectly;

   g) any other form of sales promotion, such as participation in exhibitions, the use of audio tapes, films, recordings, tapes, video recordings, the Internet, electronic media, interactive data systems and other similar means.

2. "**comparative advertising**" means any form of advertising which explicitly or implicitly identifies a competing product and / or comparative description.

3. "**misleading advertising**" means any form of advertising which in any way, including by way of presentation, misleads or may mislead any person to whom it is addressed or who comes into contact with it.

4. "**subliminal advertising**" means advertising that uses advertising messages that the receiver is unaware of, for example, expressed with very low sound intensity or that are displayed on a screen for a very short period of time, less than one second.

5. "**promotional materials**" means any tool used for promotional purposes as defined in the "promotion" above.

6. "**non-prescription medicinal product**" means: (a) any substance or any combination of substances which is presented as having properties for treating or preventing disease in humans; or b) any substance or combination of substances which may be used in or administered to humans, either for the purpose of restoring, correcting or altering physiological functions by the performance of a pharmacological, immunological or metabolic action, or by establishing a medical diagnosis requiring a marketing authorization.

7. d) "**medical device**" means any instrument, apparatus, equipment, software, material or other article, used separately or in combination, including software intended by its manufacturer to be used specifically for diagnostic and / or therapeutic purposes and necessary for the proper functioning of the medical device, intended by the manufacturer to be used for humans for the purpose of: a) diagnosing, preventing, monitoring, treating or ameliorating a disease; b) diagnosis, monitoring, treatment, amelioration or compensation

of an injury or a disability; c) investigation, replacement or modification of the anatomy or of a physiological process; d) control of the conception, and which does not fulfill its main action for which it was intended in the human body or on it by pharmacological, immunological or metabolic means, but whose functioning can be assisted by such means. In the context of this document, "medical device" designates "medical device for personal use".

8. "**food supplements**" means foods which are intended to supplement the diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dosage or presentation such as capsules, tablets, pills or similar forms, sachets of powder, liquid ampoules, drop counters and other similar forms of liquids and powders intended to be taken in small, measured units.

9. "**personal care product(s)**" means over-the-counter medicines, food supplements and medical devices for personal use, as defined above.

10. "**healthcare professional**" means members of the medical, dental, pharmaceutical and healthcare professions and their assistants.

11. "**health care organization**" means any legal person(s) which is an association or organization of medical or scientific care (regardless of legal or organizational form) such as a hospital, clinic, public health institution or non-governmental organizations (affiliated to public health institutions or having medical specialists on the board), the medical society, universities or other educational institutions or the knowledge society (except for patient organizations covered by the RASCI Code) whose address the registered office or the main place of operation is in Romania and (ii) through which one or more health professionals provide medical services or carry out research.

12. "**decision-makers**" means the representatives of the staff of public and private institutions, as well as, but not limited to, persons holding a position or mandate in a governmental authority related to health policies and regulations, members or chairs of advisory committees, members or chairs of the National Committee for the Coordination of Specialized Committees, members or chairs of expert committees, members of the Romanian Parliament and of the European Parliament.

13. "**market research**" means the collection and analysis of information and must be objective and non-promotional. Statistics or information may be used for promotional purposes. The two phases must be distinct. The market research should not collect data about every patient.

14. "**representative**" means a representative who visits health professionals and / or relevant decision-makers to present promotional and non-promotional information on medicines, such as, but not limited to, medical representatives, regional directors, zonal sales directors, sales managers, product managers, marketing directors, medical science affiliated persons, etc.

15. "**conformity assessment body**" means a body that performs conformity assessment activities as a third party, including calibration, testing, certification and inspection.

16. "**sample**" means a product, provided free of charge, labeled as a free sample, provided to healthcare professionals so that they can become familiar with it and gain experience in its use.

17. "**label**" means the written, printed or graphic information which appears on the packaging of the product.

18. "**CE conformity marking**" or "**CE marking**" means a marking by which a manufacturer indicates that a medical device complies with the applicable requirements set out in (a) Directive 93/42/EEC on medical devices (MDD)/GD no. 54/2009; b) Directive 90/385/EEC on active implantable medical devices (AIMD)/GD no. 55/2009 or c) Directive 98/79 EC on in vitro diagnostic medical devices (IVD)/GD no. 798/2003.

19. "**proposed purpose**" means the proposed use of a medical device in accordance with the information provided by the manufacturer on the label, in the instructions for use or in the materials or slogans used in advertising or sales, or as specified by the manufacturer in the performance evaluation.

20. "**user**" means any healthcare professional or non-specialist using a medical device.

21. "**instructions for use**" means the information provided by the manufacturer to inform the user of the intended purpose of a medical device or dietary supplement, its correct use, as well as of any precautions to be taken.

22. "**Nutritional Reference Value (NRV)**" means a set of recommended daily nutritional targets based upon available scientific evidence. These goals are intended for healthy individuals at different stages of life.

23. "**Reference Intake (RI)**" means an estimated daily level of nutrients to meet the requirements of a healthy individual at a certain stage of life and by gender. The daily reference consumption for adults aged 19 to 64 is 8400kj/2000kcal.

24. "**Recommended Daily Intake (RDA)**" means the average level of daily intake sufficient to meet the nutritional requirements for approximately all (97% -98%) healthy individuals.

25. "**allergen**" means a substance that may cause an allergic reaction.

26. "**additive**" means any natural or chemical substance which is not consumed as a food by itself and is not used as a constituent ingredient of a food, whether or not it has nutritional value and which is intentionally added for technological purposes (including organoleptic changes) becoming a component or affecting in one way or another the characteristics of food.

27. "**nutrients**" means nutrients or other substances having a nutritional or physiological effect.

28. "**nutrition claims**" means any claim that states, suggests or hints that a food has certain beneficial nutritional properties due to its presence, absence, increased or reduced energy levels or of a nutrient or other substance. Nutritional claims are only allowed if they are included in the Annex to the Regulation.

29. "**health claims**" means any claim that states, suggests or hints to a relationship between a food category, a food or one of its ingredients and health.

30. "**field of view**" means all surfaces of a package that can be read from a single visual point.

31. "**average consumer**" means the average consumer who is informed, careful, cautious and diligent, taking into account linguistic and socio-cultural factors.

32. "**distance selling**" means the sale of products through websites, by telephone and in catalogs.

Article 2. The interaction with civil servants and staff in public institutions

In carrying out their own activities, RASCI member companies may interact with civil servants, including decision-making health professionals.

