RASCI

CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC

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

(Edition 2020)

CONTENTS

INTRODUCTION

The Romanian Association of the Self-Care Industry[1] was founded in 2016 with a view to promoting responsible self-care in Romania, creating a positive and sustainable environment for the self-care industry and becoming a trusted partner for the Romanian authorities.

We are the association that supports the common objectives of the non-prescription medicines (OTCs), food supplements and medical devices for personal use (in accordance with the definition provided by the Association of the European Self-Medication Industry ("**AESGP"**)) manufacturers, importers and distributors operating in Romania.

Since its incorporation in 2016, RASCI is affiliated to the AESGP, the official industry trade association representation of manufacturers of non-prescription medicines (OTCs), food supplements and medical devices for personal use in Europe. It is composed of national associations and the main multinational and local companies manufacturing self-care products. In addition, there are a number of sectoral associations and companies focusing on specific areas in direct membership. The primary mission of AESGP and, implicitly, of RASCI, is to ensure a sustainable positive development of the self-care industry.

Dissemination of scientific and educational information ensures that the results of years of scientific work and huge investments in research and development shall also be made available to the healthcare professionals ("**HCPs**") and to the general public. In all healthcare-related activities, the representatives of the healthcare industry believe that high standards should be defined and observed and they are convinced that, as far as its promotional activities are concerned, self-discipline is the process which best serves the public interest. Ethical criteria for promotion of self-care products are regarded as the foundation for proper behaviour, consistent with the search for truthfulness and righteousness.

In January 2007, Romania became an EU Member State. In order to apply the same high ethical standards for promotional activities performed by the pharmaceutical industry in the EU, it is recommended to implement in Romania a code of conduct aligned to the one applied in the EU countries. Considering that, RASCI has adopted the RASCI Code on the 28.09.2018, revised at 29.09.2020

The RASCI Code of Interaction with Healthcare Professionals and General Public (hereafter "**RASCI Code**") is a voluntary set of standard practices that all RASCI Members follow, and is in compliance with the appropriate Romanian laws, regulations and guidelines and shall represent a reference that should thus assist in judging if promotional practices related to self-care products are in alignment with acceptable ethical standards and legal provisions.

RASCI is committed to ensuring that all of its Members are conscious of the importance of providing accurate, fair and objective information about self-care products, so that rational decisions can be made as to their use.

The RASCI Code also reflects the principles contained in requirements of the AESGP Code

[1] For the purpose of the RASCI Code, references to the self-care industry or self-care products shall be interpreted as including references to non-prescription medicines (OTCs), food supplements and medical devices for personal use, in line with the purpose and objectives of RASCI.

and complies with the requirements of the European Union Council Directive 2001/83/EC[2], as amended, relating to medicinal products for human use (the "**Directive**"). The RASCI Code fits into the general framework established by the Directive, which recognizes the role of voluntary standards of practice control of advertising of medicinal products by self-regulatory bodies and enforcement of these standards by the appropriate industry and government recourse to such bodies when complaints arise.

RASCI encourages a loyal competition among self-care companies operating in Romania. The RASCI Code is not intended to restrain the appropriate promotion of self-care products or to enforce legal and ethical limits to the interaction with HCPs to be upheld in a manner that is detrimental to fair competition law and practice. Instead, it aims to ensure that the promotional activities and other related activities are performed in a truthful, compliant manner, avoiding deceptive practices and potential conflicts of interest with HCPs, and in compliance with European and Romanian laws and regulations. The RASCI Code thereby aims to foster an environment where the general public can be confident that choices regarding the recommended self-care products are being made on the basis of the merits of each product and the healthcare needs of the individual.

SCOPE OF THE RASCI CODE

The RASCI Code covers the promotion of self-care products and interactions of RASCI Members with HCPs and general public. This includes interactions with a variety of HCPs including physicians, dentists, pharmacists, and nurses or pharmacy assistants. It also recognizes the dual-interactions that self-care products' manufacturers, importers and distributors may have with pharmacists in their capacity as HCPs and as owners of their retail stores/ pharmacies to ensure that appropriate non-promotional and promotional materials are being used in accordance with these interactions.

The RASCI Code is applicable to all RASCI Members and their affiliates[2] and subsidiaries[3] in Romania.

RASCI Member companies shall be responsible for the obligations imposed under any relevant applicable code (defined below in "APPLICABILITY OF THE RASCI CODE") even if they commission other parties (e.g. contract sales forces, consultants, market research companies, advertising agencies) to design, implement or engage in activities covered by the applicable code on their behalf.

Normal commercial trade practices related to terms of trade, including, but not limited to, sale-promotions, discounts, margins and any other commercial terms are subject to applicable laws and regulations, shall always be unilaterally and independently established by each RASCI

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

[2] Affiliate means, with regards to any entity, any other entity that, directly or indirectly, controls, is controlled by, or finds itself under common control, individually or through several intermediaries, of that particular entity; for the purpose of this definition, "control" (including "controlled" or "controlling") refers to the power to direct or dispose the targeting of the policies of that particular entities, directly or indirectly, either by holding collaterals or partnerships or any other proprietary rights, through a contract or differently.

[3] A stand-alone trading company operating independently, autonomously, in its own premises, endowed with legal personality, constituted by and under the control of another company (known as parent company) that holds the majority of the capital.

Member in relation to its customers and are otherwise beyond the scope of this RASCI Code.

The RASCI Code covers all methods of promotion as described in this document and all other interactions with HCPs and healthcare organisations with the exceptions mentioned below. The following materials are not regulated by this RASCI Code as they are governed by other provisions:

- Summary of Product Characteristics ("SmPC") and other full prescribing information documents, including patient/ professional information leaflets included in medication packs;
- Labelling and instructions for use for food supplements and medical devices;
- Correspondence, possibly accompanied by materials of non-promotional nature, made in response to individual enquiries from HCPs or appropriate decision makers or in response to specific communications from them whether of enquiry or comment, including letters published in professional journals, but only if they relate solely to the subject matter of the letter or enquiry and are not promotional in nature;
- Factual, informative announcements and reference material concerning licensed medicinal products and relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and price lists, provided that they include no promotional statement in relation with the product;
- Non-promotional information relating to human health or diseases, provided there is no reference either direct or indirect to specific medicinal products;
- Non-promotional, general information about companies (such as information directed to investors or to current/ prospective employees), including financial data, descriptions of research and development programs, and discussion of regulatory developments affecting the company and its products.

Attached to the RASCI Code are:

- Annex A - "Implementation and Procedure Rules";
- Annex B - "Guidelines for Websites Available to Healthcare Professionals, Patients and the General Public";
- Annex C - “Guidelines for Commercial Communication of Food Supplements”;
- Annex D - “Guidelines for Commercial Communication of Medical Devices”.

APPLICABILITY OF THE RASCI CODE

The RASCI Code sets out the minimum standards, which RASCI Members have voluntarily committed to apply.

The provisions of the RASCI Code are applicable to each and all RASCI Members, together with any affiliates or subsidiaries which promote self-care products and each will be held responsible for compliance with all provisions of the Code.

RASCI Member companies must comply with the RASCI Code and all relevant applicable European and domestic laws and regulations.

In the event of a conflict between the provisions of the applicable code, laws and regulations set forth above, the more restrictive of the conflicting provisions shall apply.

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

- The Law no. 95/2006 regarding the reform in healthcare field with all subsequent amendments;
- Health Ministry Order no. 194/2015 regarding the approval of the Norms for the evaluation and approval of advertising about human medicines;
- Government Decision no. 54/2009 concerning the conditions for introducing medical devices on the market;
- Government Decision no. 798/ 2003 on establishing the conditions for introducing on the market and using in vitro diagnostic medical devices;
- Law no. 491/2003 (as amended by Law no. 239/2010), regarding the medicinal herbs aromatic herbs, as well as hive products;
- Health Ministry Order no. 1069/2007 regarding the applicable rules for the food-supplements;
- Ministry of Agriculture and Regional Development Order no. 1946/2014 for the approval of the Procedure regarding the medicinal and aromatic herbs as well as hive products notice;
- Ministry of Agriculture and Regional Development and Health Ministry Joint Order no. 244/2005 regarding the processing and merchandising of the medicinal and aromatic herbs, partially processed or processed as pre-dosed food supplements;
- Commission Regulation (EC) no. 1170/2009 amending Directive 2002/46/EC of the European Parliament and of Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards the lists of vitamin and minerals and their forms that can be added to foods, including food supplements;
- Commission Regulation (EC) no. 1924/2006 on nutrition and health claims made on foods;
- EU Council Directive 92/28/EEC of 31 March 1992 regarding advertising of medicinal products for human use;
- EU Commission Regulation (EU) no. 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health and Corrigendum to 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;
- Council Directive 93/42/EEC of 14 June 1993 concerning medical device for personal uses;
- Directive 98/79/EC of 27 October 1998 on in vitro diagnostic medical devices;
- Council Directive no. 2001/83/EC relating to medicinal products for human use amended by Council Directive 2004/27/EC and amended by Directive 2010/84/CE;
- Decisions, guidelines, provisions of the National Agency for Medicines and Medical Devices of Romania ("ANMDM") regulating the activity of non-prescription medicines and medical devices promotion.
- „Food Supplements" Guide (2013 edition) issued by the National Institute of Public Health;
- „Guide to Food Supplements based on Medicinal and Aromatic Plants and Hive Products" (2018 edition) issued by the National Research and Development Institute

for Food Bioresources - IBA Bucharest;

- 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 development of online trade activities for OTC medicines).

The above laws and regulations represent a non-exhaustive list and may change from time to time, and in this situation the RASCI Members should reference and comply with all the laws and regulation in force at the moment of applicability.

This RASCI Code concerns the advertising and promotion of self-care products to the public and to HCPs.

The self-care industry explicitly acknowledges that promotional practices bring a legitimate benefit to the healthcare industry and professionals. By clarifying this, the self-care industry is taking a proactive step in collectively recognizing its legitimate and beneficial interests as well as those of the HCPs and general public.

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

- Any kind of advertising (product brochures, visual aids, non-scientific posters, ads, folders, mailings, gifts etc.);
- Product monographs;
- Educational material if used for external audiences;
- Educational websites supporting products or associated diseases;
- Social Media sites (or similar) that are written by or sponsored by Member companies.

