Code of Conduct

GENAS Generic and Biosimal Medicines Association

The updated version of the Code of Ethics was adopted by the General Meeting on June 25, 2020

GENAS and shall enter into force on 1.7.2020.

PREAMBLE

1. GENAS Association for Generic and Biosimal Medicinal Products (hereinafter also referred to as "GENAS" or The “Association”) is committed to ensuring universal acceptance and adherence to high standards when advertising * human drugs.

2. Due to this purpose, the Association has adopted this GENAS Code of Ethics (hereinafter also referred to as the “Code”), which provides:
a) ethical rules for the advertising of medicinal products for human use (hereinafter referred to as "medicinal product"),
b) ethical rules for advertising activities towards healthcare professionals * and communication with as well as the interrelationships between members * and health professionals,
(c) ethical rules for the interrelationships between members and patient organizations * as well as relations between members and decision-makers *.

3. The purpose of this Code is not to lay down rules for the provision of non-advertising material medical, scientific and factual information, or to control or modify activities to the general public * which relate exclusively to medicinal products the expenditure of which is not linked to prescription (OTC).

4. This Code does not apply to the following:
(a) labeling of medicinal products and package leaflets;
b) correspondence, possibly supplemented by attached material of a non-advertising nature, necessary to answer a specific question about a particular medicine;
(c) factual, informative notices and reference materials concerning, for example, the change packaging, warnings of side effects, provided that they do not contain any drug declarations;
(d) non-promotional information relating to human health or disease;
(e) activities relating exclusively to non-prescription medicines;
(f) non - promotional general information about companies (such as information intended for investor or current / potential employee), including financial data, descriptions of research and development programs and discussions on the development of impact on society and its medicines.

5. Adoption and compliance with the Code is a condition of membership in GENAS, and the member must subject to both the word and the spirit of this Code. Members must ensure that everyone employees and / or representatives acting on their behalf, including all their branches, and

subsidiaries, have been fully acquainted with the provisions of this Code and this Code observed.

6. Members must ensure that all are followed in their marketing activities relevant legislation governing the advertising of medicinal products, such as Act no. 147/2001 Coll. on advertising, or Act no. 308/2000 Coll. on broadcasting and retransmission. In case conflict between the Code and the legal norm governing rights and obligations in the field advertising of medicines, the wording of the legal norm takes precedence. Such a discrepancy shall not be deemed to exist if The Code imposes stricter obligations on a member than are required by law.

7. Members shall be responsible for fulfilling the obligations imposed by this Code, including:
in cases where they entrust third parties (for example, medical representatives, consultants, market research companies, advertising agencies) to propose, implement or engaged in activities governed by this Code on their behalf. The members are in addition, they must always take the necessary steps to ensure that any third party person they have entrusted with the design, implementation or involvement in the regulated activities this Code, which, however, does not act on behalf of a member (for example, joint ventures licensed persons) has complied with the provisions of this Code.

8. Generic pharmaceutical companies that are not members of GENAS are hereby invited to: they have also adopted and complied with this Code.

9. Compliance with the Code is supervised by the Ethics Committee. The ethics committee may continuously issue interpretations aimed at interpreting certain parts of the Code. Complaints in the case of suspected violations of the Code should be reported to the Ethics Committee.

10. The basic guiding principle of the Code is that at any time with respect to the drug will make an advertising statement *, it must include information about the drug * in the Slovak language.

11. Failure to comply with the Code will result in sanctions being imposed pursuant to Administrative Procedure Code adopted by the Ethics Committee. Compliance with this Code by any means does not reduce the obligations of members to comply with generally binding legislation.

12. GENAS undertakes, in the light of the legislation in force, to assist its individual members are aware of the obligations arising from this Code and to be aware of their content educated; GENAS undertakes to prevent infringements of the provisions of this Agreement The Code may also achieve this objective by providing advice to its members.

13. Advertising and other activities that take place within Europe must be consistent with the applicable legislation and the national code of the member association in force in the state where the advertising or other activity took place.

14. In applying the Code as well as in its interpretation, it is first and foremost necessary to follow itself the text of the Code and the intentions that GENAS pursued in formulating the individual provisions.

In case of ambiguity of any part of the Code, it is necessary to perceive the spirit of the Code and the interest in transparency and ethical behavior of pharmaceutical market players. When judging individual activities of members and their compliance with the Code will be based on real intent, which the member was guided in the implementation of the activity.

Note: A glossary of defined terms used in this Code forms an Annex to the Code.
The first use of a term in the Code defined in the dictionary is always marked with an asterisk (*) and is underlined. If the term needs to be emphasized in the text of the Code, the term is highlighted by an asterisk (*) and underlining can also appear in several places of this Code.

CONTENTS

1. NATURE AND AVAILABILITY OF INFORMATION AND CLAIMS

1.1. Responsibility

It is the responsibility of members, their employees and their medical / technical advisors ensure that the medical content * contained in all promotional materials * is true, correct *, accurate, current, verifiable and fully documented by information about the medicine, the literature * or archived data * and not to contradict later information earlier without being substantiated by new scientific knowledge. Representative activities companies * must always comply with the Code.

EXPLANATORY NOTES

1.1.

(a) This liability applies not only to the medicinal product which is the subject of the advertisement, but also to any information provided or claims made concerning other medicinal products.

(b) Any statement made must be in accordance with the Slovak information on the medicinal product, regardless of to the source on which the claim is based.

1.2. Provision of justification

1. In addition to the information that must be provided or made generally available, a member shall provide upon reasonable request to members of the medical community, further precise and relevant information on the medicinal products which it offers on the market, taking care to: acted in accordance with applicable law in providing such information.

2. Sources from which data are cited in promotional materials in support of claims, including archived data or data in print must be made available on request members of the medical community and other members.

EXPLANATORY NOTES

1.2.

(a) All data substantiating claims must be easy to find so that they can be provided on request within 10 working days.

(b) The information contained in the application for marketing authorization for a medicinal product may be used to substantiate claims. In case requirements to substantiate the claim, such information must be provided in detail. Statement that data are "confidential" will not be allowed.

(c) If the information on which the claim is based must not be disclosed, e.g. an article in the press which subject to confidentiality provisions, then such information cannot be used to substantiate the claim for the purpose of meeting the conditions of this Article.

(d) Data on the cost-effectiveness of a medicinal product may be used to substantiate advertising claims, however, these data must be in accordance with Articles 1.1, 1.2, 1.3, 1.5 and 1.7 of this Code.

1.3. False or misleading claims

1. Information, medical claims * and graphics must be current, accurate and balanced and not misleading, either directly, indirectly or by omission.
2. Information, claims and graphics * must be substantiated *, and such justification shall be provided without undue delay at the request of the medical staff the public.

EXPLANATORY NOTES

1.3.

Examples of situations in which advertising material may violate the Code. This list is not exhaustive and based on the experience of the Ethics Committee:

(a) References to literature or citations selected from the study or studies and citations of individual opinions,
which are significantly more favorable or unfavorable than indicated by the clinical evidence, or experiences. It is inappropriate to cite results that are disproportionately favorable (or disproportionately unfavorable in
comparable drug) study in a way that suggests that these results are typical, whereby may mislead.

(b) Information or conclusions of the study, the design, scope or conduct of which is clearly insufficient to support such information or conclusions.

(c) Citation of data that were previously in force but that, based on the evaluation of new data, are overcome or are incorrect.

(d) Suggestions or representations of uses, doses, indications or other aspects of information on the medicinal product which:
*have not been registered *.*

(e) Shortening the approved indication (eg in a subtitle) so as to remove the qualification or indication restriction.

(f) Use of data obtained from animal experiments or laboratory data directly clinical claim support.

*(g) Presentation of information in such a way, e.g. font size * and graphic design that would it could have aroused a misconception in the average reader. Font size used for qualified the positions must not be less than 2 mm. A qualified opinion may not be included in another reference material, but must be placed on the same page as the initial opinion. Original the opinion and the qualified opinion must be linked together by using an asterisk or similar symbol.*

(h) Opinions regarding a competing medicinal product, especially negative opinions that are not balanced relevant information on the medicinal product which is the subject of the advertisement.

(i) Abbreviation of the title of a graphic representation, which is reproduced from the literature in a way that changes
original meaning intended by the author.

(j) Use of foreign information on the medicinal product in support of the claim if the information does not match
with the summary of product characteristics valid in the territory of the Slovak Republic.

(k) Literal or implied claims that any parameter in the information on the medicinal product that is the subject of the article
warning, caution or adverse reaction is not a cause for concern.

(l) Insufficient substantiation of claims of a non-medical or non-scientific nature. This is information or claims relating to marketing parameters, such as pricing or share in
market. Care should be taken to extrapolate prescribing practices from sales data.

(m) If animal or laboratory data are used, they must be prominent on the same page a statement identifying the particulars as such, at a reasonable distance from those data in a way that does not obscure the label with other material.

1.3.1. Unregistered medicinal products and unregistered indications

Medicines that do not have a valid marketing authorization decision for the territory of Slovakia may not be subject to advertising, unless otherwise provided by law. This prohibition also applies for the advertising of unregistered indications of authorized medicinal products as well as for the advertising in any inciting the use of the medicinal product in contravention of a valid marketing authorization decision.

1.4. Good taste

Advertising material (including graphic and other visual presentations) should be consistent with generally accepted standards of good taste and respect for professional status its recipients.