In the case of such interactions, which are not covered by the provisions of this Code, other than those of this chapter, RASCI member companies will have the following obligations:

a) In every interaction with civil servants, the RASCI member companies must comply to an appropriate conduct and ethical practices. The RASCI member companies will not participate in and / or engage in any activity or relationship that could impact the integrity of the civil servant or the reputation of the personal care industry of RASCI or any other RASCI member company.

b) The interactions between the RASCI member companies and the civil servants should be conducted in accordance with the highest standards of ethics and professionalism, and the RASCI member companies should avoid any perception of conflict of interest.

c) the RASCI member companies will not provide the public servant with any misleading, false, prejudicial and / or discriminatory information.

In order to increase transparency, the RASCI member companies may include in their agreements with health professionals and decision-makers references to the obligation of health professionals and decision makers to comply with all the legal provisions governing incompatibility and / or conflict of interest, if appropriate.

In addition, in support of the member companies, the following is an example of a contractual provision that may be included by RASCI member companies in agreements with healthcare professionals / decision makers.

The model clause presented is only an example and should be considered a minimum recommended protection for RASCI member companies to which they may add as they see fit, without RASCI confirming the degree of compliance ensured by such a clause.

Example of a contractual clause (indicative content, minimum) More

general commitments:

[The healthcare professional/decision-maker] declares that he/she is not in a state of incompatibility, as required by the applicable law. [The Healthcare professional/decision maker] declares and undertakes to comply with the obligations regarding conflicts of interest under the applicable law.

More detailed commitments:

A new paragraph may be added to the first paragraph:

[The healthcare professional/decision-maker] declares that he/she is not in a state of incompatibility, as required by the applicable law. [The Healthcare professional/decision maker] declares and undertakes to comply with the obligations regarding conflicts of interest under the applicable law.

[The healthcare professional/decision maker] guarantees that he/she will complete and forward to the unit in which he / she works or to other competent or interested authorities and entities all the statements indicated in any applicable legal provisions stipulating the presentation of declarations of interests, incompatibility statements, declarations of ownership or any other similar obligations of the [healthcare professional/decision maker].

Article 3. Sponsorships / Donations / Grants / Free rentals

In order to support the efforts of technical-medical and scientific development for the benefit of patients, donations, sponsorships or rents free of charge (*loan*) of medical and/or technical equipment for general/medical use, for hospitals, clinics in the public health sector (except for private health institutions) or for non-governmental organizations (affiliated to public health institutions or having health professionals on the board) are allowed in the following cases:

a) **Donations or sponsorships** made specifically for (and proven by official contracts) medical or technical equipment for general use or for the renovation and adaptation of hospitals / clinics. This support is specifically based upon an unsolicited request from that organization and it is subject to disclosure for which the provisions of the relevant RASCI Code must be observed.

b) **The free** (*loan*) **leases** are specifically based on an unsolicited request from the organization concerned.

c) **Items used strictly for medical purposes** may be provided only to public institutions (not to individual health professionals). These items should cover the shortcomings caused by insufficient funding of the health system (for example, but not limited to, items such as peak flow meters, stethoscopes, thermometers, sphygmomanometers, otoscopes, ophthalmoscopes, laryngoscopes, reflex hammers), front mirrors, rhinoscopes, glucometers, tongue retractors, weight and height scales, etc.). These items may bear the logo of the company or product in accordance with existing and applicable law.

This type of support must be provided in accordance with the applicable legal provisions, strictly unconditional (no prescriptions or other types of commitments must be prescribed instead) and it must be directly related to medical activities and it must be directly or indirectly for the benefit of the patient.

ANNEX B - GUIDE TO WEBSITES AVAILABLE FOR HEALTHCARE PROFESSIONALS, PATIENTS AND THE GENERAL PUBLIC

Article 1. Transparency of the origin, content and purpose of the website

Each website must clearly identify:

a) The identity and the physical and electronic addresses of the sponsor (s) of the website;

b) The complete references regarding the source (s) of all the medical information included on the website;

c) The target audience of the website for over-the-counter medicines (e.g. healthcare professionals, patients and the general public or a combination thereof);

d) The purpose or objective of the websites;

e) Approval visa number, as appropriate;

f) Any other elements that are expressly provided for by the specific legislation, if applicable.

Article 2. The website content

a) The information included on the website must be regularly updated whenever there are significant changes to the product information (if applicable) and / or medical practice and, subject to the approval of the competent authority (if applicable), the website should clearly display, for each page and / or item, the most recent date this information was updated.

b) The following are examples of information that may be included in a single website or on multiple websites:

   i. General company information;

   ii. Health education information;

   iii. Information for healthcare professionals and the general public, in accordance with the applicable law;

   iv. The transparency of value transfers to healthcare professionals and healthcare organizations.

General company information. The websites may contain information that may be of interest to investors, the media and the general public, including financial data, descriptions of research and development programs, discussions of regulatory developments impacting the company and its products, information for potential employees, etc. The content of this information is not governed by this guide or by the legal provisions on advertising of medicinal products.

Health education information. The websites may contain non-promotional information for health education on disease characteristics, methods of prevention, detection and treatment and other information intended to promote public health. These may relate to therapeutic options, provided that the discussion is balanced and correct. Relevant information on alternative treatments may be provided, including, where appropriate, surgery, diet, behavioral changes and other non-drug interventions. The websites that contain information for health education should always recommend that people consult a healthcare professional if they need additional information.

Information for healthcare professionals. Any information on websites addressed to healthcare professionals that constitutes promotion must comply with the applicable code(s), applicable regulations and any other regulations governing the content and format of the advertising and promotion of products.

Article 3. Questions asked via e-mail

A website may provide healthcare professionals and patients or the general public with the option to communicate by e-mail requesting additional information on the products of RASCI member companies or other matters (e.g. feedback on the website). The RASCI member company concerned may respond to such communications in the same way as it would respond to requests received by ground mail, telephone or other means. In communication with patients or members of the general public, discussions about personal health issues should be avoided. If personal health information is disclosed, it must be kept confidential. For more information, depending on the case, the answers should recommend that one should consult a healthcare professional.

Article 4. Links to other websites for over-the-counter medications

The links can be created to a company-sponsored website from websites sponsored by others, but RASCI member companies should not establish links from websites intended for the general public to company-sponsored websites that are designed for the professionals in the field of health. Similarly, links may be established to separate websites, including websites sponsored by RASCI member companies or others. The "links" should usually be created to the homepage of a website or managed otherwise so that the reader is aware of the website's identity.

Article 5. Website addresses on the packaging

Subject to any applicable Romanian laws and regulations, the product packaging may include uniform addresses for locating resources (URLs) of company-sponsored websites that comply with this guide.

Article 6. Scientific analysis

The RASCI member companies should ensure that the scientific and medical information they prepare for inclusion on their websites is analyzed for the correctness and compliance with the RASCI Code. Where applicable law, the scientific service established within the company must perform this function or it may be entrusted to other suitably qualified persons.

Article 7. Privacy

The website must comply with the applicable laws and codes of conduct governing the privacy, security and confidentiality of personal information.