RASCI Member companies must in good faith observe the requirements set forth by the Code, and they shall be bound to it with regard to both their direct and indirect actions when they operate by means of third party contractors (e.g. distributors, agents, foundations etc.).

PROVISIONS OF THE RASCI CODE

Article 1. Market Placement

Section 1.01. Advertising of self-care products is allowed only for:

- Non-prescription medicines that have a marketing authorization issued by the NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES OF ROMANIA/ EUROPEAN COMMISSION;
- Food supplements which contain only vitamins and minerals that have a notification issued by the MINISTRY OF HEALTH;
- Herbal Food or mixed supplements that have a notification issued by the NATIONAL SERVICE FOR MEDICINAL AND AROMATIC PLANTS AND HIVE PRODUCTS within the NATIONAL RESEARCH AND DEVELOPMENT INSTITUTE FOR FOOD BIORESOURCES - IBA BUCHAREST or PUBLIC HEALTH DEPARTMENTS (DSP);

- Medical devices for personal use that hold a EU Declaration of conformity of the manufacturer and / or EC Certification from a Notified Body, in accordance with the European legislation in force.

Section 1.02. A self-care product must not be promoted outside of its approved/ notified indications/ purposes.

Article 2. Promotion and its Substantiation

Section 2.01. RASCI Members hereby express their commitment to observe and comply with the provisions of the European and Romanian legislation applicable to the promotion methods within all marketing and promotion activities performed in relation to self-care products. Promotion must always be in compliance with applicable laws, regulations and the present RASCI Code.

Section 2.02. Promotion must never bring discredit upon or reduce confidence in self-care products and must always recognize the special nature of self-care products and safeguard public health. Promotion should be appropriate and encourage responsible use of self-care products.

Section 2.03. All interactions with HCPs are to be conducted in a highly professional and ethical manner and respect the independence of HCPs' and general public with regards to taking decisions.

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

Section 2.05. Advertising and promotion must be accurate, balanced, decent fair, objective and sufficiently complete to enable the recipient to form his or her own opinion on the therapeutic value of, for example, self-care products concerned.

Advertising and promotion must be consistent in medical/ scientific content and interpretation and not misleading in any way related to product information.

Claims should not be stronger than scientific evidence can support, where applicable, and every effort should be made to avoid ambiguity. Important information must not be omitted in order not to mislead the people to whom advertising is directed.

Promotion should be based on an up-to-date assessment of all relevant evidence and it should reflect that evidence clearly. It must not mislead by distortion, exaggeration, and undue emphasis, omission or in any other way.

Section 2.06. Comparative advertising must comply with the applicable legislation in force (e.g. Law no. 363/2007, Law no. 158/2008 with all subsequent amendments). Any comparison made between different medicinal products must be based on relevant and comparable aspects of the products. Comparative advertising must not be misleading or disparaging.

Within comparative advertising, it is not allowed:

a) To denigrate the products of another company;
b) To use the brand (trademark) name of another company;
c) To compare products which have different indications/ intended purpose or which otherwise cannot be compared;

d) To make a non-objective comparison with one or more of the essential, relevant, verifiable and representative features of the products, including the price;
e) To create confusion on the market between the advertiser and a competitor or between different trademarks or other distinguishing marks of the advertiser and those of a competitor;
f) Discredit or denigrate the trade mark, other distinctive signs, activities or any other characteristics of a competitor;
g) To take unfair advantage of the reputation of a trade mark, the distinguishing marks of a competitor or any other characteristics of a competitor without having any evidence in support of the asserted.

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

Section 2.08. The wording "safe", "involving no risks" or similarly must not be used to describe a self-care product without proper substantiation.

Section 2.09. It must not be stated that a product has no side effects, toxic hazards or risks of addiction or dependency.

Article 3. Transparency of Promotion

Section 3.01. Promotion must not be disguised.

Section 3.02. Post marketing surveillance or any other data collection must not be used to disguise promotion. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose.

Section 3.03. When promotional materials are published in the press following services engaged by an RASCI Member, its subsidiary or a related company (e.g. the PR company of the RASCI Member), such promotional material should clearly reveal the RASCI Member, beneficiary of the publication service. Such article must not resemble independent editorial matter.

Section 3.04. Every RASCI Member is accountable for all educational and promotional materials referring to its products. In case such materials are disseminated by public relations agencies under contract, RASCI Member companies assume responsibility for the manner in which the materials were conceived, distributed and used.

Article 4. No Advice on Personal Medical Matters

Section 4.01. In the case of requests from the general public for advice on personal medical matters, the enquirer must be advised to consult a HCP.

Article 5. Promotional Objects, Informational and/ or Educational Materials and Items of Medical Utility

Section 5.01. The transmission of promotional objects, informational/ educational items and items of medical utility to HCP is permitted, provided the following apply simultaneously:

a) of "modest value", recommended value of 150 RON, including VAT, before the

personalization;

b) relevant to the practice of HCP; and

c) beneficial to the care of patients.

Section 5.02. Promotional objects/ items of medical utility aimed directly at the education of healthcare professionals and patient care can be provided if they have modest value and do not offset routine business practices of the recipient.

Section 5.03. The scope of informational and educational materials and items of medical utility considered may not constitute a circumvention of the prohibition of gifts defined under Article 6 of this Code.

Section 5.04. The transmission of such materials or items shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a self-care product.

Article 6. Prohibition of Gifts

Section 6.01. No gift, pecuniary advantage or benefit in kind may be supplied, offered or promised to a HCP. Payments in cash or cash equivalents (such as gift certificates or coupons) are prohibited.

Article 7. Events and Hospitality

Section 7.01. All promotional, scientific or professional meetings, congresses, conferences, symposia, and other similar events (each, an "**event**"), including but not limited to visits to production sites or research laboratories, advisory board meetings, planning meetings, education (courses) or investigator meetings for clinical or non-interventional studies, organized or sponsored by a RASCI Member must be held in an appropriate venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate and otherwise complies with the provisions of the RASCI Code.

Section 7.02. It is recommended that no RASCI Member may organize or sponsor an event that takes place outside Romania, with the following exceptions:

a) Most of the invitees are from outside of Romania and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country, or

b) Given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country (an "international event").

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

a) Any such promotional material (excluding promotional aids) has attached a suitable statement indicating countries in which the product is registered and makes clear that the product or use is not registered locally, and

b) Any such promotional material which refers to the prescribing information (indications, warnings etc.) authorized in a country or countries where the self-care product is registered should have attached an explanatory statement indicating that registration

conditions differ internationally, if applicable.

Section 7.04. Hospitality extended in connection with promotional, professional or scientific events shall be limited to travel, meals, accommodation and genuine registration fees.

It is not allowed to sponsor participation of HCP to independent fashionable, sporting or cultural events or congress linked.

Section 7.05. RASCI Member companies shall not provide or offer any meal (food and beverages) and accommodation to HCP, unless, in each case, the value of such meal (food and beverages) does not exceed the monetary threshold set below. The monetary threshold set in the country where the event takes place by relevant applicable code (e.g. the "host country") shall prevail.

Section 7.06. Any kind of hospitality may only be extended to persons who qualify as participants in their own right.

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

Section 7.08. In order not to influence the HCP, RASCI Members should avoid using venues that are renowned for their entertainment or sporting facilities or for their "extravagance" or “luxury”.

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

a) Airline travel (both domestic and abroad): economy (coach) class. Business class or beyond is not allowed.
b) The accommodation is recommended at hotels classified at maximum 4*;
c) Meals: for domestic meals, the maximum limit is 300 RON (including VAT) per day, for every person, when the hospitality includes two meals and 150 RON (including VAT) per person, when the hospitality includes only one main meal;
d) For coffee breaks, the maximum limit is of 35 RON (including VAT) for every person. For events that last all day long, maximum 2 coffee breaks for each day of the event are allowed.
e) In countries - host countries - where local provisions do not set a limit for meals, the maximum limit is 150 EUR per day (or the relevant equivalent) for lunch plus dinner. This limit does not apply to "*official dinner*" organized as part of the international congresses (as described in the documentation of the event).

RASCI Member companies shall not provide or offer any meal (food and beverages) to HCPs, unless the value of such meal (food and beverages) complies with the monetary threshold set hereby.

Article 8. Sponsorship/ Donations/ Grants/ Free-Leases that Support Healthcare or Research

Section 8.01. Sponsorship/ Donations/ Grants (in cash or in kind or otherwise) and/ or Free-Leases to/ by public institutions, organizations or associations that are comprised of HCPs and/ or that provide healthcare or conduct research (that are not otherwise covered by the RASCI Code) are allowed only if, cumulatively:

a) They are made for the purpose of supporting healthcare or research;
b) They are documented and kept on record by the donor/ grantor;
c) They do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific self-care products; and
d) Are specifically based on a request from the respective organization/ association/ institution.

Donations and grants to individual HCPs are not permitted under this section. Company sponsorship of HCPs to attend international events is covered by Article 10. Beneficiary companies are encouraged to make available publicly information about donations and grants (in cash or in kind or otherwise) received by them covered in this Section 8.01, should the legal provisions regulate as such.

RASCI Members are responsible (i) to include in the sponsorship contracts the interdiction of using the equipment in personal interest or in order to obtain material advantages by the recipient's employees, (ii) to track if the recipient uses the object obtained by such donation or sponsorship exclusively to the free benefit of the patients and (iii) to request the recipient a complete disclosure of these activities, as regulated by the current legislation.

Article 9. Fees for Service

Section 9.01. Contracts between RASCI Members and institutions, organizations or associations of HCPs under which such institutions, organizations or associations provide any type of services to RASCI Members (or any other type of funding not covered under Article 8 or not otherwise covered by the RASCI Code) are only allowed if such services (or other funding):

a) Are provided for the purpose of supporting healthcare or research; and
b) Do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific self-care products.

Article 10. Sponsorship of HCPs

Section 10.01. Companies must comply with criteria governing the selection and sponsorship of HCPs to attend trainings or events as provided in, or in connection with, any applicable code(s). Funding must not be offered to compensate merely for the time spent by HCPs in attending events. In the case of international events for which a RASCI Member sponsors the attendance of a HCPs, if any funding is provided to such HCPs in accordance with the provisions of this Section 10.01, such funding is subject to the rules of the jurisdiction where such healthcare professional carries out his/ her profession, as opposed to those in which the international event takes place. For the avoidance of doubt, this Section 10.01 is not intended to prohibit the extension of hospitality to healthcare professionals in accordance with Article 7 hereof.