1.5. Unauthorized superlatives

Unauthorized superlatives must not be used. The claims must not give the impression that the medicinal product or its active ingredient is unique *, or that it has any particular advantage, quality or property, unless this can be demonstrated. The word "safe" must never be used unauthorized. It must not be stated that the medicine has no side effects, that there is no risk of poisoning or addiction.

1.6. New drugs

The word "new" may not be used to describe any medicinal product, presentation or therapeutic indications that have been available and generally advertised on the market in Slovak Republic for more than 12 months.

1.7. Comparative statements

1. The comparison of medicinal products must not be misleading or derogatory. It must be matter-of-fact, honest, based on the relevant and comparable properties of the medicinal product and must be justified and evidenced by reference to the source. When making a comparison, care must be taken to ensure that: the comparison was not misleading by distortion, improper emphasis or otherwise.

Comparative comparisons must not be used which only claim that the medicine is better, stronger, more often prescribed and the like.

2. Where archived data are used to substantiate comparative statements, they shall comply with the requirements of Article 1.2 above.

EXPLANATORY NOTES

1.7.

*(a) A comparative efficacy or safety statement shall not be based solely on a comparison of the summary Product Characteristics * (SPC), as these documents are based on different databases and are not directly comparable. This applies to Slovak as well as foreign information on medicines. Claims of comparable efficacy or safety should be substantiated in all respects aspects of efficacy or safety.*

(b) If the comparative statement relates to a specific parameter, it must be from all statements Obvious that it only applies to this parameter. The accepted level of statistical significance is p <0.05. if If comparative data are used which are not statistically significant, such data must comply with under the following conditions:

the data must be clearly identified as such by a statement and not only by the value of p;

these data may not be used in generalizations or indications of higher or lower quality.

(c) The statement that the claim is not statistically significant must be linked in some way to the original statement made on the same page and in reasonable proximity to the original statement in such a way as to:

has not been covered with other material using a font size of not less than 2 mm.

1.8. Imitation

Advertising information should not mimic resources, copy slogans or a general graphic design chosen by other members in a way that could easily mislead or confuse.

1.9. Medical ethics

The names of doctors or their photographs must not be used in a way that would contradict medical ethics.

1.10. Resolution of advertising material

Advertising material as such must be clearly distinguishable. Whether it is advertising material it depends primarily on the actual intention pursued by the member through its use.

EXPLANATORY NOTES
1.10.
*For example, ads in a magazine * should not be designed to resemble editorials, unless they are clearly marked as advertising. See also Articles 3.2 and 3.3.*

2. INFORMATION ON THE MEDICINAL PRODUCT

2.1. General provisions

1. Part of every advertisement for medicines and part of all types of advertising materials specified in Article 3, the abbreviated information on the medicinal product * shall include:
(a) basic information on the medicinal product which is in accordance with the summary of product characteristics of medicinal product (the scope is specified in Article 2.3),
b) the date on which the product information was approved and / or last updated,
(c) the method of dispensing the medicinal product.
2. Whenever required, abbreviated information on the medicinal product must appear in printed size fonts not less than 2 mm and sufficiently distinguishable from the background in such a way that it is readable. The main headings should be easy to identify.
3. The abbreviated information on the medicinal product may not be overprinted or translated by advertising phrases or graphic means and must clearly mark each latest clinically significant change *.
4. When the term "information on medicinal products" is used in the Code, abbreviated information is meant on medicinal products, unless the provision in question expressly states otherwise.

2.2. Complete product information

1. In the case of advertising carried out through a personal meeting of the member's representative, the complete information on the medicinal product shall be provided with the expert by making it available to the expert or provide a summary of product characteristics.
2. Advertising material used in a personal meeting must contain information on the medicinal product referred to in Art. 2.1 par. 1.

2.3. Scope of abbreviated product information

1. The basic information on a medicinal product shall correspond to the summary of product characteristics, and may be an appropriate paraphrase / summary thereof.
2. Under the heading "Summary of Product Characteristics", the following must be indicated:

(a) approved indications for use;
b) contraindications;
(c) clinically relevant warnings;
(d) clinically relevant warnings for use;
(e) clinically significant adverse reactions and interactions;
(f) available dosage forms;
(g) dosing regimens and routes of administration;
(h) clinically relevant potential for potential drug dependence;
(i) a reference to a special group of patients;
(j) method of dispensing the medicinal product;
(k) the date of approval or revision of the summary of product characteristics.

2.4. Clinically significant changes

1. If a clinically relevant change in the safety of the medicinal product is included in the information on the medicinal product should be included in all statements of information on the medicinal product for a period of 12 months from the date of this change with an (asterisk or asteriks) to the footnote with a font size of not less than 2 mm with the following text: "Please note change (s) in the product information. "
2. The full text of the amended part should appear in each abridged period during that period information on the medicinal product.
3. If a member does not actively promote a medicinal product, a change in the product information must be notified in writing relevant member of the medical community.

3. ADVERTISING MATERIAL

3.1. Admissibility and legality of advertising

3.1.1.

Members must maintain a high ethical standard in all circumstances. Advertising must be such that:
(a) never discredited or diminished the credibility of the pharmaceutical industry;
(b) by its nature, recognizes the special nature of medicinal products and its professional reputation of their addressees;
(c) did not provoke outrage.

3.1.2.

Unless expressly provided otherwise in this Code, a medicinal product may not be the subject of advertising unless isregistered for the territory of the Slovak Republic, as well as the subject of advertising which would go beyond the approved SPC.

3.1.3.

Advertising must be accurate, balanced, honest, objective and sufficiently complete to enable its recipient to form his or her own opinion on the therapeutic value of the medicinal product which is the subject to advertisements. It should be based on an up - to - date evaluation of all relevant evidence and clearly reflect them. It must not mislead, exaggerate, improperly emphasize,

by omission or in any other way. The ad for the medicine must contain information on the medicinal product (Article 2.1).

3.1.4.

Advertising must promote the prudent use of medicines by presenting them objectively and without exaggerating their properties. Claims must not indicate that the medicinal product or its active substance has a particular advantage, quality or property, unless this can be demonstrated.

3.1.5.

The advertisement must always comply with the information given in the summary of characteristics drug.

3.1.6.

1. Any advertising or information on a medicinal product addressed to the public healthcare professionals (hereinafter referred to as "the provision of information to the medical community") may be carried out or provided only to persons designated by the Member to provide such professionally qualified information.
2. When providing information to the medical public, the said persons are obliged to hand over or make available a summary of product characteristics, price and amount its reimbursement by the health insurance company.
3. When providing information to the medical community about a medicinal product, it is prohibited to donate, to offer or promise a pecuniary advantage or a non-pecuniary advantage to members of the healthcare public and persons close to them.

3.1.7.

1. According to Slovak law, towards any of the general public * it is prohibited to advertise:
a) medicinal products which are not registered *,
b) medicinal products subject to medical prescription,
c) medicines containing narcotic drugs, psychotropic substances and preparations,
(d) medicinal products the supply of which is not subject to a prescription but which are reimbursed on the basis of public health insurance.
2. The prohibition referred to in paragraph 1 does not apply to vaccination campaigns organized by the holder of marketing authorization decisions or the representative of the marketing authorization holder, if any authorized by the Ministry of Health.
3. The advertising referred to in paragraph. 1 is also prohibited against members of the medical community if they do not have professional status *.

3.1.8.

Any advertising material must be in accordance with everything in all circumstances the requirements for the admissibility and legality of advertising set out in this Article 3.1., as well as with other conditions of this Code (eg see Article 1, Article 2).

3.1.9.

Advertising may not be disseminated by an automatic telephone call system, fax, by electronic mail, text messages and other electronic data forms of communication if the addressee has not demonstrably consented to the delivery of such advertising in advance.

3.2. Advertising in magazines

Advertising in magazines must comply with the requirements set out in Articles 3.2.1 to 3.2.3 of this Code. Abbreviated information about the medicine must appear in every issue of the journal printed in a font size of not less than 2 mm and must be legible for readability sufficiently distinguishable from the background.

EXPLANATORY NOTES
3.2.
Care must be taken to ensure that where the advertising is on both sides or where it goes for a multiple-page printout, the information contained on each individual page was not false or misleading if read separately.

3.2.1. Full advertising

1. A complete advertisement * must include, within the content of the advertisement itself, the following:
a) the trademark of the medicinal product,
b) INN * of active substances (substances),
c) the name of the holder of the marketing authorization for the medicinal product and his postal address in the Slovak Republic
(d) complete (SPC) or abbreviated information on the medicinal product (hereinafter information on the medicinal product).
2. Full advertising is mandatory for the advertising of all new chemicals * or new ones indications for a period of 12 months from the date of their first advertisement in medical publications, or longer, at the discretion of the member.
3. The product information should be placed next to the main body of the advertisement. If not practicable, the ad must include a statement printed in font size at least 2 mm with the following wording: "Before prescribing, please read the information on drug. For information about this medicine, see page ... ". At this point, the number of
pages in the publication where the product information is located, or a reference to the appropriate reference regarding drug information section or advertiser index.
4. Medicinal product information should always be an integral part of the journal.
EXPLANATORY NOTES
3.2.1. par. 1:
(b) The INN should appear next to the most prominent presentation of the trade name.
(d) See Articles 2.1, 2.2 and 2.3.
3.2.1. paragraph 3:
The wording used to guide the reader to the location of the product information may be different, but it must include guidance on studying the product information before prescribing it.
A loose-leaf letter does not meet the requirements of this article.