ANNEX C - COMMERCIAL COMMUNICATION GUIDE ON FOOD SUPPLEMENTS

Article 1. Introduction

The advertising of food supplements helps to increase the level of information and awareness of consumers about health issues and encourages them to better document their own health. Thus, the advertising of food supplements can support the proper contribution of personal care to a country's health system. The RASCI member companies have the responsibility to manufacture and / or market products in accordance with the requirements of local law, which are honestly advertised and labeled in such a way as to provide clear information to consumers.

The RASCI member companies want to achieve the following goals through this Voluntary Self-Regulatory Guide:

- Ensuring that member companies recognize their responsibility towards the consumer, the producer and the market;
- Promoting and supporting innovation in the field of food supplements;
- Educating the consumer about the proper and responsible use of food supplements personal care products;
- Coordinating market efforts to achieve these goals.

This guide is not intended to cover the following activities for food supplements:

- Pricing or other commercial activities;
- Provision of non-promotional information by member companies;
- The label and the instructions for use, as required by the relevant legislation, insofar as they are not of a promotional nature;
- The correspondence, possibly accompanied by non-advertising material, sent in response to individual questions from healthcare professionals, but only if it relates exclusively to the subject of the letter or question and it is not of a promotional nature;
- General, non-promotional information about companies (such as information to current/ potential investors or employees), including financial data, descriptions of research and development programs and discussions of regulations affecting the company and its products;
- Commercial / promotional campaigns, such as 1+1, “buy and earn”, etc.;
- Appearances in retailers' magazines (e.g. weekly magazine), such as picture and price reduction, picture page with picture and promo message / contests;
- Visits by sales representatives to qualified people to recommend food supplements;
- Sponsorship of any kind according to the following examples, but not limited to: promotional meetings attended by qualified people to recommend or distribute medical devices, scientific conferences attended by qualified people to recommend or distribute food supplements, corporate sponsorships, sponsorships of TV/radio programs, sponsorships of public events;
- Educational materials.

Article 2. General provisions applicable to all promotional activities

The promotional methods must not provoke unfavorable comments or discredit the industry. No exaggerated statements will be made and all-encompassing and superlative statements will be avoided. The word “safe” should not be used and the statement should not state categorically that a food supplement has no side effects, does not present a risk of toxicity or dependence.

Defamatory references to other products or manufacturers by design or involvement will be avoided. The consumers of food supplements will be instructed to read and follow the instructions on the labels, package leaflets, packaging or box.

The promotional activities will not directly or indirectly encourage the unjustified or excessive use of food supplements.

Article 3. Legal and self-regulatory requirements

These provisions apply to food supplements legally available to the general public. All promotional activities must be carried out in accordance with existing legislation in the food supplement industry and this Guide.

Article 4. Information on food supplements to regulate consumer advertising and labelling requirements for food supplements

The information on the labels, packaging and advertising materials of food supplements must not be misleading.

The information about food supplements must be accurate, clear and easy to understand and it must not attribute to food supplements effects or properties that they do not possess. Food supplement formulas must comply with the specific requirements, such as the inclusion of the percentage specification (%) of the Nutrition Reference Value (NRV) for a nutrient. The wording "It does not contain" must be accurate and not misleading. For example, the terms "gluten-free" are governed by Regulation (EU) no. 609/2013 of the European Parliament and of the Council of 11 July 2017 and the Regulation (EU) no. 1169/2011.

Food supplements should not be attributed properties to prevent, treat or cure human diseases, and the advertising should not refer to them. The disease risk reduction claims are allowed in accordance with the European Council Regulation (EU) no. 432/2012 on nutrition and health claims.

Section 4.01. Labelling of food supplements - requirements regarding what should be mentioned in the field of view

There are requirements (Regulation (EU) 1169/2011) on the placement of information in certain visual fields.

An additional requirement is to place certain information in the same "field of view":

- The category of products to which it belongs (food supplement) and the name;
- The net amount of food supplement;
- The product batch and expiration date (L / EXP);
- If relevant, the alcoholic strength by volume (ABV);
- If relevant, the caffeine warning and the amount of caffeine in the product, per portion of daily consumption;
- If relevant, "it contains added plant stanols" / "it contains added plant sterols". Therefore, the good practice suggests keeping at least the name of the food supplement in the main field of vision to enable the consumer to identify the specifics, nature and trade name of the product.

In the case of food supplements marketed in a tube or vial container included in a package, it is likely that most consumers will discard the box with the information on it. Therefore, it is recommended that all mandatory or optional warnings be included on the inner packaging label; for instance, information on allergens or the warning about iron and young children, which could pose a risk to the consumer if not available for the shelf life of the product(s).

The mandatory information must appear in the format required by European and national legislation.

The mandatory information must be clearly visible and intelligible. The information shall not be ambiguous, diminished or interrupted in any way. In the case of labels whose backs are detached, it is recommended that they be assessed on a case-by-case basis to ensure that the requirements for

the availability, visibility and location of mandatory information are complied with, including that the information can be easily found.

Section 4.02. Font size and largest area (applicable to local packaging and stickers)

The minimum font size of the text that appears on the package and is defined as "x" is equal to or greater than 1.2 mm.

Approximately "x" 8 in standard Arial

Approximately "x" 9 in Times New Roman standard

In cases where the largest available area is less than 80 cm^2, the minimum font size is defined as "x" equal to or greater than 0.9 mm.

Section 4.03. Labelling of allergens

Any ingredient or processing agent or derivative of such a substance or product that is used in the manufacture of the food supplement or an ingredient in a product, even if in a modified form, must be highlighted on the list of ingredients so that it is clear that it is present in the product. This can be done by using a different font, a different font style (bold or italic), a different font color, or a different background color.

If it is not clear from the name of the ingredient that it is derived from or it contains one of the allergens listed, this should be made clear by reference to the allergen, for example "lactose (milk)".

The allergen-related information must be clear and visible and not hidden or ambiguous. The use of allergen recommendation statements such as "it contains ..." will not be allowed to ensure that allergen information is provided in a standard format in all food sectors, helping to avoid consumer confusion.

If an ingredient is derived from crustaceans or mollusks, this must be stated in the list of ingredients as follows:

- Omega 3 oil (mollusk) if, for example, it is derived from mussels with green edges;
- Glucosamine (crustacean) if, for example, it is derived from the crab shell.

To help consumers understand the different types of shellfish, one can also include their type in the list, for example:

- Omega 3 oil (mollusk (mussels));
- Glucosamine (crab).

The allergen-related information will appear in the ingredient list only in the form specified above and will not appear elsewhere on the labels. However, because consumers are more familiar with finding allergen information in the box format, it is allowed to report allergen-related information. For instance, a box may be inserted just below the list of ingredients, with the text: "The allergy-related information is shown in bold in the list above."