Article 11. The Use of Consultants

Section 11.01. It is permitted that RASCI Members engage HCPs for services such as, but not limited to: lectures, consulting and/ or advising (participation in but not limited to advisory board meetings), and involvement in medical/ scientific activities and studies, training services, and participation in market research whether in groups or individually.

The arrangements that cover these genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

a) A written contract or agreement is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;
b) A legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
c) The criteria for selecting consultants are directly related to the identified need and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular HCPs meet those criteria;
d) The number of HCPs retained is not greater than the number reasonably necessary to achieve the identified need;
e) The contracting company maintains records concerning, and makes appropriate use of, the services provided by consultants;
f) The hiring of the HCPs to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular self-care product; and
g) The compensation for the services is reasonable and reflects the fair market value of the services provided.

Section 11.02. For services provided, external consultants shall be offered reasonable compensations, including the reimbursement of reasonable travel expenses, meals and accommodation (if the case). The limits considered reasonable (gross hourly rates) are described below and it is recommended that they are followed by RASCI Member companies.

Section 11.03. Starting from the public information related to the activities carried out by the HCPs within private clinics or pharmacies, RASCI Members recommend as fair market value for Romanian HCPs the following gross amounts (hourly rates) VAT excluded:

a) Up to 450 RON (four hundred and fifty RON) / hour for HCPs, 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 HCPs, who find themselves in the following situations: specialist doctor with or without a university degree;
c) Up to 285 RON (two hundred and eighty-five RON) / hour for HCPs, who find themselves in the following situations: pharmacists;
d) Up to 150 RON (one hundred and fifty RON) / hour for HCPs, who find themselves in the following situations: resident doctor;
e) Up to 70 RON (seventy RON) / hour for HCPs, who find themselves in the following situations: nurses.

For other categories of specialists associated with the healthcare field, such as, but not limited to - psychologist; health economist; specialist in medical devices - the above hourly fees can 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) for fees of RON 2,700 (two thousand seven hundred) per activity will be taken into account for the services provided at events, for

example, but not limited to conferencing and moderation, and respectively 5,400 (five thousand four hundred) RON per activity for services provided at events, for example, but not limited to advisory councils, trainings. The total value of service fees includes preparation and execution time. There are no maximum limits for NON-event-related consulting services (non-event-related services, which may involve a considerable amount of preparation and/ or execution time).

Section 11.05. Transparent communication to the audience of the speaker's affiliation with a RASCI member company as a beneficiary of the service must be made explicitly. RASCI member companies will internally define reasonable limits for such services, which can be paid to a HCP within one year.**Section 11.06.** In their written contracts with consultants, companies are strongly encouraged to include provisions regarding the obligation of the consultant to declare that he/ she is a consultant to the company whenever he/ she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that company. The provisions of this Section 11.06 apply even though the RASCI Code does not otherwise cover non-promotional, general information about companies (as discussed in the "Scope of the RASCI Code" section).

Section 11.07. If a HCP attends an event (an international event or otherwise) in a consultant or advisory capacity the relevant provisions of Article 8 shall apply.

Article 12. Samples

Section 12.01. Samples are allowed to be distributed in accordance with the national applicable regulations.

Section 12.02. Each sample must be adequately marked, for example with “free sample – not for sale”, and must be accompanied by a copy of the summary of product characteristics (SmPC), respectively of the leaflet, instructions or label, as may be the case, in line also with relevant legal requirements.

Article 13. RASCI Member Staff

Section 13.01. Each RASCI Member shall ensure that its representatives, including personnel retained by way of contract with third parties, and any other RASCI Member representatives who call on HCPs, pharmacies, hospitals or other healthcare facilities in connection with the promotion of self-care products (each a "representative") are familiar with the relevant requirements of the RASCI Code and all relevant Romanian and European laws and regulations and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the self-care products they promote.

a) Representatives must comply with all requirements of the RASCI Code, and all relevant Romanian and European laws and regulations, and each RASCI Member is responsible for ensuring their compliance.
b) Representatives must approach their duties responsibly and ethically.
c) Representatives must transmit immediately to the relevant department of their companies (medical, pharmacovigilance, quality assurance, marketing) any information they receive in relation to the use of the OTCs out of the indications approved in Romania or with respect to their use during pregnancy and also the reports related to the side effects or reports of quality deficiencies of their company’s marketed OTCs.

Section 13.02. All RASCI Members' staff, and any personnel employed by way of contract with third parties, who are concerned with the preparation or approval of promotional materials or activities must be fully familiarized with the requirements of the RASCI Code and relevant Romanian and European laws and regulations.

Each RASCI Member shall implement a training program for all the relevant employees which will be re-iterated whenever there are significant changes of the RASCI Code or in the Romanian and European laws and regulations in force, in line also with the internal policies of each RASCI Member.

Article 14. Market Research

Section 14.1. Market research refers to any organised effort to collect information about the market and consumers of self-care products.

Section 14.2. Market research is a valid method for recording the data and characteristics of the pharmaceutical self-care market.

Section 14.3. Market research can be conducted:

a) Either through questionnaires to which subjective answers are given by a sample that is representative of the reference population (e.g. the HCPs); or
b) Through questionnaires given to groups comprising a representative sample of the population under examination (focus groups - qualitative market research) (e.g. the HCPs), in order to obtain a synthesis of answers.

Section 14.4. Market research must be unbiased, must not be focused on promoting sales, and must not aim at influencing the opinion of the participants.

Section 14.5. In each market research, care must be taken to ensure the random and representative selection of the participants.

Section 14.6. Market research may be retrospective/ prospective; or a snapshot.

Section 14.7. Information and statistical results of market research may be used for promotional purposes, provided that the information about the research (who, when, where, which sample) is clearly stated. In any case, the collection and the use of research data must be clearly distinct processes.

Section 14.8. Market research must be conducted in a manner that does not affect the credibility and reputation of the self-care industry.

Section 14.9. Market research must be conducted by certified market research companies, which must abide by the principles of ESOMAR/ EphMRA (European Society of Market Research, http://www.ephmra.org).

Section 14.10. Any communication between a patient and his familiars and the market research companies dealing with the trade/ allocation/ promotion of a self-care product, is forbidden within the framework of these market research activities – as described above.

Section 14.11. RASCI Member staff must not perform or directly conduct market research.

Section 14.12. When RASCI Members enter into contracts with market research companies, they may grant to HCP a reasonable compensation, which may not in any case exceed rates - as enumerated in Section 11.

Article 15. Settlement of Complaints

Section 15.01. Reception of Complaints

Any interested person/ entity can submit a complaint to RASCI via email at office@rasci.ro (www.rasci.ro) to the attention of the RASCI CEO.

Section 15.02. Complaint Requirements

Matters of interpretation, compliance, application and/ or violation of the Code can stand for the object of the complaints. The complaints are analysed and evaluated by the Ethics & Compliance Working Group of RASCI, through its designated representatives.

A valid complaint must be addressed in writing and must contain:

a) Identification data of the person/ entity that makes the complaint;
b) Relevant details on which the complaint is based;
c) Proposed/ requested corrective actions, if the case.

The Ethics & Compliance Working Group of RASCI consists of designated representatives of each RASCI Member company.

Section 15.03. Processing the Complaint

Within maximum 10 (ten) working days from the receipt of the complaint, the RASCI CEO will inform the Ethics & Compliance Working Group of RASCI.

Within maximum 10 (ten) working days the Ethics & Compliance Working Group of RASCI will form ad-hoc the Evaluation Committee. The Ethics & Compliance Working Group of RASCI will delegate as part of the Evaluation Committee from its members 3 representatives from different RASCI Member companies, except the parties involved, to preliminary evaluate the documents by reference to the regulations of the RASCI Code.

In order to delegate the 3 representatives who would form the Evaluation Committee, potential incompatibilities and conflicts of interest shall be considered in order to ensure impartiality in the evaluation of complaints.

The decisions of the Evaluation Committee are being taken by consensus.

The Evaluation Committee has the following competences:

a) To analyse the complaint in terms of conformity with the regulations of the RASCI Code and to issue decisions, evaluation reports, settlement proposals;
b) In case additional information is needed for the analysis of the complaint, to request the involved parties for their provision;
c) In case it considers the complaint unfounded or if it considers that it doesn't have competences for tackling the issue, to reasonably dismiss the complaint;
d) To initiate an evaluation procedure when there is a reasonable indication of breaching

the RASCI Code and to solve the complaint through an evaluation report that would also include a settlement proposal;

e) To communicate any decisions, evaluation reports, settlement proposals to the Ethics & Compliance Working Group of RASCI and to the RASCI CEO.

Section 15.05. Performing the Evaluation Procedure of the Complaint

Within the evaluation procedure of the complaint, if the case, the Evaluation Committee could request a point of view to the parties involved with regards to the subject of the complaint. Persons/ entities involved could prepare and communicate to the Evaluation Committee their point of view and the supporting documents, if the case, within maximum 10 (ten) working days from the request.

A hearing/ point of view from the persons/ entities involved can be requested to be performed/ to be submitted to the Evaluation Committee within maximum 10 (ten) working days from the request.

Section 15.06. The Settlement

After the conclusion of the evaluation procedure, the Evaluation Committee will prepare an Evaluation Report, which can:

a) Establish that the breach did not occur and dismiss the case; or
b) Consider that the breach took place and issue settlement proposals.

The communication of the Evaluation Report will be made by the RASCI CEO within maximum 10 (ten) working days, via e-mail, to the person/ entity that formulated the complaint, to other parties involved, if the case, and to the Board of Directors.

It remains in the responsibility of the notified person/ entity to implement the settlement proposals, if the case.

Section 15.07 Confidentiality

RASCI will ensure the confidentiality of the information obtained as a result of any of the procedures described in this article.

Neither persons/ entities involved, nor RASCI can publish the decisions, evaluation reports, settlement proposals of the Evaluation Committee.