3.2.2. Short advertisement

1. A short advertisement is intended to remind a person authorized to prescribe the existence medicinal product and may not contain advertising claims. Use only short advertising within any advertising medium (magazine, audio, video advertising, etc.) is not allowed before 12 months after the first publication of the advertisement for the new chemical substance or before 12 months after the clinically significant change * observed in the summary characteristics of the medicinal product
2. The short advertisement must contain:
a) the trademark of the medicinal product,
b) INN of active substances (substances),

c) the name of the holder of the decision on the marketing authorization of the medicinal product and his postal address in the Slovak Republic,
d) a statement that further information may be obtained on request from the member,
(e) other requirements arising from the relevant legislation.
3. A short advertisement may include:
a) up to 5 words describing the therapeutic class *, but without the use of advertising phrases,
b) graphic means,
c) a statement on the available dosage forms,
(d) a statement referring to the location of the product information in the reference material *.
4. No material or information other than that referred to in paragraph 2 and 3 in short advertising is not allowed.

EXPLANATORY NOTES

3.2.2. par. 2 letter b:

The INN should be listed next to the most important presentation of the trade name.

3.2.3. Articles ordered by

1. Articles ordered by the company must be identifiable as such in font size less than 2 mm.
2. The member responsible for the inclusion of an article ordered by his company must be clearly identified, either above or below the ordered article in font size of at least 2 mm. Articles ordered by a member may not be presented as, or remind, independent third party opinion and / or editorial material.
3. Articles ordered by a member must comply with all relevant provisions Articles 1 and 3.1 of this Code. Articles ordered by a member must also comply with requirements set out in Articles 3.2.1 and 3.2.2 of this Code.

EXPLANATORY NOTES

3.2.3.

The Member should ensure that the statements of third parties quoted in the Articles ordered by it comply with the following requirements.

*Independently edited appendices published by the proceedings of a recognized congress * are not considered articles ordered by a member. In the event that a member sponsors such an annex, this fact must be clearly stated.*

3.3. Materials for use by medical representatives

The main guiding principle of this Code is that an advertising claim is made at any time concerning a medicinal product, it must be accompanied by the abbreviated information on the medicinal product and must be comply with requirements set out in Articles 1 and 3.1 of this Code.

3.3.1. Printed advertising material

1. All printed advertising materials of a member shall contain the following information:
a) the trademark of the medicinal product,
b) INN of active substances (substances),
c) the name of the holder of the decision on the marketing authorization of the medicinal product and his postal address in the Slovak Republic,
d) complete or abbreviated information on the medicinal product,
(e) the date of issue or revision of the printed advertising material.
2. If it is impractical to print the product information on the main body of the advertising material, so this promotional material shall include the following statement printed in font size

at least 2 mm: "Please read the product information before prescribing medicinal. Information about product is attached to this object. "
3. The object must then be accompanied by a document containing the complete or abbreviated information on the medicinal product.
4. Any template, including graphs, illustrations, photographs and tables taken from published studies that form part of advertising material should:
(a) clearly specify the exact source (s) of the template;
(b) be faithfully reproduced except where adaptation or modification is necessary for compliance with any applicable code (s), in which case it must clearly state that the model has been adapted and / or modified.
5. Special care must be taken to ensure that the design contained in the advertisement is not misleading as to the substance of the medicinal product (for example, whether it is suitable for children) or as to the claim or comparisons (for example, by using incomplete or statistically irrelevant information or unusual scales).

EXPLANATORY NOTES
3.3.1.
This article applies to devices, leaflets, posters and other materials prepared on the basis of available literature which are intended for distribution to members of the medical community and which contain advertising claims.
3.3.1.ods 1.
(b) The INN should appear next to the most significant presentation of the trade name.
(d) See Articles 2.1., 2.2. and 2.3.
3.3.1. par. 2.
The wording used to direct the recipient of the advertisement to familiarize himself with the product information may be diverse, but must always include a clear call to study the information about the medicine before its prescription.

3.3.2. Audiovisual advertising material

1. Each audiovisual material must be accompanied by a document which contains the following
Information:
a) the trademark of the medicinal product,
b) INN of active substances (substances),
c) the name of the holder of the decision on the marketing authorization of the medicinal product and his postal address in the Slovak Republic,
(d) complete or abbreviated information on the medicinal product.
2. If an audiovisual object is presented, the information must be provided at the end of the presentation to the person who watched the promotional material or presentation offered to the audience if this presentation is watched by a group of spectators.
3. Audiovisual material containing advertising of a medicinal product broadcast as commercial media communication through the broadcaster on the basis of a special regulation may be aimed only at the advertising of over-the-counter medicines and must meet the conditions of a special legislation.

EXPLANATORY NOTES
3.3.2.
This article covers audio and video recordings for private use by professionals

the medical community or for demonstration purposes to groups of members of the medical profession the general public (paragraphs 1 and 2) as well as television and radio advertising (paragraph 3)

3.3.2. par. 1 (b):
(b) The INN should appear next to the most significant presentation of the trade name.
3.3.2. par. 1 (d):

(d) See Articles 2.1, 2.2 and 2.3.

3.3.3. Medical literature / reprints

1. Main content of each reprint of articles from the journal, proceedings of the sponsored symposium * or the summary of the literature used in the advertisement must be in accordance with the product information.
2. Quotations from medical and scientific literature or personal communications must be faithful reproduced, they must accurately express the opinion of the author and the significance of the study and accurately indicate resources.

EXPLANATORY NOTES
3.3.3.
(a) Members of the medical community may request literature on facts that are not captured in the product information, such as unapproved indications. It is not acceptable to do such literature disseminated without request. It is also unacceptable for such literature to be disseminated as part of the advertising of medicinal products, as this would constitute a breach of the condition that the advertising corresponds to the summary characteristics of the medicinal product.
(b) The non-advertising reprint does not need to be accompanied by information on the medicinal product. However the product information must be included with each accompanying material (eg leaflet) or presentations that contain advertising claims.
(c) Quotations concerning medicinal products that are excluded from public distribution or private events, such as such as medical conferences or symposia, should not be reproduced without written permission cited person, unless published immediately. Care must be taken to avoid doing so attributed to the authors unpublished claims or opinions concerning medicinal products the expenditure of which is linked to prescription if such claims or opinions no longer represent or need to be represented current opinion of the author.

3.3.4. Computer advertising material

1. Computer advertising material must comply with all relevant provisions of this Code.
2. When advertising an individual medicine, the person viewing the advertising material must have information on the medicinal product.
3. If the product information is entered into the interactive data system, the instructions for making it available must be clearly displayed.

EXPLANATORY NOTES
3.3.4.
This article addresses at least the following:
(a) Advertising material created by members for the purpose of advertising their medicines directly to the healthcare public, including such advertising tools as the software programs used by medical representatives during professional communication with members of the medical community.
(b) The use of outsourced computer programs by members for advertising purposes their medicines, including programs such as prescription and dispensing software.
Use of links on the Internet by members. Members who use the Internet should know the Slovak

law which prohibits the advertising of prescription medicines to the layman public.

3.4. Postal items

1. Postal items shall comply with all relevant provisions of Articles 1 and 3.1 of this Code.
2. It shall, where appropriate, be included in all postal items in which advertising claims appear, complete or abbreviated information on the medicinal product.
3. Postal items should only be sent to those categories of members of the medical community for whom their need or interest in obtaining the relevant information can reasonably be expected. Requests for exclusion from the advertising directory must be complied quickly, and no name may be renewed without a specific request or written consent.
4. Unprotected consignments, including postcards, envelopes or packages, shall not contain which could be considered as advertising to the general public or which could be considered unsuitable for public viewing.

EXPLANATORY NOTES

3.4. par. 1:

Envelopes encouraging urgent attention should only be used for withdrawal of medicines or important safety information. They should not send advertising material in envelopes with words indicating that the content is of a non-promotional nature. Unsolicited reprints of journal articles must be consistent with the product information and each cover letter should be in accordance with Articles 1, 2 and 3.1 of this Code.

3.5. Media used to transfer documents

Electronic media may be used to transmit advertising in accordance with applicable law regulations, in particular subject to the prior consent of the addressee of such electronic communication.

4. MEDICAL REPRESENTATIVES

4.1.

Medical representatives * must only use advertising material that is compliant with the provisions of Article 3 of this Code. Verbal statements about the medicine must be consistent with the provisions of Article 1 of this Code.

4.2.

Members are responsible for maintaining high ethical standards in their activities medical representatives and for their regular retraining in this field.

4.3.

Medical representatives should have sufficient expertise to present information on the company's medicines accurately, up-to-date and balanced and must be familiar with all provisions of this Code. Each member must ensure that its medical representatives, including employees acquired under contract to a third party, as well as any other representatives of the company who turn to members of the staff of healthcare

public in connection with the advertising of medicinal products have been made aware of the relevant requirements of this Directive Code and all applicable legislation and to be adequately trained and have sufficient scientific knowledge to be able to provide accurate and complete information on medicines they promote.

4.4.

Medical representatives must adhere to a high standard of ethical conduct in the performance of their duties. All medical representatives of GENAS member companies must be in the beginning of medical representative work trained and certified in knowledge and in the application of this Code. The certification is valid for a maximum of 3 years, while a shorter interval training from the Code of Ethics may be determined by the Ethics Committee. Conditions of certification and its forms are determined by the Ethics Committee. The certificate is issued by the GENAS office.