Section 4.04. Labelling of additives

The detailed regulation of food additives is established by the Regulation 1333/2008 on food additives with the consolidated version of 28.10.2019 and the Regulation 1129/2011 with the consolidated version of 21.11.2013 which establishes a list of allowed food additives. The flavors

are regulated by the Regulation 1334/2008 with the consolidated version of 21.05.2019, as amended and supplemented.

The food additives and food enzymes present because they are contained in one or more ingredients and do not serve any technological function are subject to the principle of "transfer" and are exempt from labeling requirements, as the food additives used exclusively as processing aids, except if they are derived from one or more allergens. If they are derived from one of the allergens on the list, even if no original substance remains, they must be labeled as follows:

- "The name of the additive" (category) (derived from allergen X);
- The "Transfer" allows the presence of an authorized additive in a compound food to the extent that the additive is allowed for use in one of the ingredients of the compound food supplement. For example, the principle of "transfer" does not apply to foods for infants and young children.

In addition, there are requirements for warning statements for certain ingredients, including phytosterols and phytostanols, some sweeteners, "Southampton dyes" and caffeine, if they have been added for physiological purposes and not as flavoring.

Section 4.05. Nutrition labelling requirements

Despite the fact that dietary supplements are specifically exempt from nutrition labelling requirements, vitamins and minerals should be expressed as a percentage of the Nutrition Reference Value (VNR) or Reference Consumption (CR) and not as a percentage of the Recommended Daily Allowance (DZR), (which no longer exists). The nutritional reference value (VNR) was previously known as the Recommended Daily Intake (RDA).

Food supplements are subject to their own nutrition labelling requirements, according to the Directive no. 46/2002 on the food supplements, in which the directive and the national regulation transposing the directive include the intention to set minimum levels. Clearly, in cases where claims are made, they may be made only in respect of vitamins and / or minerals which contain at least 15% of these substances. In cases where no mention is made, RASCI believes that it would be good practice to list all vitamins and minerals present in the product in the table of nutritional reference values, regardless of the percentage of VNR.

Section 4.06. Labelling of caffeine

Any beverage to which caffeine has been added must include the statement "*High caffeine content. Not recommended for children or pregnant or breastfeeding women*" in the same field of vision as the food name, followed by a reference, in brackets, to the caffeine content, expressed per serving, as recommended for daily consumption on the label.

The law does not require foods, including food supplements, to include a warning unless caffeine has been added to the product for physiological purposes. However, the European Commission has stated that any product that contains caffeine, regardless of the source, must include the warning "*It contains caffeine. Not recommended for children or women who are pregnant or breastfeeding*" in the same field of vision as the food. Food supplements should also include caffeine content, expressed per serving, as recommended for daily consumption on the label.

Section 4.07. Optional information

The optional information, such as nutrition and health claims, may be included on labels and in advertising materials; however, it is stipulated that the optional information:

- The optional information will not be displayed to the detriment of the space for mandatory information;
- The optional information will not mislead the consumer;
- The optional information will not be ambiguous or confusing for the consumer;
- The optional information will be based on relevant scientific data (where applicable).

The optional information on the following topics may also be provided:

- Information on the possible unintended presence of substances that cause allergies or intolerances (e.g. “produced in a factory where nuts are processed”, “it may contain traces of nuts”);
- Information on the compatibility of use by vegetarians or vegans;
- Information on public health messages;
- The use of a nutrition or health claim;
- And others.

Section 4.08. Regulation (EC) no. 1924/2006 on nutrition and health claims on food supplements

The Regulation on nutrition and health claims shall apply to claims in commercial communications concerning the final consumer. The regulation does not control claims made in materials intended for health professionals or for commercial purposes. Where the information is presented for scientific or informational purposes, it is not a commercial communication and the Regulation does not apply.

The authorization of health claims is a two-step process. First, the European Food Safety Authority (EFSA) issues an opinion on scientific data. Following discussions with the Member States, the European Commission will then decide whether the entry will be authorized. The details of the procedure differ depending on the type of health claim.

The Regulation on nutrition and health claims also applies to trademarks and other trade names which may be construed as nutrition or health claims. Trademarks and trade names that suggest nutritional or health claims do not require authorization but must be accompanied by an authorized related statement. The trademarks and trade names in use before January 2005 are not required to comply with the Regulation by 2022.

Section 4.09. The average consumer

The terms must be understood by the average consumer (this effectively prohibits the use of nutrition and health claims in materials intended for children).

Section 4.10. The availability of nutrients in a diversified diet

The advertising materials should not suggest that it is difficult to obtain adequate amounts of nutrients from a diverse diet (except for folic acid in pregnancy and vitamin D for specific risk groups). E.g:

- "*Even if you eat healthy, it is difficult to get all the vitamins and minerals you need*" is not an acceptable statement because it suggests that it is difficult to get an adequate intake of vitamins and minerals exclusively from a healthy diet;
- "*If you fail to have a balanced diet, you can get a daily vitamin and mineral supplement*" would be an acceptable statement because the person currently does not have a balanced diet.

Section 4.11. Health-related claims

The advertising materials should not suggest that dietary supplements may be used to prevent or treat ailments and should not include references to such properties. Such claims are referred to as "health claims". However, the RASCI member companies have the opportunity to state that a product helps to sustain or maintain good health.

Eliminate all the health claims, including all references to medical conditions and symptoms.

Section 4.12. Examples of health-related claims

"It helps reduce joint stiffness"	X
"It helps keep joints supple and flexible"	V
"It helps prevent colds"	X
"It helps maintain a system healthy immune system"	V

The following phrases are other examples of health claims: "treatment", "deficiency", "prevention", "spina bifida", "joint stiffness", "medical research", etc.

Section 4.13. Tone-related claims

Discard all tone-related mentions, such as "restore vitality", "give you energy", unless there are clinical trials in this respect.

Section 4.14. Examples of tone-related particulars

"An extraordinary tonic"	X
"It helps maintain health and well-being"	V

Section 4.15. General health and well-being related particulars

If you have included a "general health and well-being" statement such as "it contributes to the maintenance of health and well-being", you must also include a specific health claim, according to the list of allowed health claims for foods other than those that refer to the reduction of the risk of illness and the development and health of children.

Section 4.16. Energy-related particulars

Make sure that the safety statements clearly reflect the role of that nutrient. The particulars of certain vitamins and minerals may say that it helps the body release energy from food, but it is unusual for food supplements to be a source of energy (calories) or they may claim that the product increases energy levels.

Section 4.17. Opinion from health professionals

The Regulation on nutrition and health claims prohibits the use of health claims which refer to recommendations from health professionals.

Section 4.18. Recommendations from the Associations of Professionals in the Medical, Nutrition and Dietetics Fields

Recommendations from associations of medical, nutrition and dietetics professionals are not allowed.