The debates of the Evaluation Committee, as well as any documents, information and point of views analysed by the Evaluation Committee are strictly confidential.

Article 16. Amendments to the RASCI Code

Section 16.01. The Ethics & Compliance Working Group of RASCI shall regularly review this Code and any guidance issued regarding compliance with this Code.

Proposed amendments to this Code shall be reviewed by the Ethics & Compliance Working Group of RASCI following consultation with the RASCI Members and the relevant RASCI Committees. Any proposed amendments to the Code will be submitted for the RASCI Board of Directors assessment and the RASCI General Assembly ratification.

ANNEX A - IMPLEMENTATION AND PROCEDURE RULES

Article 1. Definitions

1. "**promotion**" means all activities of the representatives of a company and any activity organized or sponsored by any RASCI Member or undertaken with the authority of an RASCI Member, which promotes the prescription, supply, sale, administration, recommendation or consumption of a self-care product. It includes, but it is not limited to:
   a) oral, written, online, radio and TV advertising and communication addressed to the general public and/or to persons qualified to prescribe, to recommend or to release self-care products;
   b) journal and direct mail advertising addressed to the general public and/ or persons qualified to prescribe, to recommend or to release self-care products;
   c) supply of samples;
   d) provision of objects relevant for the medical and pharmaceutical practice;
   e) sponsorship of scientific or promotional meetings, including payment of the expenses related to the participation at such meetings;
   f) provision of information to the general public either directly or indirectly;
   g) all other sales promotion in whatever form, such as participation in exhibitions, the use of audio-cassettes, films, records, tapes, video recordings, the internet, electronic media, interactive data systems and the alike.
2. "**comparative advertising**" means any advertising which explicitly or implicitly identifies a competing product and/ or its comparative description.
3. "**misleading advertising**" means any advertising which in any way, including its presentation, misleads or is likely to mislead the persons to whom it is addressed or whom it reaches.
4. "**subliminal advertising**" means advertising using advertising messages the recipient is unaware of, e. g. they are expressed with a very low sound intensity or are displayed on the screen for a very short time, less than a second.
5. "**promotional material**" means any tool used for promotional purposes, as defined under "promotion" above.
6. "**non-prescription medicine (OTC)"** means (a) any substance or any combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis, which requires a marketing authorization.
7. "**medical device**" means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/ or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: a) diagnosis, prevention, monitoring, treatment or alleviation of disease; b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; c) investigation, replacement or modification of the anatomy or of a physiological process; d) birth control, in a way which does not achieve its main

intended purpose in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in operation by such means. In the current document "medical device" refers to "medical device for personal use".

8. "**food supplement**" means foodstuffs, the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

9. "**self-care product(s)**" means non-prescription medicines (OTCs), food supplements and medical devices for personal use, as defined above.

10. "**healthcare professional** (**HCP)**" means members of the medical, dental, pharmacy and nursing professions and their assistants.

11. **"healthcare organisation"** means any legal person (i) that is a healthcare, medical or scientific association or organization (irrespective of the legal or organizational form) such as a hospital, clinic, public health institutions or the Non-Governmental Organizations (affiliated to public healthcare institutes or which have healthcare professionals in their managing board), medical society, university or other teaching institution or learned society (except for patient organizations within the scope of the RASCI Code) whose business address, or primary place of operation is in Romania and (ii) through which one or more HCP provide healthcare or conduct research.

12. **"decision makers**" means representatives of the staff of the public and private institutions, as well as but not limited to persons that hold a function or a mandate in a government authority with connection with health policies and regulations, members or presidents of consultative Commissions, members or presidents of National Committee for Coordination of specialized commissions, members or presidents of expert commissions, members of the Romanian and European Parliament.

13. "**market research"** means the collection and analysis of information and must be unbiased and non-promotional. The use of the statistics or information could be done with promotional purposes. The two phases must be kept distinct. Market research should not collect individual patient data.

14. "**representative"** means a representative calling on healthcare professionals and/ or appropriate decision makers in relation to presenting promotional and non-promotional information on medicinal products, such as but not limited to medical representatives, district managers, area sales managers, sales managers, product managers, marketing managers, medical scientific liaisons 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, supplied for free, labelled as free sample, provided to healthcare professionals so that they may familiarize themselves with it and acquire experience in dealing with it.

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

18. "**CE marking of conformity**" or "**CE marking**" means a marking by which the manufacturer indicates that a medical device is inconformity with the applicable

requirements set out by 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/EEC on in vitro diagnostic medical devices (IVD) / GD No. 798/2003.

19. "**intended purpose**" means the use proposed for a medical device according to the information supplied by the manufacturer on the labelling, in the instructions for use or in materials or in advertising or sale, or as specified by the manufacturer in the performance evaluation.

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

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

22. "**Nutrient Reference Value (NRV)**" means a set of recommended daily nutrient targets based on available scientific knowledge. These targets are intended for healthy individuals at different stages in life.

23. "**Reference Intakes (RIs)**" means a daily nutrient level estimated to meet the requirements of a healthy individual in a particular life stage and gender group. Daily reference intake for the average adult aged 19 to 64 is 8,400kJ/ 2,000kcal.

24. "**Recommended Daily Allowance (RDA)**" means the average daily level of intake sufficient to meet the nutrient requirements of nearly all (97%-98%) healthy people.

25. "**allergen**" means the substance that can produce an allergic reaction.

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

27. "**nutrients**" means nutrients or other substances with nutritional or physiologic effect.

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

29. "**health claims**" means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.

30. "**field of vision**" is defined as all the surfaces of a package that can be read from a single viewing point.

31. "**the average consumer**" means the consumer considered to be reasonably informed, careful and cautious, while taking into consideration the social, cultural and linguistic factors.

32. "**distance selling**" includes the sale of products through web sites, telephone and catalogue sales.

Article 2. Interaction with Public Officials and with Personnel of Public Institutions

RASCI Members may interact for the performance of their activity with public officials,

including HCP holding position of decision makers.

For this type of interactions which are not regulated by the provisions of this Code, other than in this chapter, RASCI Members will have the following obligations:

a) In any interaction with public officials, RASCI Members shall observe a proper conduct and ethical practices. RASCI Members will not participate and/ or initiate any activity or relation that can affect the public official's integrity or the reputation of the self-care products' industry, of RASCI or of any other RASCI Members.
b) Interactions between RASCI Members and public officials should be conducted under the highest standards of ethics and professionalism and RASCI Members should avoid any perception of conflict of interests.
c) The RASCI Members will not provide any misleading, false, injurious and/ or discriminatory information to the public official.

In order to increase transparency RASCI Members may include in the agreements concluded with HCP and decision makers, references to the obligation of the HCP and of the decision makers to respect all legal provisions regulating incompatibility and/ or conflict of interest, if applicable.

In addition, for the support of the Members an example of a contractual provision that can be included by RASCI Members in the agreements concluded with the HCP/ decision makers is presented below.

The model clause provided are only an example and should be regarded as a minimum protection recommended to the RASCI Members to which they can add as they see fit, without any acknowledgement by RASCI on the degree of compliance granted by such clause.

Example of contractual clause (orientative, minimum content)

More general obligation:

The [HCP/ decision maker] declares that he/ she is not under a state of incompatibility, as provided by the applicable legislation. The [HCP/ decision maker] declares and undertakes that he/ she will observe the obligations regarding the conflicts of interests prescribed by any applicable legislation.

More detailed obligations:

A new paragraph can be added to the first paragraph:

The [HCP/ decision maker] declares that he/ she is not under a state of incompatibility, as provided by the applicable legislation. The [HCP/ decision maker] declares and undertakes that he/ she will observe the obligations regarding the conflicts of interests prescribed by any applicable legislation.

The [HCP/ decision maker] guarantees that he/ she shall fill and submit to the unit where he/ she carries out his/ her activity or to any other competent or interested authorities and entities all the declarations indicated in any applicable legal provisions stipulating the submission of declarations of interests, declarations concerning the incompatibilities, declarations of property or any other similar obligations for the [HCP/ decision maker].

Article 3. Sponsorships/ Donations/ Grants/ Free-Leases

In order to support the efforts towards technical-medical and scientific development in the benefit of patients, donations, sponsorships or free-leases (*commodatus*) of medical and/ or

technical equipment of general/ medical use, for hospitals, clinics within the public health sector (except the private healthcare institutes) or to the Non-Governmental Organizations (affiliated to public healthcare institutions or which have healthcare professionals in their managing board) are allowed in the following cases:

a) **Donations or sponsorships** specifically made for (and proven by means of official contracts) medical or technical equipment of general use, or for renovation and adaptation of the hospital/ clinic locations. Such support is specifically based on an unsolicited request from the respective organization and is subject of disclosure for which provisions of the relevant RASCI Code must be followed.

b) **Free-leases** (*commodatus*) are specifically based on an unsolicited request from the respective organization.

c) **Items strictly for medical use** may be provided to public institutions only (not to individual HCP). These items should intend to cover the gaps of insufficient funding of healthcare system (for example, but not limited to, items like peak flow meters, stethoscopes, thermometers, sphygmomanometers, othoscopes, ophthalmoscopes, laryngoscopes, reflex hammers, head mirrors, rhinoscopes, glucometers, tongue retractors, weight and height scales, etc.). These items could carry the company's or the product's logo as per the existing and applicable legislation.

This type of support must be performed in line with the applicable legal provisions, strictly unconditioned (no prescriptions or other types of commitment should be performed in exchange) and it must be directly connected to the medical activities and to be directly or indirectly in benefit of the patient.

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

Article 1. Transparency of Website Origin, Content and Purpose

Each website shall clearly identify:

a) The identity and physical and electronic addresses of the sponsor(s) of the website;
b) Full references related to the source(s) of all medical information included on the website;
c) The target audience of the website in case of non-prescription medicines (e.g. healthcare professionals, patients and the general public, or a combination thereof);
d) The purpose or objective of the websites;
e) Visa approval number, if applicable;
f) Any other elements that are expressly provided by the specific legislation, if the case.

Article 2. Content of Websites

a) Information included on the website shall be regularly updated whenever there are significant amendments of the product information (if applicable) and/ or of the medical practice and, subject to the approval of the competent authority (if applicable), the website must clearly display, for each page and/ or item, the most recent date as of which such information was updated.
b) Examples of the information that may be included in a single website or in multiple websites are:
    i. General information of the company;
    ii. Information for health education;
    iii. Information intended for HCPs and for the general public, in accordance with the applicable legislation;
    iv. Transparency of transfers of value to healthcare professionals (HCPs) and healthcare organizations (HCOs).