4.5.

Medical representatives must not use any fraudulent tricks or motivations or excuses in order to reach a meeting with a member of the medical community. During a meeting or when negotiating the date of the meeting, medical representatives must take action from the beginning appropriate measures to ensure that their identity is not misleading or the company they represent.

4.6.

Medical representatives must ensure that the frequency, timing and duration of their meetings with a member of the medical community, as well as the way in which they are carried out, members of the medical community do not disturb the medical community. Medical representatives must adhere to the organizational regulations in force in the specific installation. Medical representatives may not visit doctors authorized to prescribe medicines during their office hours if the purpose of their visit is drug advertising.

4.7.

Telephone contact and telephone communication may not be used to advertise medicines for this purpose, if a member of the medical community did not give prior consent.

4.8.

The medical representative shall submit or make available a summary of each advertising characteristics of the medicinal product as well as other information required by law, and this Code.

4.9.

Under no circumstances may a medical representative gain access to a national the medical community or to obtain an unjustified advantage to promise to anyone or provide monetary or non-monetary benefits.

4.10.

Each member must set up a scientific service responsible for providing information on its medicines.

This scientific service must include a doctor or pharmacist who will be responsible for approval of any promotional material prior to its release. This person must confirm that it has examined the final form of the advertising material and by their conviction it is in accordance with the requirements of this Code and all applicable laws and regulations,

it corresponds to the summary of product characteristics and is correct and true display of facts about the medicine.

4.11.

Each member must appoint at least one employee to be responsible for supervision that the member and its subsidiaries ensure compliance with the Code.

4.12.

Medical representatives must immediately send any information they receive in connection with the use of their company's medicinal products to the scientific services of their companies, in particular information or reports of adverse reactions.

EXPLANATORY NOTES

4.

Members must ensure that medical representatives are familiar with the provisions of this Code. Particular attention should be paid to Article 3.3 on materials used by medical representatives, Article 5 on samples and Article 6 on exhibitions at professional, scientific and professional events.

5. SAMPLES OF MEDICINAL PRODUCTS

5.1.

Members must carefully ensure that the provision of samples is carried out in an appropriate manner in accordance with the law.

5.2.

Samples of medicinal products may be provided by the marketing authorization holder in written application only to the person authorized to prescribe medicinal products in the range of two samples of the smallest packaging of the authorized medicinal product per year marked "FREE MEDICAL SAMPLE - NOT FOR SALE "and the accompanying summary of product characteristics.

5.2.

Sample packages must be clearly identifiable as such and must be marked as follows to make it clear that these are medical samples, that they are free of charge and that they are not intended for sale: "Free medical sample - not for sale."

5.3.

The members undertake to proceed in ensuring the implementation of the sampling process in accordance with the relevant rules of good distribution and pharmacy practice, in particular they must have an adequate system of control and traceability of the samples which: provide. Members should set up an appropriate registration system so that in case the product needs to be withdrawn, the relevant samples are also withdrawn.

5.4.

Upon request, members must promptly accept returned samples of their products.

5.5.
It is not permitted to provide samples of drugs that contain narcotics or psychotropic drugs substances.
EXPLANATORY NOTES
5.
Members should ensure that they are informed of any changes in Slovak legislation concerning with the provision of samples.

6. ORGANIZATION AND SUPPORT OF PROFESSIONAL EVENTS

6.1.
Professional events * are important for the dissemination of knowledge and experience among members of the medical community. The only goal of organizing such professional events is to increase knowledge directly related to the performance of the medical profession of their participants. If hospitality is also part of professional events, it must always be secondary to the main purpose of the professional event.
6.1.
Professional events must be intended only for members of the medical community.
6.2.
All professional events must focus exclusively on scientific, professional or educational purposes and hospitality must always be only incidental to the main purpose professional event.
6.3.
A member is prohibited from financing or sponsoring directly or through a third party or otherwise directly or indirectly financially or materially support non-professional event or participation of a healthcare professional in a non-professional event.
6.4.
The professional event must have the name of the sponsor in a clearly visible place or a financing member.
6.5.
Participating members must respect all the requirements of the organizer of the professional event.
6.6.
Accompanying advertising activities may be a part of the professional event to a reasonable extent (especially in the form of exhibition stands), the time range of which does not exceed 20% of the total time range of the professional event and which must not be in conflict with the law. To the total time scope of the professional event does not take into account the time required for travel and overnight.

6.7.
Summary of Product Characteristics, which is presented within the permitted limits advertising activities at a professional event must always be available.
6.8.
All promotional materials used at professional events must be in accordance with the requirements set out in this Code.

7. EDUCATION

7.1. Adequacy of the location of the professional event

1. Members who sponsor the participation of health professionals in professional events held within or outside the Slovak Republic must comply with the provisions of this Code and relevant legislation.
2. All professional events organized or sponsored by a member must take place in a reasonable place that corresponds to the main purpose of the event, while hospitality may only be offered if such hospitality is reasonable and in other respects in accordance with the provisions of this Code.
3. An extravagant place * or a place famous for its reasons shall not be considered a suitable place
4. The rule of an appropriate venue must also apply to the sponsorship of the participation of healthcare professionals in professional events that are not directly or indirectly organized by the member.

7.2. Professional event outside the territory of the Slovak Republic

1. No member may organize or sponsor a professional event taking place outside the Slovak Republic, if:
(a) the majority of the invited participants are not from abroad and have, given the origin of the majority of participants, greater logistical sense to organize an event in another country; or
(b) with regard to the location of relevant resources or expertise that is subject or purpose of the event, it makes more sense in terms of logistics to organize event in another country.
2. All international professional events must be notified to the relevant subsidiary company or branch of a member in that State (if established in that State), or must request consultation at national level, except for events organized professional companies.

EXPLANATORY NOTES
7.2.
An adequate location is the Slovak Republic in the case of an event organized by the locals representation of the company in Slovakia (international and domestic). Location is not limited in the case of international events organized by international professional societies, and separate symposia of a member with significant international participation. International events organized by a "parent" company from abroad must comply with the applicable local legislation, and code of ethics.

7.3. Hospitality

1 Hospitality offered in connection with professional, scientific or educational events must be limited to covering travel, food, accommodation and registration fees. Hospitality can only be provided to qualified participants of the event. For the avoidance of doubt, only suitably qualified healthcare professionals may be invited to meetings and conferences and other educational activities, and only to those people the hospitality may be offered. Guests, partners, family members or friends of invited healthcare professionals who are not members of the otherwise invited healthcare professional community (hereinafter referred to as "uninvited guests") may not be invited to meetings, conferences and other educational activities. Similarly, they must not be provided with hospitality, reimbursement of travel expenses or any other value. The pharmaceutical company cannot allow and should actively discourage uninvited guests from accompanying invited guests to educational activities organized or funded by the company.

2. The decision on who will be invited must be based on objectively defined criteria directly related to the beneficiary's educational needs and educational value program.

3. All forms of hospitality offered to members of the medical community must be to a reasonable extent and strictly limited to the main purpose of the event. As a general rule is to provide such hospitality that a participant - member of the medical community - would be willing to pay himself. Hospitality must not include sponsorship of entertainment events (such as sports or recreation).

4. Members should avoid locations primarily known for their entertainment facilities. The itinerary and the program of events must be approved by the CEO of the member concerned.

5. Attendance at an event may not be conditional on an application for prescription of a particular medicinal product.

7.4. Prohibition of benefits for time spent at a professional event

The time spent by members of the medical community at a professional event the member of the medical community may not be provided with no compensation or monetary advantage of a non-monetary nature.

7.5. Priority of the professional purpose of the event

All professional events must be aimed at scientific, professional or educational purposes and hospitality must always be only incidental to the main purpose of the event. Independent hospitality or entertainment, not directly or directly connected with a professional purpose is prohibited.

7.6. Visits to production premises

1. A visit to and inspection of a member's manufacturing, research and development facilities may help members of the medical community to better understand the effectiveness and quality of the member's products and operations. It helps build understanding and confidence in generics and biologically similar drugs and assists healthcare professionals in making decisions for the benefit of patients and the public.

2. Visits to a member's premises shall be of educational value and shall never be provided as a means of unduly influencing a member of the medical community in the field of healthcare. Members of the medical community should always be taken to visit only the most logistically advantageous place that can demonstrate the main production capabilities or technology that is essential for educational purposes.

3. All site visits must have a specific and complete program. In general, such visits should be limited in time to match closely for the purpose of and may not contain any side trips, extensions, stops or recreation or fun. The arrival and departure of the participants should closely coincide with the beginning and the end meetings.

8. RESEARCH

8.1. General provisions

1. The following provisions shall apply to all research relating to remuneration, which are performed and / or sponsored by a member, with the exception of a clinical trial regulated in § 29 - § 44 of Act no. 362/2011 Coll. on medicines and medical devices and on amending certain laws, whether carried out by the manufacturer or by the manufacturer an organization acting according to or on the instructions of the manufacturer.
2. For the purposes of Article 8, research shall mean:
a) a non-interventional clinical study (hereinafter also referred to as a "non-interventional clinical trial"), as defined in § 45 of Act no. 362/2011 Coll. on medicines and medical devices and on amendment of certain laws,
(b) other studies and studies where data collection is not directly linked to the prescription of a particular medicinal product
(eg epidemiological studies, marketing surveys).
3. For the avoidance of doubt, any services provided by the healthcare provider shall be prohibited helth care professionals or members of the healthcare community who are not tied to a specific research or if not permitted by this Code.