Section 4.19. Communications related to charities

Companies may declare that they donate money or support a specific charity. In situations where the partnership is concluded solely for fundraising purposes, this should be clearly communicated to consumers. Please note that any implicit statement must be acceptable in accordance with applicable regulations and codes.

Section 4.20. Distance selling

All the mandatory information, except the date of minimum durability (expiry date) and batch number, relating to the food, must be made available to the consumer before the purchase of the food. The "mandatory information" includes information required by the Food Supplements Directive and the national regulations.

This information must be provided at no additional cost to the consumer (e.g. the use of paid or premium telephone lines for sales is not allowed). If the information is provided by telephone, that line must be a toll-free number or a landline network, with no cost for the consumer.

All the mandatory information, including the date of minimum durability or expiry date, must be available to the consumer at the time of delivery.

Section 4.21. Allergenic substances or products to be mentioned in the list of ingredients

The list below is subject to change and future amendments may be applied; therefore, it can be treated exclusively as an example.

a) The cereals containing gluten, namely wheat, rye, barley, oats, white rye, Khorasan wheat or hybrids thereof, and products thereof, except:

i. Wheat glucose syrups, including dextrose (1);

ii. maltodextrins obtained from wheat (1);

iii. glucose syrups obtained from barley;

iv. cereals used in the manufacture of distillates or ethyl alcohol of agricultural origin;

b) Crustaceans and derived products;

c) Eggs and derived products;

d) Fish and derived products, except:

i. fish gelatin used as a support substance for vitamin or carotenoid preparations;

ii. fish gelatin or ichthyocol used to clear beer and wine;

e) Peanuts and derived products;

f) Soybeans and derived products, except:

i. the fully refined soybean oil and fat (and derived products, insofar as the process to which they have been subjected is not likely to increase the level of allergenicity assessed by the Authority for the relevant underlying product); ii. natural mixtures of tocopherol (E306), natural D-alpha tocopherol, D-alpha tocopherol acetate and D-alpha tocopherol succinate, obtained from soybeans;

iii. the phytosterols and phytosterol esters derived from vegetable oils, obtained from soybeans;

iv. the vegetable stanol ester made from vegetable oil sterols, obtained from soybeans;

g) The milk and milk products (including lactose), except:

i. whey used in the manufacture of distillates or ethyl alcohol of agricultural origin

ii. lactitol.

h) Nuts, namely: almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), walnuts (Anacardium occidentale), pecans (Carya illinoinensis (Wangenh) K. Koch), Brazil nuts (Bertholletia excelsa), pistachios (Pistacia vera), macadamia nuts and Queensland nuts (Macadamia ternifolia), as well as derived products, other than nuts used for the manufacture of distillates or ethyl alcohol of agricultural origin.

i) Celery and derived products.

j) Mustard and derived products.

k) Sesame seeds and derived products.

l) Sulfur dioxide and sulphites at concentrations greater than 10 mg / kg or 10 mg / liter in total SO2 shall be calculated for ready-to-eat products or reconstituted in accordance with the manufacturer's instructions.

m) Lupine and derived products.

n) Mollusks and derived products.

Section 4.22. Label verification proposal

Please note: The main field of vision will generally be the front of the pack **NAME OF THE COMPANY**		
NAME OF THE PRODUCT:		
DATE OF RECEIPT:	**REVISION DATE:**	
REQUIREMENT	**FIELD OF VISION**	**YES/NO**
Brand and name (s) of the product	Main	
Legal name of the food ("food supplements")	Main	

Net amount of food	Accompanied by the name of the food	
Date of minimum durability	Anywhere on the label	
Batch number / batch code	Easily visible, clearly legible and indelible	
Details of the commercial operator	Not specified	
Sweetener claims (if relevant)	Accompanied by the name of the food	
Instructions for use	Not specified	
Specific conditions of use (if relevant)	Not specified	
The list of ingredients (in descending order of quantity) which will include:	Not specified	
The correct names of vitamins / minerals, other substances including botanical / plant names	List of ingredients	
Excipients	List of ingredients	
Labeling of food additives in accordance with Regulations 1333/2008 and 1129/2011	List of ingredients	
Allergen information – highlighted	List of ingredients	
Phenylalanine-related claims (if relevant)	Not specified	
Polyol-related claims (if relevant)	Not specified	

A statement that each tablet / capsule / serving, etc. contains X amount of active ingredients	Above the table of nutritional values	
Any additional information required by the conditions of use for any nutrition or health claim (if relevant)	Right next to or immediately after the particulars	
A warning for products or ingredients that may pose a health risk if consumed in excess (e.g. warning of iron intake in children) (if relevant)	Not specified	
Caffeine-related warning (if relevant)	Accompanied by the name of the food	
Quantities of active ingredients with correct unit values (mg, µg, etc.) and including percentage of NRV (where applicable)	Table of nutritional values	
"The food supplements do not replace a varied diet and a healthy lifestyle"	Not specified	
"The recommended dose should not be exceeded."	Not specified	
"Keep out of the reach of children"	Not specified	
FSA recommendations (if applicable)	Not specified	
Storage conditions	Not specified	
Country of origin (if applicable)	Not specified	
Packaging damage warning (if applicable)		
Weight and dimensions		
Reviewed by	**Date**	

Section 4.23. Additional advertising requirements for vitamin and mineral supplements

In order to state that the product is a source for a particular vitamin or mineral or to mention a vitamin or a mineral, it must contain a significant amount of that vitamin or mineral. "A significant amount" is considered to be at least 15% of the RDA.

Section 4.24. "Source of vitamins and minerals" or "It contains vitamins and minerals"

According to the Regulation on nutrition and health claims, it is not acceptable to simply state that a product contains vitamins or minerals or that it is a source of vitamins or minerals, but quantities must also be included.

Section 4.25. Particulars on "High content of"

In order to claim that the product is "rich in" a certain vitamin or mineral substance, the product must contain twice the value for "source of". In most cases, this amount will be at least double the minimum of 15% of the RDA required by law.

Section 4.26. Particulars on "Complete"

For many years, food supplement manufacturers have used the term "complete" to describe the fact that the product contains a significant amount of every planned vitamin and mineral (e.g. every vitamin and mineral that has an RDA). However, the statement "complete" was not included in the list of allowed nutrition claims.

To state that a product is "complete", it must contain a significant amount of every vitamin and mineral substance that has an RDA. "A significant amount" is considered to be at least 15% of the RDA.

Section 4.27. Health particulars - Flexibility of written wording

The European Commission stated that some flexibility in written wording is allowed, provided that it helps the consumer to understand and that the amended wording has the same meaning for the consumer as the original statement.