General information of the company. Websites may contain information that would be of interest to investors, the media and the general public, including financial data, descriptions of research and development programs, discussion of regulatory developments affecting the company and its products, information for prospective employees, etc. The content of this information is not regulated by these guidelines or provisions of medicines advertising law.

Information for health education. Websites may contain non-promotional information for health education about the characteristics of diseases, methods of prevention and screening and treatments, as well as other information intended to promote public health. They may refer to therapeutic medicine options, provided that the discussion should be balanced and accurate. Relevant information may be given about alternative treatments, including, where appropriate, surgery, diet, behavioural change and other interventions that do not require use of medicinal products. Websites containing information for health education must always advise persons to consult a HCP should they need further information.

Information for HCPs. Any information on websites directed to HCPs that constitutes promotion must comply with applicable code(s), with the regulations in force and with any other regulations governing the content and format of advertisement and promotion of products.

Article 3. E-mail Enquiries

A website may invite electronic mail communications from HCPs and patients or the general public seeking further information regarding the RASCI Members' products or other matters (e.g. feedback regarding the website). The RASCI Member concerned may reply to such communications in the same manner as it would reply to enquiries received by post, telephone or other means. In communications with patients or members of the general public, discussion of personal medical matters must be avoided. If personal medical information is revealed, it must be held in confidence. Where appropriate, replies shall recommend that a HCP be consulted for further information.

Article 4. Links from Other Websites for Non-Prescription Medicines

Links may be established to a company-sponsored website from websites sponsored by other persons, but RASCI Members should not establish links from websites designed for the general public to company-sponsored websites that are designed for HCPs. In the same manner, links may be established to separate websites, including websites sponsored by the RASCI Member or by other persons. The "links" should ordinarily be made to the home page of a website or otherwise managed so that the reader is aware of the identity of the website.

Article 5. Website Addresses on Packaging

Subject to any applicable Romanian laws and regulations, uniform resource locators (URLs) of company-sponsored websites addresses that comply with these guidelines may be included on packaging of products.

Article 6. Scientific Review

RASCI Members should ensure that the scientific and medical information prepared by them for inclusion in their websites is reviewed for accuracy and compliance with the RASCI Code. Where applicable legislation is in place, the scientific service established within the company must perform this function, or it may be entrusted to other appropriately qualified persons.

Article 7. Privacy

The website must conform to legislation and applicable codes of conduct governing the privacy, security and confidentiality of personal information.

ANNEX C - GUIDELINES FOR COMMERCIAL COMMUNICATION OF FOOD SUPPLEMENTS

Article 1. Introduction

Advertising of food supplements helps raise consumer information and awareness level on health matters and drive the consumers to seek out more information about their own health condition. Food-supplements advertising may thereby assist in supporting the proper contribution of self-care to a country's healthcare system.

It is the responsibility of RASCI's Members to manufacture and/ or market products that comply with local legislation requirements, truthfully advertised and labelled to help consumer understanding.

RASCI's Members wish to achieve the following objectives through this voluntary self-regulating Guideline:

- Ensure that Members recognize their responsibility to the consumer, the manufacturer and the market;
- Promote and support innovation in the food supplements field;
- Educate the consumer in the proper use of food supplements and responsible self-care;
- Coordinate the efforts of the market's stakeholders towards the accomplishment of these objectives.

This Guideline does not seek to regulate the following activities for food supplements:

- Pricing or other trade activities;
- The provision of non-promotional information by Member companies;
- Correspondence, possibly accompanied by non-promotional materials, sent as a response to specific questions from HCPs, but only if it refers exclusively to the subject-matter of their letter or of their question and it is not of a promotional nature;
- General, non-promotional information about companies (such as information for investors or current/ potential employees), including financial data, descriptions of research and development programs, and discussions on the regulations impacting the company and its products;
- Commercial/ promotional campaigns, such as 1 + 1, "buy and earn", etc.;
- Presence in retailers' magazines (e.g. Revista săptămâna), such as image and price discount, graphic page with image and promotional message/ competititions;
- Visits of commercial representatives to persons qualified to recommend food supplements;
- Any kind of sponsorship including, but not limited to: promotional meetings attended by persons qualified to recommend or distribute medical devices, scientific congresses attended by persons qualified to recommend or distribute food supplements, corporate sponsorships, sponsorships of TV/ radio programs, public events sponsorship;
- Educational materials.

Article 2. General Provisions Applicable to all Promotional Activities

Promotional methods must never be such as to incite unfavorable comments and bring discredit upon the industry.

Exaggerated claims should not be made, and all-embracing claims and superlatives are to be avoided. The word “safe” must not be used and claims must not state categorically that a food supplement has no side effects, toxic hazards or risk of addiction.

Disparaging references to other products of manufacturers should be avoided by design or implication.

Consumers of food supplements should be urged to read and follow the instructions contained in labels, leaflets, cartons or package inserts.

No promotional activities shall encourage directly or indirectly the unnecessary or excessive use of any food supplement.

Article 3. Legal and Self-Regulatory Requirements

These provisions apply to food supplements which are legally available to the public. All promotional activities must observe all existing legislation governing the industry of the food supplements and this Code.

Article 4. Food Supplement Information for Advertising to Consumers Regulation and Labelling Requirements for Food supplements

It is required that food supplements information on labelling, packaging, advertising should not be misleading.

Food supplements information must be accurate, clear and easy to understand and cannot attribute any effect or property to food supplements which it does not possess. Food supplements are formulated to fulfil specific requirements, such as including the percentage specification (%) of the Nutrient Reference Value (NRV) of a nutrient.

“Free from” claims must be accurate and not misleading. It is worth noting that gluten free claims are regulated under EU Regulation 609/2013 of the European Parliament and Council from 11 July 2017 and EU Regulation 1169/2011.

Food supplements shouldn’t be attributed the property of preventing, treating or curing a human disease, and advertising must not make any reference to these. Disease Risk Reduction claims are permitted under the EU Regulation 432/2012 of the European Council regarding nutrition and health claims.

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

There are requirements (EU Regulation 1169/2011) for the placement of information within specific fields of vision.

There is an additional requirement for certain information to be held within the same “field of vision”:

- The category of products which it belongs to (food supplement) and the name;
- The net quantity of the food supplement;
- Batch and expiry date of product (L/EXP)
- If relevant, the alcoholic strength by volume (ABV);
- If relevant, the caffeine warning statement and the amount of caffeine in the product, per portion for daily consumption;
- If relevant, “with added plant stanols”/ “with added plant sterols”.

Best practice would therefore suggest that, at the least, the name of the food-supplement should be held in the principal field of vision to allow the consumer to identify the character, nature and brand name of the product.

Where food-supplements are contained within a tube or bottle inside and outer carton, it is likely that the majority of consumers will discard the carton and with it the information held on this. Therefore, it is advisable to include any mandatory or voluntary warnings on the label of the inner packaging; for example, allergen information or the warning in relation to iron and young children, which could present risk to the consumer if it were not available throughout the use life of the product(s).

Mandatory information must appear in the format required in the European and national legislation.

Mandatory information must be clearly visible and intelligible. It must not be obscured, detracted from or interrupted in any way. For peel-back labels it is advisable that these should be assessed on a case-by-case basis to ensure that the requirements of the availability, visibility and placement of the mandatory information are fulfilled, including whether the information can easily be found.

Section 4.02. Font Size and Largest Surface Area (applicable to local packaging and stickers)

Minimum font size of the text displayed on the pack is defined as where the "x" is equal to, or greater than, 1.2mm.

Approximately point 8 in standard Arial "x"

Approximately point 9 in standard Times New Roman "x"

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

Section 4.03. Allergen Labelling

Any ingredient or processing aid or derived from a substance or product of such kind that is used in the manufacture of the food-supplement or an ingredient contained within a product, even if it is in altered form, must be emphasized within the ingredients list in such a way as to make clear that it is present in the product. This can be achieved by the use of a different font, font style (bold or italic), font color or background color.

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

Allergen information must be clear and noticeable and not in any way hidden or obscured.

The use of allergen advisory statements such as "contains…" will not be permitted to ensure that allergen information is provided in a standard format across all food sectors, helping to avoid consumer confusion.

If an ingredient is derived from either crustaceans or mollusks this must be listed in the ingredients list as shown:

- Omega 3 oil (mollusk) if, for example it is derived from green lipped mussel;
- Glucosamine (crustacean) if, for example it is derived from crab shell.

To aid consumer understanding of the different types of shellfish you may also wish to consider including the type, as for example:

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

Allergen information should only appear in the ingredients list as outlined above and should not appear anywhere else on labels. However, as consumers are more familiar with viewing allergen information in a box format, it is allowed that allergen information may be signposted. For example, a box could be placed directly below the ingredients list with a statement such as: “Allergy information is in bold in the list above.”

Section 4.04. Additive Labelling

Detailed regulation of food additives is contained within Regulation 1333/2008 on food additives with the updated version from 28.10.219 and Regulation 1129/2011 with the updated version from 21.11.2013 which establishes a list of permitted additives. Flavorings are covered by Regulation 1334/2008 with the updated version from 21.05.2019, as modified and completed.

Food additives and food enzymes which are present because they were contained in one or more ingredients and serve no technological function are subject to the “carry-over” principle and are exempt from labelling requirements, as are food additives which are used solely as processing aids unless these are derived from one or more of the allergens. If derived from any of the listed allergens, even if none of the original substance remains, they must be labelled as:

- “Additive name” (category) (derived from X allergen);
- “Carry over” allows the presence of a permitted additive in a compound food to the extent that the additive is permitted for use in one of the ingredients of the compound food-supplement. It is worth noting that the “carry over” principle 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, the “Southampton colors” and caffeine, where it has been added for physiological effect rather than as a flavoring.

Section 4.05. Nutrition Labelling Requirements

Despite food supplements being specifically exempt from the nutrition labelling requirements, vitamins and minerals will need to be expressed as percentages of Nutrient Reference Values (NRVs) or Reference Intakes (RIs) rather than percentages of RDAs (which does no longer exist). Nutrient Reference Value (NRV) used to be known as Recommended Daily Allowance (RDA).