8.2. Non-interventional clinical trial (NCT)

8.2.1.

1. The aim of the NCT is to obtain the scientific and professional information defined in the NCC protocol.
The purpose of the NCT must be to obtain an answer to a scientific question that has not been the case so far
answered.
2. The provisions of Act no. 18/2018 Coll. on protection of personal data, as amended, and other binding legislation applicable for the protection of personal data.
3. The NCT may not constitute an incentive to recommend, prescribe, purchase, the supply, sale or administration of a particular medicinal product.

8.2.2.

1. NKS is defined by § 45 of Act no. 362/2011 Coll. on medicines and medical devices and on amending certain laws.
2. NKS can be performed only with the prior written consent of the health insurance company NKS participant on the basis of the NCT protocol submitted by the expert guarantor.

8.2.3.

1. Each NCC must have a formal report containing the following information:
a) name and surname or name of the contracting authority NCT,
b) the address of residence or registered office of the contracting authority NCT,
c) name of NCT,
d) the objective of the NCT,

e) start and end date of the NCT,
f) name and surname of the professional guarantor,
g) the method of processing NCT data,
h) the date, form and time of publication of the results of the NCT, which may not be less than two months from the end of the NCT,
i) financial evaluation of the NCT professional guarantor.
2. Each NCT must contain its own code on each sheet of the protocol as well as the questionnaire in order to be NCT identifiable.
3. The protocol must be approved by the scientific service of the member (sponsor), which is also mandatory to supervise the implementation of the NCT, as well as the health insurance company of each NCT participant.
4. The contracting authority is obliged to send the NCT protocol approved by the health insurance company of the NCT participant to National Center for Health Information, which will publish it within three days of delivery to their website.
5. The contracting authority sends a copy of the processed results of the NCT to the participant's health insurance company and the National Center for Health Information.

EXPLANATORY NOTES
8.2.3.
c) Title: It should describe the essence of the NCT in one sentence.
d) Objective (s): Description of what the contracting authority is pursuing and, if possible, hypothesis (s).
f) Name and surname of the professional guarantor: Name of the expert - doctor from the area in which the NKS is performed.
It should be a guarantee of the professional level of the NCT. He must not be in a permanent employment relationship with the contracting authority NCT.
g) The test design should include at least the following information:
number of centers,
number of patients,
number of doctors (examiners),
form of evaluation (eg questionnaire),
statistical evaluation of NKS.
The number of patients and physicians involved must not exceed what is absolutely necessary for the response of *issues arising from the purpose of the NKS.*
g) Method of NKS data processing: Statistical methods planned in the evaluation of the collected data.
g) Form of reporting adverse reactions: To whom and how adverse reactions will be reported.
h) Expected date and form of publication of results: publication means submission
results of the professional public. The form can be a lecture or a poster or a publication
in a professional journal.

8.2.4.
The protocol must be handed over to each NCT examiner at the beginning of his / her cooperation with the NCT.
In addition, a written contract setting out the conditions of cooperation and rewards must be concluded with each examiner

8.2.5.
Distribution of drug samples must not be part of the NCT. Encouraging the examiner to start treatment or to change it by the sponsor's drug is not allowed.

8.2.6.
Remuneration to the examiner for cooperation on the NCT can only be provided for what was actually performed

work relating to the NCT and may not exceed the usual price due to the nature of the work performed
work.
8.2.7.
The results of the NCT must be published within 12 months from the date of completion of data collection in accordance with the NCT Protocol (Article 8.2.3 (1) (h)).
8.2.8.
Medical representatives are excluded from the implementation of the NKS and may not perform in connection with the NCT either supporting administrative activities in which they would come into contact with the examiner, patients or other persons interested in NKS in the medical facility where NCT is performed (eg delivery of the contract to the examiner for signature, etc.).
8.2.9.
1. Each NCT must notify the GENAS Secretariat before commencing its implementation.
2. In the event of a complaint, the Ethics Committee shall request a complete report from the GENAS Secretariat.
3. The mandatory notification must contain the following:
a) name and objectives of the test,
(b) the identification of the sponsor as well as other organizations participating in the NCT; or NCT-related activities,
c) time schedule - expected date of beginning and end of data collection,
d) number of patients / centers involved,
e) planned date and form of publication of results,
(f) the complete test report and documentation, including all supporting documents required by legal regulations for the implementation of the NCT,
(g) the financial conditions under which the testing is performed, including financial data services for examiners.
8.3. Other studies
8.3.1.
The purpose of other studies performed and / or sponsored by members (hereinafter “other studies”) may be, in addition to obtaining scientific and professional information, the acquisition of other information in accordance with the legitimate business need of the contracting authority.
EXPLANATORY NOTES
8.3.1.
Some examples of other studies:
a) marketing surveys to determine the position of the drug in relation to other drugs in the group,
b) marketing surveys to determine the quality of the contracting authority's work (medical representatives, marketing, etc.),
c) marketing surveys to determine the therapeutic habits of physicians,
(d) epidemiological surveys for the presence of a specific disease.
8.3.2.
No promotion of the member (sponsor) or his medication may be associated with other studies.
An offer to collaborate on other studies may not be linked to prescribing or

by recommending medicines to the sponsor. Collaboration on another study can only be arranged with a person authorized to provide the requested data (hereinafter referred to as the "respondent *").

8.3.3.

Remuneration to the respondent for cooperation in other studies can only be provided for work actually performed on another study and shall not exceed the usual cost due to the nature of the work performed.

8.3.4.

Medical representatives are excluded from the following phases of other studies:

a) formal processing of the agreement (listing of the necessary forms, etc.),

b) agreement on remuneration for cooperation,

(c) payment of any remuneration.

EXPLANATORY NOTES

8.3.4.

Medical representatives may only submit a contract that is already prepared by the sponsor and, if so, the doctor signs, they bring it back to the sponsor.

Medical representatives distribute protocols, questionnaires and agreements and, if not by post, collect them

questionnaires.

8.3.5.

1. Any other study must be notified to the GENAS Secretariat before it is carried out. IN In the event of a complaint, the Ethics Committee will request a complete study documentation. report from the GENAS Secretariat.

2. The mandatory notification must contain the following:

a) name and objectives of another study,

(b) the identification of the sponsor as well as other organizations participating in another study; or activities related to it,

c) time schedule - expected date of beginning and end of data collection,

d) in case of planning the publication of results - planned date and form,

e) in case of non-planning of publication of results - justification.

8.4. Access to NKS notifications and notifications of other studies

Only an authorized employee has access to notifications of NKS and notifications of other studies

Secretariat and members of the Ethics Committee in the event of a complaint being dealt with directly or indirectly concerned by the research.

9. RELATIONS WITH MEMBERS OF HEALTH PUBLIC

9.1. Hospitality

1. Members may choose to support professional activities financially or otherwise medical community. Such aid must succeed before a detailed examination by the lay and medical public and must be in line with professional standards of ethics and taste.

2. Members shall not directly or indirectly promote recreational or entertainment activities members of the medical community.

3. The hospitality provided to members of the medical community must be appropriate and at all times only incidental to the educational content and corresponding to the opportunity, and meeting.
4. Depending on the nature of the event, it may be necessary to include an adequate hotel accommodation, food and beverages. The entertainment or entertainment itself, without links to professional events are prohibited.
5. The meeting should take place in the place that is most logical from the point of view the participants or resources necessary for the event come. Such places are major arteries and cities with appropriate infrastructure.
6. Venues must be adequate and serve the main purpose of the professional event. Extravagant sites are never adequate.
7. The path should follow the most direct and logical route, taking into account the costs of the member.
Stops, side exits, optional excursions and extended extensions financed or allowed by the member are prohibited. Arrivals and departures should, if logistically possible, correspond to the beginning and end of the meeting. Flights should be booked in economy class, higher class may be reimbursed only in exceptional circumstances, if justified.

9.2. Professional educational materials

1. Materials provided for the education of the medical community must be authorized or contain the name of the manufacturer or the contracting authority and its postal address in Slovak Republic.
2. Material provided to a member of the medical community may include advertising material statements and / or statements, but in that case it will no longer be educational material but o Advertising material, which must meet the conditions of this Code and applicable laws regulations.

9.3. Payments for services

1. Any kind of remuneration provided to a member of the medical community shall be permitted only provided that it is provided for the service actually supplied for the acquisition of which it existed the actual need of the member and at the usual price depending on the nature of the performance by a member of the medical community.
2. Contracts between members and members of the medical community or providers health care, or other organizations operating in health care, on the basis of which these entities provide any type of service to members (or any other type of funding not covered by Article 9.5 or any other provision of this Code) are permitted only provided that such services (or other financing):
(a) the member actually needs and has a legitimate reason and interest in these services from a Party
(b) are provided to support health or research or education in areas of healthcare and
c) do not constitute an illicit incentive to recommend, prescribe, purchase, the supply, sale or administration of a particular medicinal product.

9.4. Prohibition on the provision of services for the advertising of medicinal products

1. Where medicinal products are promoted to members of the medical community, such persons shall be prohibited to be delivered, offered and promised gifts, pecuniary and material benefits or advantages, regardless of to the value of such monetary or non-monetary advantage.

2. It is also prohibited to deliver, offer and promise any gifts, monetary or in kind.
benefits or benefits to members of the professional community * for the purpose of incitement
recommendation, prescription, purchase, supply, sale or administration of a medicinal
product.
3. The prohibition referred to in Paragraphs 1 and 2 shall not apply where provided for by law
and this Code.