Article 5. Advertisement

No food supplement will be advertised in a manner that is likely to lead to the use of the product by young children without parental supervision. Such advertising materials will not be specifically aimed at young children.

The advertising materials will convey true information and will not mislead. The advertising materials will not contain exaggerated, direct or implied statements.

The advertising materials will be easy to be understood.

The advertising materials will not contain suggestions for diagnosis, prescription or treatment.

The advertising materials will not discourage consumers from consulting their doctor.

All the descriptions, statements and comparisons relating to verifiable matters must be duly substantiated.

All the comparisons will be balanced and correct. The comparative claims, in any reasonable interpretation, will not mislead consumers as to the product being advertised or as to any other product with which it may be compared.

The advertising materials will not mislead as to the novelty of a preparation / formula; the term "new" is generally acceptable only for a reasonable period of time in association with the brand in order to distinguish the product from other products on the market.

The advertising materials will not suggest, expressly or implicitly, that a product contains unknown active ingredients.

No advertising material will be intimidating to increase and / or induce the use. The testimonials will give the honest opinion of the user, provided that it relates to the wording marketed at the time the testimonial was distributed. Caution is advised when editing the testimonials so as not to alter the original meaning in any way. The testimonials containing materials in opposition to the legal provisions of the RASCI Code will not be used.

Article 6. Social networks

The rules that apply to advertising for food supplements through traditional means also apply to the promotional activity on Twitter, Facebook and other social platforms.

These guidance notes were created to inform and educate about the responsibilities of the RASCI member companies on social media. These include all forms of social networking (unless otherwise stated) in which RASCI member companies and consumers can interact directly with each other. These are relevant for the employees of the RASCI member companies who use digital media and third parties who undertake obligations on behalf of RASCI member companies.

The RASCI member companies must monitor any user-generated content published in their own media, where consumers can post their own comments or generate content of any kind. The blogging can fall into all three types of social media, so caution is advised to consider the relevant issues. Traditionally, bloggers are “opinion-makers” who provide advice and reviews to consumers on a topic in a daily journal format. The bloggers' style and appearance are usually approachable and independent, meaning they can be very popular and seen as “experts” in certain topics. The RASCI member companies can use standalone blogs as a way to raise awareness of a product, although there are some important issues to consider. According to this Code, the bloggers are considered to be journalists. Therefore, communications sent by RASCI member companies to bloggers are considered PR material.

The RASCI member companies can provide bloggers with information about campaigns or products. However, steps will be taken to ensure that all the content provided to bloggers complies with the legal requirements.

Section 6.01. Facebook and Instagram

The responsibility for the communications on Facebook / Instagram extends to content published on behalf of the RASCI member companies and to the respective profile page. This includes posts, “stories”, content sharing and post replies. The content shared by consumer users, such as links and articles, does not become the responsibility of the RASCI member companies at the time of sharing, although it is necessary to verify that the content is appropriate and to clarify whether the content is under separate editorial control.

The RASCI member companies may respond to written communications sent to the RASCI member companies by wall posting, tagging (using@ brandname) or private messages. Where appropriate, the general questions will be answered.

The user references to the product in the status updates, without addressing the media held by the RASCI member companies do not fall within this competence and do not require a response.

The media monitoring can exist in pre- or post-moderation format. It is recommended that this be done at least once every 24 hours during the working week. If the page / feed is not monitored for longer than specified, it is recommended that a notification be sent to the consumer.

When promoting an advertisement or campaign using a third party's Facebook / Instagram page, it should be made clear that this is a promotional communication. This can be done by making sure that the post is referred to as a “sponsored post”. This is not the case with charities or similar organizations that have chosen to share content about you without notifying you.

Section 6.02. Twitter

Where there are space restrictions, such as postings with a character limit, if additional information is required for a statement of conditions of use, this may be accompanied by a link that provides additional information in a clear and legible manner, such as the brand's website.

Most of the content on Twitter is user-generated and it does not appear in the feed of the RASCI member companies, even if it is referenced directly.

The content for which the RASCI member companies are responsible includes only information written on behalf of RASCI member companies, with the designated name on Twitter. This includes tweets generated by the RASCI member companies, including retweeted tweets, content sharing, and replying to posts.

The shared content, such as articles, does not become the responsibility of the RASCI member companies at the time of sharing, although it is necessary to verify that the content is appropriate and to clarify whether the content is generated separately.

Reposting tweets to other users is also the responsibility of the RASCI member companies. Once the tweet has been reposted by the RASCI member companies, it is under the editorial control of the RASCI member companies and it must comply with all regulations.

It is recommended that the media monitoring be performed at least once every 24 hours during the work week.

When an advertisement or campaign is promoted using a third-party Twitter feed (e.g. a magazine) or when there is sponsorship involved, it should be made clear that this is an advertisement and that it was paid to post it. These are usually posted by inserting #ad or #spon at the end of the tweet.

Section 6.03. YouTube and blogs

As a form of owned media, the responsibility for communication lies with the RASCI member company. Depending on the platform, the RASCI member companies may use pre- or post-moderation to monitor their own content. It is recommended that media monitoring be performed every 24 hours during the work week.

It is recommended that RASCI member companies respond when a comment is left on their media platforms, as it is considered to be addressed directly to them. The RASCI member companies can decide whether to answer general questions.

The RASCI member companies may use online reviews as testimonials, provided that all the other requirements regarding the use of testimonials are met.

As a form of earned media, the responsibility for communication does not lie with the RASCI member companies. However, it is recommended that the RASCI member companies regularly monitor this content to identify any inappropriate content. If possible, such content will be answered or removed, if need be; however, it is important not to adopt an extreme attitude and to maintain a natural flow of comments. The RASCI member companies can respond to comments (if possible, on the selected media).

The user-generated reviews on third-party websites may be monitored by brand agencies/teams, although this is not required.

The RASCI member companies may use online reviews as testimonials, provided that all the other requirements regarding the use of testimonials are met.

Article 7. Promotions involving giveaways

The member companies can offer food supplements as gifts to consumers. The gift may or may not depend on the purchase of a food supplement.

Section 7.01. Giveaways offered at purchase

If the member companies wish to provide a giveaway on purchase, the giveaway must be relevant to the product purchased and have a lower value to the consumer than the cost of the food supplement. This will avoid the purchase of food supplements that consumers do not need, just to get a desired giveaway. The member companies must take into account both the actual cost (the amount paid for the gift) and the amount charged (the price at which the consumers could purchase a similar product). The promotional materials should promote the benefits of the product, not the giveaway, as the main argument for purchasing the food supplement.

Section 7.02. Promotional items

The promotional items are items that are intended to promote a food supplement and are marked with a product / brand name, as a reminder. They are usually provided free of charge, regardless of the purchase of a food supplement. The examples include, but are not limited to, T-shirts, pens, mugs, cup holders, notebooks and mouse pads. It is not necessary to include essential information for the consumer on promotional items where only the product name or a reasonable abbreviation of it and the trademark protection are present. The umbrella brand name can be used as an alternative to the product name. For instance, there is no need to include additional information on a pen marked “Brand name X” or the full name of the product.