Food supplements are subject to their own nutrient labelling requirements under the Food Supplements Directive no. 46/2002, where the directive and the domestic regulation transposing the directive include the intention to set minimum levels. Clearly, where claims are made, they can only be made against vitamins and/ or minerals where a minimum of 15% of these substances is present. Where claims are not made it is RASCI’s view that best practice would be to list all vitamins and minerals present in the product in the nutrition reference panel, irrespective of the percentage of NRV.

Section 4.06. Caffeine Labelling

Any drink where caffeine is added, from any source, must include the warning statement "*High caffeine content. Not recommended for children or pregnant or breast-feeding women*" in the same field of vision as the name of the food, followed by a reference, in brackets, to the caffeine content, expressed as per portion as recommended for daily consumption on the label.

The legislation does not require food, including food supplements, to include a warning statement unless caffeine itself has been added to a product, for a physiological purpose. However, the European Commission has stated that any products containing caffeine, from any source should include the warning statement "*Contains caffeine. Not recommended for children or pregnant women*" in the same field of vision as the name of the food. Food supplements must also express the caffeine content per portion as recommended for daily consumption on the labelling.

Section 4.07. Voluntary Information

It is allowed for voluntary information to be provided on labels and in advertising such as nutrition and health claims; however, it stipulates that voluntary information must:

- Not be displayed to the detriment of space for mandatory information;
- Not be misleading to the consumer;
- Not be ambiguous or confusing for the consumer;
- Be based on relevant scientific data (where appropriate).

Voluntary information on the following may also be provided:

- Information on the possible unintentional presence of substances causing allergies or intolerances (e.g. "produced in a factory which processes nuts"; "may contain nuts");
- Information on the suitability for 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 Made on Food Supplements

The Nutrition and Health Claims Regulation applies to claims made in commercial communications aimed at the final consumer. The Regulation does not control claims made in materials aimed at HCPs or with commercial purpose. Where the information is presented for scientific or informative purposes, this is not a commercial communication and the Regulation will not apply.

The authorization of health claims is a two-stage process. Firstly, European Food Safety Authority (EFSA) provides an opinion on the scientific data. The European Commission, after the discussion with Member States, decides whether or not the claim will be authorized. The details of the process differ depending on the type of health claim.

The Nutrition and Health Claims Regulation also applies to trademarks and other brand names which may be construed as nutrition or health claims. Trademarks and brand names that imply nutrition or health claims do not have to be authorized but must be accompanied by an authorized related claim. Trademarks and brand names in use before January 2005 do not have to comply with the Regulation until 2022.

Section 4.09. The Average Consumer

Claims must be understood by the average consumer (this effectively prohibits the use of nutrition and health claims in materials aimed at children).

Section 4.10. Availability of Nutrients from a Varied Diet

Advertising must not suggest that it is difficult to obtain adequate quantities of nutrients from a varied diet (exception: folic acid in pregnancy and vitamin D for specified at risk groups).

For example:

- '*Even if you eat healthily, it is difficult to get all the vitamins and minerals you need*' would not be acceptable as it implies that it is difficult to obtain an adequate vitamin and mineral intake from healthy eating alone;
- '*If you are not managing to eat healthily, you may benefit from a daily vitamin and mineral supplement*' would be acceptable as the person is not currently eating a balanced diet.

Section 4.11 Health Claims

Advertising must not imply that food supplements can be used to prevent or treat illness or include any reference to such a property. Claims of this type are referred to as 'health claims'. It is acceptable, however, for RASCI Members to state that a product helps to or support or maintains good health.

Please remove all health claims, including all references to medical conditions and symptoms.

Section 4.12. Examples of Health Claims

'Helps reduce joint stiffness'	X
'Helps maintain supple and flexible joints'	V
'Helps prevent colds'	X
'Helps maintain a healthy immune system'	V

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

Section 4.13. Tonic Claims

Please remove any tonic claims such as 'restores vitality', 'gives you an energy lift/ boost', with the exception of those cases in which there are clinical studies to support this.

Section 4.14. Examples of Tonic Claims

'A great pick-me-up'	X
'Helps maintain good health and wellbeing'	V

Section 4.15. General Health and Wellbeing Claims

If you have included a 'general health and wellbeing' claim such as 'helps maintain good health and wellbeing', you also need to include a specific health claim as provided by the list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health.

Section 4.16. Energy Claims

Please ensure that energy claims accurately reflect the role of the particular nutrient. Several vitamins and minerals can claim to help the body release energy from food, but it is unusual for food supplements to be a source of energy (calories) or to be able to support claims that the product increases energy levels.

Section 4.17. HCPs Endorsement

The Nutrition and Health Claims Regulation prohibits the use of health claims that make reference to recommendations from individual HCPs.

Section 4.18. Recommendations from Associations of Medical, Nutrition and Dietetic

Professionals

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

Section 4.19. Advertising Related to Charitable Activities

Advertisers may state that they are donating money to, or that they support a particular charity. Where the partnership is purely for fundraising purposes, this must be made clear to consumers. Please bear in mind that any implied claims must be acceptable under the applicable regulations and codes.

Section 4.20. Distance Selling

All mandatory information, with the exception of the date of minimum durability ("use by" date) and the batch number, relating to the food must be made available to the consumer before the food is purchased. "Mandatory information" includes the information required by the Food Supplements Directive and domestic Regulations.

This information must be provided with no additional cost to the consumer (e.g. the use of paid for or premium telephone lines for sales is not permitted). If information is provided via a telephone line, it must be either a freephone number or a landline, where no cost will be incurred by the consumer.

All mandatory information, including the date of minimum durability or "use by" date must be available to the consumer at the moment of delivery.

Section 4.21. Allergenic Substances or Products that Must be Noted in the Ingredients List

The list below is subject to change and future amendments might apply, therefore it can only be regarded as an example.

a) Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof, except:
   i. wheat based glucose syrups including dextrose (1);
   ii. wheat based maltodextrins (1);
   iii. glucose syrups based on barley;
   iv. cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin;
b) Crustaceans and products thereof;
c) Eggs and products thereof;
d) Fish and products thereof, except:
   i. fish gelatine used as carrier for vitamin or carotenoid preparations;
   ii. fish gelatine or Isinglass used as fining agent in beer and wine;
e) Peanuts and products thereof;
f) Soybeans and products thereof, except:
   i. fully refined soybean oil and fat (and the products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the Authority for the relevant product from which they originated);
   ii. natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources;

iii. vegetable oils derived phytosterols and phytosterol esters from soybean sources;
iv. plant stanol ester produced from vegetable oil sterols from soybean sources;

g) Milk and products thereof (including lactose), except:
   i. whey used for making alcoholic distillates including ethyl alcohol of agricultural origin;
   ii. lactitol;

h) Nuts, namely: almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoinensis (Wangenh.) K. Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (Pistacia vera), macadamia or Queensland nuts (Macadamia ternifolia), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin;

i) Celery and products thereof;

j) Mustard and products thereof;

k) Sesame seeds and products thereof;

l) Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO_2 which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers;

m) Lupin and products thereof;

n) Molluscs and products thereof.

Section 4.22. Checklist Proposal for Labelling

To note: Principal Field of Vision will generally mean Front of Pack (FoP) **COMPANY NAME:**		
PRODUCT NAME:		
DATE RECEIVED:	**DATE REVIEWED:**	
REQUIREMENT	**FIELD OF VISION**	**YES/ NO**
Brand & Product Name/s	Principal	
Legal name of food (“food supplements”)	Principal	
Net quantity of the food	Accompanying the name of the food	
Best before date	Anywhere on the label	
Lot number/ batch code	Easily visible, clearly legible and indelible	
Responsible commercial operator details	Not specified	
Sweetener statements (if relevant)	Accompanying the name of the food	
Instruction for use	Not specified	
Any specific conditions of use (if relevant)	Not specified	

Ingredients list (in descending order of quantity) to include:	Not specified	
Correct name/s of vitamin/ mineral other substance including botanical/ plant name/s	Ingredients list	
Excipients	Ingredients list	
Additives labelling in compliance with Regulations 1333/2008 and 1129/2011	Ingredients list	
Allergen information – highlighted	Ingredients list	
Phenylalanine statement (if relevant)	Not specified	
Polyol statement (if relevant)	Not specified	
A statement that each tablet/ capsule/ serving etc. contains X amount of active ingredients	Above the nutrition panel	
Any additional information required by the conditions of use for any nutrition or health claim made (if relevant)	Next to or directly following on from claim	
A warning for products or ingredients that may represent a health risk if consumed in excess (e.g. iron warning for children) (if relevant)	Not specified	
Caffeine warning statement (if relevant)	Accompanying the name of the food	
Quantities of active ingredients with correct unit values (mg, µg etc) and including percentage of NRV (where appropriate)	Nutrition panel	
„Food supplements should not be used as a substitute for a varied diet and healthy lifestyle"	Not specified	
„Do not exceed stated/ recommended dose/ use"	Not specified	
„Keep out of reach of young children"	Not specified	
FSA Advisory Statements (if applicable)	Not specified	
Storage conditions	Not specified	
Place of origin (if applicable)	Not specified	
Tamper warning (if applicable)		
Weights & Measures		
Reviewed by	**Date**	

Section 4.23. Additional Requirements for Vitamin and Mineral Supplement Advertising

In order to say that the product is a source of a particular vitamin or mineral, or in order to make any claims about a vitamin or mineral, this must contain a significant amount of that vitamin or mineral. "A significant amount" is taken to mean at least 15% of the RDA.

Section 4.24. 'Source of Vitamins and Minerals' or 'Contains Vitamins and Minerals'

Under the Nutrition and Health Claims Regulation 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 to also include quantities.

Section 4.25. 'High In' Claims

In order to say that the product is 'high in' a particular vitamin or mineral, the product must contain twice the value of 'a source of'. In most cases, this will be at least double from the minimum of 15% of the RDA imposed by the legislation.

Section 4.26. 'Complete' Claims

For many years, food supplement manufacturers have used the term 'complete' to communicate that that product contains a significant amount of each scheduled vitamin and mineral (e.g. each vitamin and mineral that has an RDA). However, 'complete' has not been included in the list of permitted nutrition claims.