9.5. Grants to support health or research

1. In order to promote health or research on human health, they may:
members to provide grants (in the form of cash or non-cash payments)
entities consisting of members of the medical community and / or entities
who provide healthcare or conduct medical research, only for
provided that the grant:
(a) is provided for a technically justifiable research purpose or legitimate need
health system,
(b) is documented and recorded in the member 's records; and
c) does not constitute an illicit incentive to recommend, prescribe, purchase,
the supply, sale or administration of a particular medicinal product.
2. Sponsorship of members of the medical community by members for the purpose of their
participation in professional events is set out in Article 7.
3. Members shall be encouraged to provide information on gifts, grants or in-kind donations
made to them in an appropriate manner.

9.6. Donations to non-profit organizations

1. Members may, upon reasoned request, make a gift (in cash or in kind).
for non - profit organizations, civic associations or other legal entities whose principal
the aim is non-profit and non-profit-making activities in the field of healthcare,
patient safety and rights, or research in the field of human health care.
2. Private healthcare providers (natural and legal persons), as well as
members of the medical community must be excluded from giving gifts; this is not the case
Article in question 9.5.

EXPLANATORY NOTES

9.6.

Donations of medicines are only allowed for charitable reasons. Determining the nature of the organization as a non - profit
(non-profit-making) must always be made in relation to the goal that the organization pursues and which it usually is
laid down at the time of its establishment.

9.7. Prohibition of bogus leases

A sham rental of space or equipment from a health care provider is
forbidden; likewise, a lease is prohibited in which the rent exceeds, due to his
specifies the usual amount of rent.

9.8. Use of consultants

1. It is permitted to use consulting, advisory or lecture services provided by
parties of the medical community, either as a group or on an individual basis
(for example, lecturing or chairing events, engaging
in medical / scientific studies, clinical trials, training, participation
at meetings of advisory committees and participation in market research).

2. Arrangements governing such actual consultancy or other services shall, to the extent necessary relating to an individual arrangement meet all of the following requirements:
(a) the cooperation must be based on a prior written agreement specifying the nature of the services provided and the conditions for payment for the provision of the service;
(b) the justified need for such services is clearly identified by the member before requesting such services and concluding an agreement;
(c) the criteria for choosing the services relate directly to the identified need and the person authorized by the member responsible for the choice of the service and have the expertise needed to assess whether the specific members of the healthcare community addressed meet these criteria;
d) the scope of services (as well as the number of provided members of the medical community) is not greater than is reasonably necessary to achieve the identified need;
(e) the member shall keep records of the services provided by the consultants and makes appropriate use of;
(f) contracting members of the medical community for the purpose of providing relevant services is not a means of incentive to recommend, prescribe, purchase, supply, the sale or administration of a particular medicinal product, and
(g) the remuneration for the services provided is reasonable and does not exceed the usual price for the type of provided services.
3. In view of the above, symbolic remuneration arrangements should not apply providing consulting services in the remuneration of members of the medical community.
4. Members are strongly encouraged to include consultants in their written agreements provisions regarding the consultant's obligation to declare that he is a member's consultant, at any time he will write or speak publicly about the facts which are the subject of the agreement or on any other question concerning that member.
5. It is strongly recommended for members who employ part-time staff the medical community who are still practicing their profession, to ensure that such persons they were obliged to declare their employment relationship with the member whenever they will publicly write or talk about the facts that are the subject of their employment relationship or on any other question concerning that member.

10. RELATIONS WITH PATIENT ORGANIZATIONS

10.1. Introductory provisions

1. A set of principles of the generic pharmaceutical industry in Slovakia associated in the association GENAS concerning relations between members and patient organizations was created for the purpose to ensure the relationship between the pharmaceutical sector in an ethical and transparent manner between industry and patient organizations. The independence of patients' organizations will be promoted regarding their political views, attitudes and activities.
2. All partnerships between patient organizations and members shall be based on mutual respect, and the views and decisions of each partner will be attached the same meaning.
3. Members will not require and patient organizations will not commit to advertising individual medicines subject to medical prescription.
4. The objectives and scope of any partnership shall be transparent. Cash or non-monetary support provided to members will always be sufficiently demonstrable.
5. Members welcome the possibility of funding patient organizations from a variety of sources.

10.2 .Written agreements on support for patient organizations

1. Where members provide financial support and / or non-monetary support patient organizations, this support must be the subject of written agreements with the obligor the content specified in para. 2.

2. The written agreement shall contain the following:

(a) the name and objective of the activity;

(b) the names of the partner organizations (pharmaceutical companies, patients' organizations and where appropriate, third parties who, by mutual consent of the member and patient organizations will be involved in the activity);

(c) the type of activity (for example, whether the agreement concerns unlimited aid, a specific event, publications and the like);

(d) the purpose for which the aid was granted and whether the aid is linked to a specific part of the activity or it can be used for any part of the activity;

(e) the agreed roles of the member and the patient organization;

(f) time frame;

(g) amount of funding;

(h) a description of the non - monetary support (eg donations in the form of involvement of public relations agencies, free training courses and the like);

(i) a statement that all parties are aware that the information on the contractual cooperation must be from clearly confirmed and evident from the outset;

(j) information on the codes applied;

(k) the names of the signatories to the agreement;

(l) the date of conclusion of the agreement.

3. Measures concerning the transparency of the details of activities shall be subject to agreement, but nthe minimum scope must meet the requirements set out in this Code.

4. The written agreement may also provide for other rights and obligations beyond the minimum content referred to in para. 2.

5. Each member shall have an appropriate approval process for patient support agreements organizations.

10.3. Use of logos and materials

Members must request written permission from patients' organizations for public use their logos and / or materials owned by patient organizations. In the application for the permit must clearly state the specific purpose and manner in which the logo and / or materials used by patients' organizations used.

10.4. Editorial controls

Members shall not seek to influence the texts of materials which they have promoted in a manner which would promote their commercial interests. However, this policy does not prevent members from making corrections of incorrect data.

10.5. Transparency

10.5.1.

1. Each member shall publish no later than 30 June each year on its website page a list of patient organizations to which in the previous calendar year provided support and is obliged to provide additional information referred to in para. 2.

2. Additional information published for any assistance provided to the patient organization include:
(a) the purpose of the aid, which is sufficiently detailed to enable the average reader to do so understand the importance of such support,
(b) information on the amount of financial support or an indication of the value of the non - financial support provided,
(c) in the case of non-financial support to which a meaningful monetary value cannot be attributed, the description shall clearly state the non-monetary benefit that the patient organization has obtained.
3. A member who does not have a website shall fulfill the obligation set out in para. 1 so that the list patient organizations by GENAS by 30 June is sent,

10.5.2.

Members must ensure that the information on the support they have provided is clear from the beginning.

10.5.3.

1. Each member shall publish on its website no later than 30 June each year
the list of patient organizations that provided them paid services in the previous calendar year (see 10.8).
2. The publication shall include:
(a) an explanation of the nature of the services in such a way as to enable the average reader to understand the justification of the need for a member to enter into such a contract;
(b) disclosure of the total amount that, during the term of the contract, for the calendar year the member paid to the patient organization.

10.6. Exclusive funding from members

No member may claim to be the sole funder of a patient organization
or any of the major programs of patient organizations *.

10.7. Events and hospitality

10.7.1.

All events sponsored or organized by or on behalf of a member must be held in a suitable place * corresponding to their main purpose. They should not take place
in extravagant places *, or in those that are famous for their amusement equipment.

10.7.2.

All forms of hospitality provided by members to patient organizations and their members they should be of an appropriate level * and should always be only incidental to the main purpose of the event, regardless of whether the event is organized by a member or an organization
patients.

10.7.3.

1. Hospitality provided in connection with events should be limited to travel expenses, costs, meals, accommodation costs and registration fees.
2. Hospitality may be extended to persons who are qualified participants. In exceptional cases, in the case of clear medical needs (e.g. disability), are considered

for eligible and travel expenses, meals, accommodation and accompanying registration fees persons. All forms of hospitality that are offered to patient organizations and their representatives will be appropriate to the level and strictly limited to the purpose of the event.
3. Hospitality does not include sponsorship or the organization of entertainment events (eg sporting or leisure events).

10.7.4.

No member may organize or sponsor an event that takes place outside the country, in which it has its registered office, except in cases where:
(a) the majority of the guests are from a country other than their home country and are in connection and it is more sensible to hold an event in another country with regard to ensuring accommodation of invited guests; or
(b) in relation to the location of relevant resources or expertise that are the subject of or the topic of the event, it is more sensible to hold the event in another country due to providing accommodation for the invited.