ANNEX D - COMMERCIAL COMMUNICATION GUIDE FOR MEDICAL DEVICES

Article 1. General provisions, scope, regulations

Section 1.01. General provisions

In all the activities related to the advertising of medical devices, RASCI defines rules to be observed by the member companies of the association.

All the advertising and promotion of medical devices must be done responsibly, ethically and to the highest standard to ensure the safe use of medical devices.

The advertising of medical devices is accepted provided it complies with the applicable law.

These rules seek to clarify certain particulars so that advertising for any medical device, in whatever form, is of a high standard and complies with the legal requirements.

The advertising of medical devices must not include anything that could be offensive or misleading to the user.

Section 1.02. Scope

These rules cover the advertising of medical devices intended for the general public, persons qualified to recommend or distribute medical devices and the provision of samples.

These rules do not cover the following fields:

a) The label and the instructions for use, as provided for in the relevant legislation, insofar as they are not of a promotional nature;

b) The correspondence, possibly accompanied by non-advertising material, sent in response to individual questions from health professionals, but only if it relates exclusively to the subject of the letter or the question and it is not of a promotional nature;

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

d) Commercial/promotional campaigns, such as 1+1, “buy and earn”, etc.

e) Appearances in retailers' magazines (e.g weekly magazine), such as picture and price reduction, page with picture and promo message/contests.

f) Visits of sales representatives to persons qualified to recommend medical devices.

g) Sponsorship of any kind according to the following examples, but not limited to: promotional meetings attended by qualified persons to recommend or distribute medical devices, scientific congresses attended by qualified persons to recommend or distribute medical devices, corporate sponsorships, sponsorships of TV/radio programs, sponsorships of public events.

h) Promotional items;

i) Educational materials.

These rules are not intended to limit or restrict the provision of medical or scientific information to healthcare professionals or the general public.

The RASCI member companies are responsible for the compliance with the liabilities described in these rules, even in the case of assignment to third parties of the promotion, advertising or implementation activities or their commitment, on their behalf, in advertising actions provided for in these rules.

The RASCI member companies must ensure that any third party to whom they have assigned the advertising of medical devices complies with the provisions of these rules.

Section 1.03. Regulations

The advertising for medical devices is any form of organized activity aimed at informing by direct or indirect means, as well as any form of promotion designed to encourage the prescribing, distribution, sale, administration, recommendation or use of one or more medical devices. The advertising for medical devices may be intended for healthcare professionals or the general public. The advertising for a medical device:

a) It must be accurate, balanced, fair, objective and complete in order to enable those to whom it is addressed to have their own opinion as to the intended purpose and the therapeutic benefit of the medical device in question;

b) It must be based on an up-to-date assessment of all relevant evidence and clearly reflect that evidence;

c) It must encourage the rational use of the medical device, by its objective presentation, without exaggerating its properties and therapeutic qualities;

d) It must not encourage the irrational use of the medical device;

e) It must not be misleading, subliminal or deceitful by distortion, exaggeration, unjustified emphasis, omission or otherwise;

f) It must not suggest that a medical device has any special purpose, merit, quality or property, if this cannot be scientifically documented;

g) It must not include discrimination, for example discrimination based upon race, gender, language, origin, social origin, ethnic identity or nationality;

h) It must not harm the image, honor, dignity and private life of persons.

All the information contained in the advertising material for a medical device must comply with the information listed on the label and the instructions for use and it must also comply with the technical file of the medical device, as approved by the evaluating body of its compliance, as appropriate.

The advertising is prohibited to the general public and healthcare professionals who:

a) do not hold the European CE conformity marking (do not have an EU Declaration of Conformity and/or EC Certification from the Notified Body);

b) are not put into operation in Romania at the time of the advertising campaign.

The primary responsibility for the compliance with all the applicable advertising materials for a medical device lies with each RASCI member company.

The main forms of advertising used are:

a) Printed indoor and outdoor advertising materials;

b) Advertising in the audiovisual field;

c) Internet advertising and social networks;

d) Providing samples.

Article 2. Misleading advertising and comparative advertising

Section 2.01. Misleading advertising

The misleading advertising is any form of advertising which, in any way, including by way of presentation, misleads or may mislead any person to whom it is addressed or who comes into contact with it.

No form of advertising should suggest that a medical device has any particular purpose, merit, quality or property if this cannot be scientifically documented in the technical file of the product.

In determining the misleading nature of advertising, account shall be taken of all its features and, in particular, of the components relating to:

a) The characteristics of the medical device (whatever they may be), the extent to which they correspond to the intended purpose and the results expected as a result of its use;

b) The omission of essential information regarding the identification and characterization of the medical device in order to mislead the persons for whom the publicity is intended.

The advertising will not contain inappropriate, alarming or misleading statements regarding recovery. This rule forbids statements such as “miracle” and “miracle product”, but is not limited to them. It also prohibits visual cues that suggest healing, such as pre- and post-treatment imagery, which show a dramatic improvement that most users cannot expect to achieve. The following perceptions should be applied when considering the use of pre- and post-treatment photographs:

a) The pre-treatment photographs must show the level of severity of the condition in accordance with the intended purpose of the product. For example, the advertisements for products to treat pain caused by mild osteoarthritis should not include people with severe osteoarthritis;

b) Any post-treatment photographs must show an improvement that could realistically be expected by most people suffering from the condition when using the product according to the instructions;

c) The use of time intervals must accurately reflect the time interval that would be required to obtain the benefits. For example, claims that pain relief occurs instantly, when in fact it takes longer to achieve this effect, will not be acceptable.

Section 2.02. Comparative advertising

The comparative advertising is prohibited if:

a) The comparison is misleading in accordance with the provisions of Section 2.01.;

b) The brand name of a competitor is used and only the mention of generic names (e.g. soap) is allowed;

c) Medical devices that have different purposes and/or instructions for use are compared;

d) One or more essential, relevant, verifiable and representative features of medical devices are not objectively compared;

e) There is confusion on the market between the advertiser and a competitor or among the various trademarks, or other distinctive signs of the advertiser and those which belong to a competitor;

f) The trademarks, trade names, other distinctive signs, goods, services, activities or the situation of a competitor are discredited or denigrated;

g) The reputation of a competitor's trademark, trade name or other distinguishing marks or the designation of origin of competing products is unfairly exploited;

h) Goods or services as imitations or reproductions of goods or services bearing a protected trademark or trade name are presented;

i) There is a confusion among traders, between the advertiser and a competitor or among brands, trade names, other distinctive signs, goods or services of the advertiser and those of a competitor.