In order to say that your product is 'complete' it should contain a significant amount of each vitamin and mineral that has an RDA. 'A significant amount' is taken to mean at least 15% of the RDA.

Section 4.27. Health Claims - Flexibility of Wording

The European Commission has stated that some flexibility of wording is possible provided that its aim is to help consumer understanding and that the amended wording has the same meaning to the consumer as the original claim.

Article 5. Advertising

A food supplement should not be advertised in a manner which is likely to lead to its use by young children without parental supervision. Such advertisements should not be specifically directed towards young children.

Advertisements shall be true and shall not mislead.

No advertisement shall contain any exaggerated claim, direct or implied.

Advertisements shall be fairly comprehensible.

No advertisement shall contain any suggestions to diagnose, prescribe or treat.

No advertisement shall discourage the consumer from seeking medical advice.

All descriptions, claims and comparisons which relate to matters of ascertainable facts shall be capable of appropriate substantiation.

All comparisons shall be balanced and fair. No comparative statement may, on any reasonably interpretation, mislead consumers about the product being advertised or about any other product with which it might be compared.

Advertisements shall not mislead about the novelty of a preparation/ formula; "new" is generally only acceptable for a reasonable time in association with the brand, to distinguish the product from other products in the market.

No advertisement shall, by statement or implication, suggest that a product contains some

unknown active ingredients.

All advertisements should be not intimidating so as to increase and/ or induce usage.

Testimonials shall represent the genuine views of the user, under the condition that this refers to the formulation which is currently on the market at the time of the testimonial release. In editing testimonials, care shall be taken that the original meaning is not changed in any way. Testimonials containing any material that is contrary to any legal provisions and to any provisions of this RASCI Code shall not be used.

Article 6. Social Media

The rules that apply to food supplement advertising in traditional media also apply to promotional activities that appears on Twitter feeds, Facebook pages and other social media platforms.

These guidance notes have been created to inform and educate on the responsibilities of the RASCI Members engagement in social media. These include all forms of social media (unless otherwise stated) where RASCI Members and consumers are able to engage directly with each other. They are relevant for all RASCI Members employees using digital media and third parties engaged on behalf of the RASCI Members.

RASCI Members should monitor any User Generated Content posted on their owned media, where consumers can post comments or generate content in any other way.

Blogging can fall into all three types of social media, so care needs to be taken that the relevant issues are considered. Traditionally, bloggers are ‘lay people’ who offer advice and reviews to consumers in their field of choice in an online diary format. Bloggers usually have an approachable and independent style and appearance, meaning that they can be very popular and seen as ‘go-to experts’ for certain issues. RASCI Members can utilize independent blogs as a means of enhancing product awareness, although there are some important issues to be considered. Under this Code, bloggers are considered to be journalists. Therefore, communications from RASCI Members to Bloggers is considered to be PR material.

RASCI Members may provide information to bloggers about campaigns or products. However, steps must be taken to ensure that all content provided to bloggers complies with legal requirements.

Section 6.01. Facebook and Instagram

The responsibility for communications on Facebook/ Instagram extends to the content posted on behalf of the RASCI Members and the designated profile page. This includes status posts, stories, sharing content and responding to posts. Content shared by consumer users such as links and articles do not become the responsibility of the RASCI Members once shared, although care must be taken that shared content is appropriate and clarify that the content is under separate editorial control.

RASCI Members may respond to written communications directed at the RASCI Members via wall posts, tagging (using@brandname) or private messages. Responses to general queries should be given, where appropriate.

User generated mentions of the product in status updates not directed at the RASCI Members owned media do not fall under this remit and do not require responses.

Media monitoring can exist in a pre- or post- moderation format. It is advised that this is conducted at least once every 24 hours over the working week. If the page/ feed is going to be left unmonitored for longer than this, it is advised that notice is given to the consumer.

Where an ad or campaign is promoted using the Facebook/ Instagram page of a third party, it must be clear that this is a promotional communication. This can be done by ensuring that the post is listed as a 'sponsored post'. This would not be the case for charities or similar who have chosen to share content about you, without prompting.

Section 6.02. Twitter

Where space is restricted such as on character limited posts, if additional information is required for a claim under the conditions of use, this can be accompanied by a link which provides the additional information in a clear and legible manner, such as the brand website.

Most content on Twitter is user generated and does not appear on the feed of the RASCI Members even when directly referenced.

Content under the responsibility of the RASCI Member only includes what is written on behalf of the RASCI Members under the designated Twitter name. This includes RASCI Members generated tweets including re-tweeting, sharing content and responding to posts.

Shared content such as articles do not become the responsibility of the RASCI Members once shared, although care must be taken that shared content is appropriate and it is clear that the content is generated separately.

Re-tweeting the tweets of other users also falls under the responsibility of the RASCI Members. Once the tweet has been re-tweeted by the RASCI Members, it is then under the editorial control of the RASCI Members and must comply with all regulations.

It is advised that media monitoring is conducted at least once every 24 hours during the working week.

Where an ad or campaign is promoted using the Twitter feed of a third party (e.g. a magazine), or where sponsorship is involved it must be clear that this is an ad and has been paid for. This is usually accommodated for by including #ad or #spon at the end of the tweet.

Section 6.03. YouTube & Blogs

As a form of owned media, the responsibility for communication lies with the RASCI Member. Depending on the platform, RASCI Members can use either pre- or post- moderation to monitor their content. It is advised that media monitoring is conducted once every 24 hours during the working week.

RASCI Members are advised to respond when a comment is left on owned media as it is considered to be addressed directly to them. RASCI Members may choose whether they respond to general queries.

RASCI Members are allowed to use online reviews as testimonials provided all other requirements for use of testimonials have been fulfilled.

Section 6.04. Product Reviews

As a form of earned media, the responsibility of communications does not lie with the RASCI Members. However, it is advised that RASCI Members regularly monitor this content to look out for any inappropriate content. If possible, such content should be responded to or removed if necessary; however, it is important that action is not extreme in nature and natural flow of comments is maintained. RASCI Members may respond to comments (if possible on chosen media).

User generated reviews on third party websites can be monitored by agencies/ brand teams, although this is not required.

RASCI Members are allowed to use online reviews as testimonials provided all other requirements for use of testimonials have been fulfilled.

Article 7. Promotions Involving Gifts

Member companies may offer food-supplement items to consumers as gifts. The gift may, or may not, be dependent on the purchase of a food supplement.

Section 7.01. Gifts-with-Purchase

If RASCI Members wish to offer a gift-with-purchase, the gift should be relevant to the product and of lower value to the consumer than the cost of the food supplement. This is to avoid consumers purchasing food supplements they do not need, in order to obtain a desirable gift. Members should take into account both the actual cost (the amount paid for the gift) and the perceived value (the price at which consumers could purchase a similar item). Promotional materials should promote the product's benefits, and not the gift, as the main reason for purchasing the food supplement.

Section 7.02. Promotional Aids

Promotional aids are objects that promote a food supplement and which display a product/ brand name as a reminder. They are usually free giveaways that do not depend on the purchase of a food-supplement. Examples include T-shirts, pens, mugs, coasters, note pads, mouse mats, but not limited to these. Promotional aids that merely state the product name or a reasonable abbreviation thereof and a trade mark protection are not required to include the consumer essential information. The umbrella brand name may be used as an alternative to the product name. For example, a pen simply stating 'Brand X' or the full product name does not need to include any additional information.

ANNEX D - GUIDELINES FOR COMMERCIAL COMMUNICATION OF MEDICAL DEVICES

Article 1. General Rules, Scope, Regulations

Section 1.01. General Rules

In all the activities related to the advertising of medical devices, RASCI shall define rules to be complied with by the Members of the association.

The entire activity of advertising and promotion of medical devices must be done responsibly, ethically and at the highest standards, to ensure the safe use of the medical devices.

Advertising of medical devices is allowed provided it is in compliance with the legislation in force.

These rules aim to clarify certain detail issues so that advertising for any medical device, irrespective of how it is conducted, is at a high standard and complies with the legislation in force.

Advertising of medical devices should not include anything offensive or misleading for the user.

Section 1.02. Scope

These rules refer to the activity of advertising medical devices to the general public, to persons qualified to recommend or distribute medical devices and to provide samples.

These rules do not cover the following areas:

a) The labelling and the instructions for use, as provided by the applicable legislation, to the extent they are not of a promotional nature;
b) Correspondence, possibly accompanied by non-promotional materials, sent as a response to specific questions from healthcare professionals, but only if it refers exclusively to the subject-matter of their letter or of their question and is not of a promotional nature;
c) General, non-promotional information about companies (such as information for investors or current/ potential employees), including financial data, descriptions of research and development programmes, and discussions on the regulations impacting the company and its products.
d) Commercial/ promotional campaigns, of the type 1+1, „buy and win” etc.
e) Presence in retailer magazines (e.g. Revista săptămâna), such as image and price discount, graphic page with image and promotional message/ comptetitions.
f) Visits of commercial representatives to persons qualified to recommend medical devices.
g) Any kind of sponsorship including, but not limited to: promotional meetings attended by persons qualified to recommend or distribute medical devices, scientific congresses attended by persons qualified to recommend or distribute medical devices, corporate sponsorship, sponsorship of TV/radio programmes. public events sponsorship.
h) Promotional objects;
i) Educational materials.

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

RASCI Member companies are responsible to comply with the obligations described herein, even when they transfer to third parties parts of promotional, advertising or implementation activities or when they have them engaged, on their behalf, in advertising activities covered by these rules.

RASCI Member companies shall ensure that any of the third parties to whom they transferred their medical device advertising activities comply with these rules.

Section 1.03. Regulations

Advertising for medical devices (advertising) shall be considered to be any form of organised activity aiming to inform through direct or indirect methods and any form of promotional activity aiming to encourage the prescription, distribution, sale, administration, recommendation or use of one or several medical devices. The advertising of medical devices may be intended for healthcare professionals or for the general public.