10.8. Contract services

1. Agreements between members and patient organizations under which patient organizations provide services to members are only possible if such services concern the promotion of healthcare or research.
2. It is permissible to hire patient organizations as experts and consultants for services such as participation in meetings of the advisory body and the like. Agreements that cover advice or other services must meet, to the extent appropriate to the specific agreement, the following criteria:
(a) the cooperation must be based on a prior written agreement specifying the nature of the services provided and the conditions for payment for the provision of the service;
(b) the justified need for such services is clearly identified by the member before requesting such services and concluding an agreement;
(c) the criteria for choosing the services relate directly to the identified need and the person responsible for choice of the service have the expertise needed to evaluate whether specific professionals from the organization to the patient meet these criteria;
(d) the range of services does not exceed what is reasonably necessary to achieve the identified needs;
(e) the member keeps records relating to the services in question and uses those services accordingly;
(f) the involvement of the patient organization must not serve to encourage a recommendation specific drug;
(g) the remuneration for these services is reasonable and does not exceed the usual price for the types of provided services. In this respect, the agreement on symbolic advice is they must not be used as a reward for patient organizations;
(h) unless there are serious grounds for doing so, such as trade secrets or industrial property rights, it is necessary to include in a written agreement with patient organizations provisions concerning the obligation of patient organizations to disclose in an appropriate manner that they have provided paid services to a member and such contractual cooperation by a member in accordance with Section 10.5.3;
(i) each member must make available to the public, in accordance with point 10.5.3, a list of the patient organizations it has hired to provide paid services

11. RULES FOR DIALOGUE AND NEGOTIATIONS WITH PERSONS WITH DECISION – MAKING AUTHORITY

11.1. General provisions

1. Pharmaceutical companies are in an ongoing dialog and discussions with politicians and regulatory authorities to optimize the common interests of the parties, while at the same time establishing the basis for improving access of patients and citizens to the best possible medical prevention and treatment.
2. Ethical rules provide a framework for dialog between pharmaceutical companies and politicians/regulators, so that this dialog is always conducted openly, frankly, honestly and with trust. Ethical rules also aim to ensure that the parties are economically independent of each other and that their relations and dialog always allow to prevent the possibility of either party being pressured against the other party.

11.2. Definitions

Definitions of terms used in this article are given in Annex no. 1 of the Code (Glossary).

11.3. Scope

1. Ethical rules are a minimum set of rules that are binding on GENAS members.
2. Members may also have their own sets of rules that are stricter than the rules of Code.
3. The Ethical Rules apply to the Dialogue and Negotiations of Representatives of Members with Persons with decision-making powers (Politicians and Officials) at international, national, regional or local level.
4. If it is for conducting a Dialogue or Negotiating with Persons with Decision-Making Power engaged External Consultant, it is the duty and responsibility of the member to ensure full compliance with ethical rules by this External Consultant.

11.4. Transparency

1. There must be complete openness about who and what specific interests it represents Representative. Members' representatives are therefore obliged, right at the beginning and without inducement clearly state their name and the name of the member for whom they work for.This also applies in cases where it represents the interests of several members in the same case
External consultant.
2. The member is obliged to prove and ensure full openness in cases where he remunerates Decision-maker, subject to exceptions in the provisions of 11.8.3.
3. All members are required to publish on their website a list with the name of their PR agency or communications agency, legal representative or similar external consultants acting on behalf of the pharmaceutical company for the purpose of Conducting Dialog and Negotiating with Decision-makers. Disclosure must be done through publishing the name of the relevant external agency/consultant/legal representative.
4. In terms of time, publication must take place without undue delay
after concluding a contract with an External Consultant and must be placed on the public domain, while the project is running, for a minimum of three months.
5. The document in question on the member's website must further explicitly state that the member has

informed the External Consultant of the current rules of this Code and that the member accepts responsibility for ensuring compliance with these rules by a third party.

11.5. Information essentials

The information provided to decision - makers must be current and complete and they must not contain erroneous or misleading information.

11.6. Good behavior

Decentive conduct must be observed in Dialogue and Negotiations with Decision-Makers, which includes: a) honor Decision-makers may not be attacked by the Member's Representative, b) no misleading, incorrect, harmful or discriminatory allusions may be made in relation to third parties or mention, c) insignificant information of a personal nature must not be used in an intimidating or coercive manner.

11.7. Confidential information

The member's representative is obliged to always act with discretion and fully respect the information obtained in confidence from the Decision-Maker, unless it would be illegal. Confidentiality must also be respected in cases where confidential information is obtained accidentally or by mistake. Attempts to obtain confidential information by dishonest means are prohibited.

11. 8. Independence

11.8.1.

Any kind of financial dependence between the member and the Representatives of the member on one side a person with decision-making power on the other side is prohibited. Similarly, Representative of the company must not act in such a way as to give rise to a suspicion of bribery.

11.8.2.

Member 's representatives shall not provide financial support in any way; or sponsorship by Officials or Politicians individually or through organizations / associations (for example, political parties, election financing, etc.)
However, members may sponsor specific professional activities organized by public authority.

11.8.3.

1. Members and their Representatives shall not in any way remunerate Officials or Politicians performing official duties in the influence of which a member may have a direct interest.
2. The remuneration of Officials and Politicians shall be exceptionally permitted in the case of:
a) A decision-maker, primarily holding the position of permanent member of the member, whose remuneration is exclusively related to that primary employment. If a Member has employed a Decision-Maker who, within his or her main job / area of responsibility, is required to conduct Dialogues and Negotiations with Decision-Makers on behalf of the Member (for example, public and external staff), the Member is specifically responsible for ensuring:
i. that the legal rules and principles relating to the prohibition of conflicts of interest are always complied with,

ii. that the person leading the Dialogue and Negotiations with other Decision-Makers is always and without exception fully transparent as to the nature of their work so that none arise doubts about conflicts of interest;
(b) A decision-maker who also acts as a healthcare professional and who, in his / her duties, exclusively performs professional services for the member. Remuneration may be granted only in respect of such professional services and must satisfy the condition of the price customary for the provision of such a service;
(c) Decision - makers providing specific, limited services to members in connection with teaching, lectures and the like. Remuneration can only be provided in connection with teaching / lecture services and must meet the price condition usual for the provision of such a service.

11.8.4.

1. Neither Members nor their Representatives may offer Decision-Makers to Persons or provide gifts or other benefits other than such non-monetary benefits that are legitimate justified by the rules of the label; However, care must always be taken to ensure that such performance was proportionate to the circumstances and should not be directed under any circumstances to influence the Decision-Making Person, or to not be influential perceived by other persons.
2. Members and their Representatives may provide technical information materials (reports, books, analyzes, films) which are intended to provide members with appropriate information and which are simultaneously included as a natural and transparent part of the Member's Dialogue with Persons with decision-making power.

11.8.5.

1. The representative may provide reasonable and reasonable hospitality on the spot meetings between the Member's Representative and the Decision-Maker or at participation in thematic days, conferences, etc. arranged and financed by the member; it does not apply if such a meeting were at the same time in the nature of advertising medicines.
2. If objectively justified by the nature and place of the meeting, the Representative may represent the member to reimburse travel and accommodation expenses for the decision-maker, provided that:
a) a meeting at which the above-mentioned costs are to be incurred is not, for justifiable reasons, possible to be held in such a place and in such a way that these costs are not incurred,
b) the above costs are proportionate to the circumstances and to the maximum extent that the Decision-Maker would be willing to pay himself,
(c) the provisions of the Code referred to in Article 2 shall apply mutatis mutandis to the regulation of the rights and obligations of such payment. 7 and 9.

11.9. Legality of the procedure

1. All activities in connection with the Dialogue and Negotiations with Decision-Makers powers must be in accordance with the applicable legislation. If the counterparty proposes activities or quid pro quo that are against the law, these must always be rejected.
2. The member's representative is obliged to always actively intervene against the violation of the law, if learns that this is happening or that it is planned by a third party.

12. RELATIONS WITH THE PUBLIC AND THE MEDIA

12.1. Basic requirements for the provision of information on medicinal products to the general public

1. The sole purpose of providing information on medicinal products to the general public shall be to improve the state of knowledge in relation to the treatment of diseases. Information on new chemicals, new medicines * and treatments communicated to the public and the media must be:

(a) true, verified, complete, clear and comprehensible;

(b) they must not contain any unsubstantiated assumptions or expectations;

(c) they must not give the patient a false impression of the effectiveness of the treatment or an unverified hope of treatment

some improvement in his health;

d) they must not have the intention of deceiving a journalist or patient or intentionally harming a competitor,

(e) if they contain advertising of a medicinal product, they must comply with the legal requirements for the advertising of medicinal products for public.

2. Media representatives shall not be pressured to publish the information provided. They have to be free to decide how they use the information, in their professional opinion, and the interests of the reader. The media should not be financially motivated by advertising or exchange trade to publish certain information on medicinal products.

12.2. No advice on the personal affairs of members of the public

In the case of individual requests from the general public for personal advice

In matters of health, the applicant should always be advised to seek a healthcare provider or healthcare professional.

12.3. Press release

The content of the press release must comply with all the rules set out in this article and related provisions of the Code; at the same time it must consist of verifiable facts without advertising links.

12.4. Press conferences

The information provided to journalists must comply with all the rules set out in this Article and related provisions of the Code. It is recommended that when providing information about treatment methods and information on medicines as information the experts should be used , who are not employees of the member. Hospitality must be appropriate and proportional to opportunities. Press releases must be a standard part of press conferences.

12.5. Radio and television

Communication by a member via radio or television must comply with all the rules set out in this Article and in the related provisions of the Code.

12.6. Hospitality and motivation

1. The hospitality provided to journalists should be appropriate and proportionate to the occasion and it must not motivate or oblige journalists to publish information provided by members in a desirable manner.

2. Journalists may be invited by a member to stay abroad or within Slovakia only for educational or professional reasons, and hospitality must be secondary to

the main purpose of the event.