Article 3. Advertising for the general public and healthcare professionals

Section 3.01. General directives

Advertising is allowed only for those medical devices which have an EU Manufacturer's Declaration of Conformity and/or an EC Certification from a Notified Body in accordance with the applicable law.

Any form of advertising must be designed in such a way that the message of an advertising nature is clear.

Any form of advertising must include at least the following information:

a) Name of the medical device;

b) Clear definition of the intended purpose of use;

c) An express, legible invitation to read carefully the information in the user manual of the product/instructions for use or packaging, as appropriate;

d) The CE conformity marking, if applicable, the CE marking followed by the identification number of the notified body responsible for the conformity assessment procedures of the medical device (applicable from the date of entry into force of Parliament's Regulation (EU) 2017/745 European Parliament and of the Council on Medical Devices as well as the Regulation (EU) 2017/746 of the European Parliament and of the Council on Medical Devices for *in vitro* diagnosis);

e) The name/logo of the company that supported the production of the material.

In addition to the above requirements, any form of advertising may include the following information:

a) Non-promotional information related to health or hygiene (e.g.: “Wash your hands at least six times a day!”, “Brush your teeth at least twice a day!”);

b) Advice (recommendations) for increasing the quality of life of patients/consumers;

c) A design and a form of presentation that makes it clear and easy to understand.

The advertising for medical devices must not contain any material that:

a) Gives the impression that a medical consultation or surgery is not necessary, in particular by offering suggestions for remote diagnosis or treatment;

b) Suggests that the diagnosis, the result of the determination, established with a medical device is guaranteed, that it cannot be accompanied by errors or that the effect of the treatment with a medical device is guaranteed; that it is not accompanied by side effects or that the effect is better or equivalent to that of another treatment with a different medical device or other type of product;

c) Suggests that the health condition of the subject may be affected if the medical device is not used;

d) Addresses exclusively or especially to children;

e) Suggests that the medical device is a cosmetic or relaxation product or other consumer product;

f) Suggests that the safety or efficacy of the medical device is due to the fact that it is natural;

g) Is able, through a detailed description or representation of a case, to lead to an erroneous self-diagnosis;

h) Offers, in inappropriate, alarming or misleading terms, assurances regarding the healing by using the respective medical device;

i) Uses, in inappropriate, alarming or misleading terms, visual representations of changes in the human body caused by disease or injury or by the actions of medical devices on the human body or any part thereof.

Section 3.02. Regulations regarding the statements contained in the advertising materials

Statements regarding the "novelty" of a product can be made for only one year from the date when the product first became available for purchase by consumers in Romania. The RASCI member companies may use the word "new" or "now available" for one year from the date on which the medical device first became available for purchase. If the medical device is already available for purchase, it must be clearly stated which aspect of the product is new. For instance:

- "a new form" – the form is new, but the formula was already available;
- "a new formula for the X brand product" – the formula is new for the X brand, but it may also be available from other brands;
- "new for pain relief in joint conditions" – the product is now available for new therapeutic use;
- "a new orange flavor" – the term is accepted regardless of whether the products of other brands are available with orange flavor.

It is the responsibility of the RASCI member companies who promote their products to ensure that all the advertising material containing the word "new" is reviewed after the product has reached the 1-year limit and that no such advertisement is distributed after this period.

"Now" often implies that a product is "new" (e.g. "now available") and therefore the same time restrictions apply. However, "now" may also imply that the product brings something new to a particular industry. For example, the advertising message "Use the branded product X – now you can improve your vision quickly" will not be accepted because it suggests that product X is the only product that improves one's vision quickly.

All the advertising messages must be in accordance with the Technical Documentation of the medical device. The advertisements for intended uses that are not included in the instructions for use, on the label or in the clinical evaluation in the Technical Documentation are prohibited. The information in the Instructions for Use, Labeling and Clinical Evaluation Report sections of the Technical Documentation of the product will form the basis of any statements that may be made in the advertisement.

The advertising materials that refer to several products under the same trademark must specify very clearly which statements apply to each product.

Section 3.03. Forms of advertising

Sub-section 3.03.01. Indoor and outdoor printed advertising materials

The printed advertising materials can be printed indoor and outdoor advertising materials (e.g. posters, invitations to events, brochures, street banners or subway stations banners, billboards, decoration/wrapping of means of transport, print media, including articles press, visibility materials at the point of sale: wobbler, shelf liner, poster, floor display, flyers, stopper, security gates, shelves, Promo Island branding, etc.).

The printed advertising materials must comply with the requirements set out in the Sections 1 and 2 of this Annex.

Sub-section 3.03.02. Audiovisual advertising

The audiovisual advertising (radio, television) includes: radio and TV commercials, testimonials/ teleshopping.

The advertising of medical devices broadcasted on radio and television programs is subject to the legal provisions regarding the advertising in the audiovisual field.

The advertising of medical devices broadcasted on radio and television programs shall comply with the provisions set out in Sections 1 and 2 of this Annex.

The audiovisual advertising for medical devices means any form of promotion intended to stimulate their distribution, consumption / use or sale.

It is forbidden to broadcast advertising and teleshopping for medical devices presented or recommended by personalities of public, cultural, scientific, sports or other persons, who, due to their celebrity, may encourage the consumption / use of these products.

The advertising and teleshopping in which medical staff or pharmacists recommend or endorse medical devices is prohibited.

It is forbidden to broadcast advertising and teleshopping for medical devices, if the presentations contain recommendations or opinions of medical associations.

The testimonial advertising must comply with all other rules of these regulations.

The testimonials as such does not constitute evidence to support the product claim.

The testimonials should display the level of change that the average user might expect. That is why testimonials such as:

a) "*I have tried many other products, but this is the only one that has worked for me*" (this statement contradicts the provisions of Article 2, Section 2.02, "Comparative Advertising").

b) "*The X brand product made me feel better instantly*" (if this statement is not reflected by the evidence and the indication provided and approved).

c) "*This is also effective for my arthritis*" (in cases where the technical documentation for the product does not support its use for arthritis).

The testimonials must be more than three years old and must reflect the user's actual opinions.

The advertising RASCI member companies must keep evidence for each testimonial used. They must not be older than three years and the material must be edited carefully so as to avoid altering the original meanings.

All the testimonials must reflect the true opinions of consumers.

Sub-section 3.03.03. The advertising via the internet and the social networks

The advertising via the internet (e.g. social networks, web pages, e-mail, forums, blogs or any other form of electronic support, mobile applications, banners, display, online video, press articles, PR campaigns) must comply with the provisions in the Sections 1 and 2 of this Annex.

Sub-section 3.03.04. Providing samples

The provision of samples is allowed, provided that they are properly inscribed with the information "free sample - not for sale" or with a statement to that effect.