Advertising of a medical device:

a) Shall be accurate, balanced, fair, objective and complete to allow the possibility for those who are targeted to form their own opinion on the intended purpose and therapeutical benefit of the concerned medical device;
b) Shall rely on the up-to-date assessment of all the relevant evidence and to clearly reflect such evidence;
c) Shall encourage the rational use of the medical device, through an objective presentation thereof, without exaggerating its therapeutic properties, qualities;
d) Shall not encourage the irrational use of the medical device;
e) Shall not be misleading, subliminal, or deceive by distortion, exaggeration, unjustified emphasis, omission or in any other way;
f) Shall not suggest that a medical device has a purpose, merit, quality, or special property, unless it can be scientifically documented;
g) Shall not include discrimination, such as discrimination based on race, gender, language, origin, social background, ethnic identity or nationality;
h) Shall be without prejudice to the image, honour, dignity and private life of a person.

All the information included in the advertising material for a medical device shall match the information listed on the labelling or the instructions for use, respectively, and shall also be in accordance with the technical file of the medical device, as approved by the conformity assessment body, as applicable.

Advertising to the general public and to the healthcare professionals shall be prohibited for medical devices that:

a) Do not have the European CE marking of conformity (they lack a EU declaration of conformity and/ or CE Certification from the Notified Body);
b) Are not put into service on the territory of Romania at the time when the advertising campaign is released.

The main responsibility to comply with the regulations in force for all the advertising materials for a medical device shall belong to each RASCI Member.

The main forms of advertising used consist in:

a) Printed indoor and outdoor advertising materials;
b) Audiovisual advertising;

c) Internet and social media advertising;
d) Provision of samples.

Article 2. Misleading and Comparative Advertising

Section 2.01. Misleading Advertising

Misleading advertising shall be any kind of advertising which in any way, including its presentation, misleads or is likely to mislead the persons to whom it is addressed or whom it reaches.

No form of advertising should suggest that a medical device has a particular purpose, merit, quality, or special property, unless it can be scientifically documented, in the technical file of the product.

To determine the misleading nature of advertising all its characteristics shall be considered and particularly its components referring to:

a) The characteristics of the medical device (whichever they are), the extent of their compliance with their intended purpose and the results expected from its use;
b) The omission of essential information regarding identification and description of that medical device with the intent to mislead the people to whom it is addressed.

Advertising shall not contain inadequate, alarming, or misleading claims on recovery. This rule shall prohibit statements such as 'miracle' and 'wonder product', but without limitation to these. It shall also prohibit visual elements suggesting the cure, such as photographs taken before and after treatment which display a dramatic improvement which cannot be expected to be achieved by most users. The following precepts should apply when the use of photographs taken before and after the treatment is envisaged:

a) Photographs taken before the treatment shall present the level of severity of the disease according to the intended use of the product. For instance, the advertising messages for the products used to treat pain caused by mild arthropathies should not display persons suffering of severe arthrosis;
b) Any post-treatment photographs should show an improvement which could be realistically expected by most persons suffering from that disease when they use that product according to the instructions;
c) The use of time intervals should accurately reflect the time interval which would be required to obtain the benefits. For instance, claims that the improvement of pain occurs instantly, when in fact it takes longer to obtain this effect, shall not be acceptable.

Section 2.02. Comparative Advertising

Comparative advertising shall be prohibited if:

a) The comparison is misleading according to the provisions of the Section 2.01;
b) It uses the trademark of a competitor, only generic names shall be allowed (e.g. soap);
c) It compares medical devices with different usage instructions and/ or intended purposes;
d) One or several essential, relevant, verifiable, and representative characteristics of the medical devices are not objectively compared;
e) Creates confusion on the market between the advertiser and a competitor or between the different trademarks or other distinguishing marks of the advertiser and those of a competitor;

f) It discredits or contains unfair criticism of trademarks, trade names, distinguishing signs, goods, services, activities or status of a competitor;
g) Unfair advantage is taken of the reputation of a trademark or trade name or of other distinguishing signs of a competitor or of the designation of origin of competing products;
h) Presents goods or services as imitations or replicas of goods or services bearing a trademark or a protected trade name;
i) Creates confusion between traders, between the advertiser and a competitor, or between the different trademarks, trade names, other distinguishing marks, goods or services of the advertiser and those of a competitor;

Article 3. Advertising Intended for the General Public and for the Healthcare Professionals

Section 3.01 General Rules

Advertising shall be allowed only for the medical devices that have a EU declaration of conformity of the manufacturer and/or CE Certification from a Notified Body, according to the legislation in force.

Any form of advertising shall be designed so that it is clear that the message is of an advertising nature.

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

a) Name of the medical device;
b) A clear definition of the intended purpose for its use;
c) An express, legible invitation to read carefully the information from the user manual of the product/ the instructions for use or from the packaging, as applicable;
d) The CE marking of conformity, if applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures for the medical device (applicable from the date of entry into force of Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, respectively Regulation (EU) 2017/746 of the European Parliament and of the Council on *in vitro* diagnostic medical devices);
e) The name/ logo of the company that supported the elaboration of the material.

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

a) Non-promotional information related to health or hygiene (e.g. “Wash your hands at least six times a day!”, “Wash your teeth at least twice daily!”);
b) Advices (recommendations) to increase the quality of the life of patients/ consumers;
c) A design and a form of presentation that allows it to be clear and easily understood.

Publicity for medical devices shall not contain any material that:

a) Gives the impression that a medical examination or a surgical procedure is not needed, especially by providing diagnostic or distance treatment suggestions;
b) Suggests that the diagnostic, the test result established with a medical device is guaranteed, cannot be accompanied by errors or that the effect of the treatment with a medical device is guaranteed, not accompanied by side effects or that its effect is better than or equivalent to that of another treatment with another medical device or with a

different product;

c) Suggests that the subject's health condition can be affected unless the medical device is used;
d) Addresses children exclusively or especially;
e) Suggests that the medical device is a cosmetic, relaxation, or other consumer product;
f) Suggests that the safety or effectiveness of the medical device is due to the fact it is natural;
g) Can, by a detailed description or representation of a case, lead to incorrect self-diagnosis;
h) Offers, in inadequate, alarming or misleading terms, insurance regarding healing through the use of that medical device;
i) Uses, in inadequate, alarming or misleading terms, visual representations of the changes in the human body caused by diseases or lesions or actions of the medical devices on the human body or on a part of it.

Section 3.02. Regulations on the Claims in Advertising Materials

Claims on the "novelty" of a product can be made only for one year after the date when the product was first available for purchase by consumers from Romania. RASCI Member companies may use the word "new" or the phrase "now available" for one year after the date when the medical device was first available for purchase. If the medical device is already available for purchase, it should be clearly specified what product feature is new. For example:

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

It shall be the responsibility of the RASCI Member companies that promote their products to ensure that all advertising materials containing the word "new" are revised once the product reached the one-year limit and that no such advertising is distributed after that time.

"Now" often implies that a product is "new" (e. g. "now available") and therefore the same time restrictions shall apply. However, "now" may also imply that the product brings an element of novelty in a certain sector. For instance, the advertising message "Use brand X product – now you can improve your eyesight rapidly" shall not be accepted because it suggests that product X is the only product to rapidly improve eyesight.

All the advertising messages shall be in accordance with the Technical Documentation of the medical device. Advertising messages for indications that are not included in the instructions for use, on the label or in the clinical evaluation in the Technical Documentation shall be prohibited.

The information in the sections Instructions on Use, Labelling and Report on the Clinical Evaluation in the product Technical Documentation shall be the basis for the claims that can be made in advertising.

Advertising materials mentioning multiple products under the same Trademark must specify clearly which claims apply to each product.

Section 3.03. Forms of Advertising

Subsection 3.03.01. Printed Indoor and Outdoor Advertising Materials

Printed advertising materials may be both indoor and outdoor printed advertising materials (e. g. posters, invitations to events, brochures, poster display on streets or in metro stations, on billboards, on means of transport, advertising materials in the printed media, including press articles, point of sale materials: wobbler, shelf liner, poster, floor display, fliers, stopper, security gates, shelfs, Promo Island branding, etc.).

Printed advertising materials shall comply with the requirements specified in Sections 1 and 2 of this Annex.

Subsection 3.03.02. Audiovisual Advertising

Audiovisual advertising (radio, television) shall include: radio and TV spots, testimonials/ teleshopping.

Advertising for medical devices that is broadcast in radio and television programmes shall comply with the legal requirements on advertising in the audiovisual field.

Advertising for medical devices that is broadcast in radio and television programmes shall comply with the provisions specified in Sections 1 and 2 of this Annex.

Audiovisual advertising for medical devices shall mean any form of promotion intended to stimulate their distribution, consumption/ use, or sale.

It shall be prohibited to broadcast advertising and teleshopping for medical devices presented or recommended by celebrities of the public, cultural, scientific, sport personalities or other persons who, due to their celebrity, can encourage the consumption/ use of such products.

It shall be prohibited to broadcast advertising and teleshopping in which medical professionals or pharmacists recommend or endorse medical devices.

It shall be prohibited to broadcast advertising and teleshopping for medical devices if the presentations include recommendations or endorsements of medical associations.

Testimonial advertising shall comply with all the other rules herein.

Testimonials as such shall not be evidence supporting the claim about the product.

Testimonials shall reflect the level of change an ordinary user could expect. Therefore, testimonials such as the following shall be prohibited:

a) "*I tried many other products, but this is the only one that worked for me*" (this claim is contrary to the provisions mentioned in Article 2, Section 2.02, Comparative Advertising).
b) "*Brand X product made me feel well instantaneously*" (unless this claim is reflected by evidence and by the approved indication).
c) "*It is efficient for my arthritis*" (where the technical documentation for that product does not support its use for arthritis).

Testimonials shall be more recent than three years and shall reflect the user's real opinions.

RASCI Member companies that advertise shall keep evidence for each broadcast testimonial. They shall not be older than three years and the editing of the material shall be done with care to avoid altering the original meanings.

All testimonials shall reflect the consumers' real opinions.

Subsection 3.03.03. Internet and Social Media Advertising

Internet advertising (e.g. social media, websites, e-mail, forums, blogs or any other online types, mobile apps, banners, display, online video, press articles, PR campaigns) shall comply with the requirements mentioned in Sections 1 and 2 of this Annex.

Subsection 3.03.04. Provision of Samples

It shall be allowed to offer samples, provided they are properly marked with the information "Sample – It is not for sale" or with a mention with the same meaning.