EXPLANATORY NOTES
It is not possible to use the name of a drug or active substance in a member's communication to the general public for *prescription or paid by public health insurance,*

13. ADVERTISING MEDICINES ON THE INTERNET AND THROUGH SOFTWARE APPLICATIONS

13.1. general rules

1. All Internet communication concerning the presentation of members and their medicines on the Internet must comply with the provisions of this Code.
2. The Internet is considered to be informative in connection with marketing and advertising activities and an advertising medium for the general public * and members of the medical community.
3. The rules concerning the advertising of medicinal products on the Internet referred to in this Article, as well as other the related provisions of this Code also apply to communications of members to an appropriate extent, which contains advertising of medicines through software applications *.

13.2. Transparency of the origin, content and purpose of the member's website

1. Each member's website * shall contain the following information:
(a) the identity, postal and electronic address of the member;
(b) the source of all information used on the website, the date of its publication; and identity together with the recommendations (including the date they were received) of all providers of information used on the website;
(c) the procedure for selecting the content of the website;
d) the target group of the website (eg healthcare professionals, professionals, patients, the general public or a combination thereof) and
(e) the purpose or purpose of the website.

13.3. Website content

1. The information provided on a member's website shall be regularly updated and the date of the last update of the page and / or article must be clearly displayed.
2. Examples of information that may be provided on a website are:
(a) general information about the member;
(b) information on health education;
(c) information intended for the medical community, including any promotion; and
(d) non-promotional information for patients and the general public.

3. General information about the member: the website may contain information that could be of interest to investors, the mass media and the public, including financial data, research and development programs, information for potential employees, etc.

4. Information on health education: websites may contain non-promotional information on health education concerning the characteristics of diseases, methods of prevention, screening and treatment, and possibly other information to support public health. Websites containing information on health education must always be for individuals recommend that they consult an expert for further information.

5. Information to the medical community: any information to the medical community or the professional public which have the nature of advertising of medicinal products must comply with the applicable legislation and any other regulations governing the content and form of advertising, and

promotion of medicines. Such information must be clearly marked as "Information to the medical community", but need not be coded, where appropriate otherwise limited. If the content of the information is the advertising of medicines to professionals, it must be clearly marked as “information for prescribers and persons authorized to dispense medicinal products ", but may not be coded or otherwise restricted.

6. Non-promotional information for patients and the general public: under the conditions set out under current legislation, the website may contain an up-to-date list of medicinal products manufactured or distributed by members. A complete and up-to-date summary must be provided for each medicinal product: the Product Characteristics (SPC) and Patient Information Leaflet (PIL).

13.4. Questions via email

1. The website may contain a contact e-mail address for members the medical community, patients or the general public. This will allow communication by e - mail for further information (eg website feedback).
2. A member may answer questions asked in the same way (by e-mail) as he would answered telephone questions, questions received by mail or otherwise. In communication with patients or the general public, answers to personal questions should be avoided concerning health status.
3. In the event that a member obtains information in the form of communication in the nature of personal data, he is obliged to maintain confidentiality about them. If appropriate to the content of the communication, it is the member obliged to recommend the interviewer seeking professional medical assistance in order to solve the given problem.

13.5. Links from other websites

1. Links to a member's website may be established on the website sponsored by others, but members may not establish links or request their establishment on sites intended for the general public on sites with content intended for members of the professional community.
2. Links to otherwebsites may be established on the member's website in a similar manner, including sites sponsored by members or others.

13.6. Websites listed on the packaging

If permitted by law, Internet addresses (URLs) may be Internet Member-sponsored sites that comply with these rules which are listed on the packaging of drugs.

13.7. Scientific reviews

Members should ensure that all scientific and medical information intended for them the website has been revised to comply with applicable regulations.

13.8. Privacy

The website must comply with applicable laws and regulations governing privacy, security and personal data protection.

EXPLANATORY NOTES

General treatment information may not be on the same web address or linked directly to SPC, PIL or price list of a specific medicine.

14. DISCLOSURE OF TRANSFERS OF VALUES BY MEMBERS TO HEALTHCARE PROFESSIONALS, MEDICAL ORGANIZATIONS AND PATIENT ORGANIZATIONS

14.1.

1. Healthcare professionals, healthcare organizations * and patient organizations shall, in collaboration, provide the pharmaceutical industry with valuable, independent and professional knowledge gained from their clinical and management practice. This experience is an important contribution to the industry's efforts to improve the quality of patient care with benefits not only for individuals but also for society as a whole. Healthcare professionals and healthcare organizations should be fairly rewarded for the expertise and services they provide to the pharmaceutical industry.

2. GENAS believes that transparency in relationships or interactions between pharmaceutical companies and members of the medical profession helps to make informed decisions and prevents unethical and illegal behavior.

3. Subject to the rules and requirements of Article 14 of this Code, members shall disclose the monetary and non-monetary benefits provided (hereinafter referred to as "value transfers") to healthcare professionals, healthcare organizations and patients' organizations (hereinafter referred to as "beneficiaries").

4. Members shall at the same time encourage the recipients of these values to disclose such transfers as well if such disclosure would be in the best interests of patients or the public.

5. This disclosure shall also include transfers of value made by a third party on behalf of the member and for the benefit of the recipient, where the member knows or is informed of the recipient who will benefit from the transfer of value.

6. The transfer of value includes anything of monetary or non-monetary form and value provided by the member (directly or indirectly through a third party acting on his instructions) to the recipient, such as monetary payments or benefits provided in kind, such as meals, travel, hospitality, etc.

7. Members shall not be obliged to publish value transfers for the benefit of beneficiaries in accordance with the procedure set out in Article 14.2, provided that:

(a) they publish such value transfers in accordance with the principle of transparency on the grounds that: i. are committed to such disclosure and implement it by virtue of their membership in other self-regulatory associations; or ii. such disclosure is carried out as a result of the legislation of the Slovak Republic, either for individual recipients individually or in aggregate as part of the total expenditure on marketing and promotion of the drug,

b) disclosure of transfers of values on the basis of point 7 letter. a) implement at least to the extent required by this Code in Art. 14.2.

14.2.

1. Transfers of values must be published as follows:

(a) transfers of values to patients' organizations in accordance with the rules referred to in Article. 10. Code;

(b) transfers of values to healthcare professionals and healthcare organizations, including Remuneration for services and advice shall be disclosed in accordance with this Article, in particular in accordance with

par. 2. This includes aggregate remuneration (excluding the cost of food, drink, travel and accommodation) provided by a member to a member of the professional medical community for provision of services, such as participation in an advisory body, performance at an educational event, participation in a working group, etc. Remuneration for services related to research activities and market research are excluded from this obligation.
2. As part of the publication of the transfer of values for the beneficiaries referred to in para. 1 letter (b) members can choose from the area of support for educational activities and visits to production facilities the following disclosure options:
a) Option 1: Total number (but not monetary value) of events for which the beneficiary received support (this may include the payment of registration fees, travel expenses and / or hotel costs). The aid must be published individually for each beneficiary and included in the following categories and subcategories:
i. Sponsorship for participating in an event organized by a third party where the member pays registration fees, travel and accommodation. At the same time, it is necessary to indicate whether the event is domestic, taking place within or outside Europe.
ii. Visits to production premises
iii. Meetings organized by the member in which the beneficiary is provided with accommodation in hotels and / or air travel.
b) Option 2: Aggregate total amount of support provided to the beneficiary for a specific activity
as follows:
i. Sponsorship for participation in an event organized by a third party:
event name
the total amount of funds spent on the event,
the number of participating beneficiaries to be sponsored.
ii. Visits to production premises:
the total amount of funds spent on the event
the number of participating beneficiaries to be sponsored.
iii. Event organized by the company:
the total amount of funds spent on the event
the number of participating beneficiaries to be sponsored.
iv. Transfer of values to the recipient:
remuneration for services and advice. This includes total remuneration (excluding food costs, beverages, travel and accommodation) provided to the recipient for the provision of services such as participation in advisory body, presentation at an educational event, participation in a working group, etc.
Remuneration for services in connection with research activities and market research is excluded from this obligation.
the total financial amount of grants and donations provided, including a brief description.
14.3.
1. Within the framework of the said disclosure mechanisms, each member shall publish a description of the methodology, applied in the preparation and identification of the transfer of values for each category. The mentioned will include classification criteria and should also regulate the way in which multi-annual contracts are accessed, tax and monetary aspects, and other issues related to time factor and amount of value conversions. It is recommended to include VAT and all other taxes in in accordance with the law.
2. Each member shall comply with the applicable data protection regulations. If necessary to the extent and in accordance with applicable data protection legislation

members should seek the consent of individual beneficiaries to publish the transfer values that affect them. If the beneficiary refuses to give the consent required under applicable data protection regulations, the member shall publish the transfer of values to anonymous basis. If the consent is refused by more than one beneficiary, the transfer of values may be published in aggregate, indicating the number of beneficiaries concerned.
3. Members shall publish transfers of values in such a way as to facilitate the public access to this information, ie through its website, and / or on a central portal (operated by the state, regulatory or professional institution).
4. Publication must take place annually and each publication period will be cover the whole calendar year. The first period to be published will be the calendar year 2017 and the first publication of data will take place from January 2018. Members are encouraged to publish relevant data as soon as possible, but no later than 30 June following the end of the relevant calendar year in which the member carried out the value transfers.
14.4.
Further clarification and clarification of the content of the obligations regarding the publication of transfers may be adopted by the Ethics Committee in the form of guidelines.

15. TECHNICAL PROVISIONS

1. After approval of the Code of Ethics or its amendments by the General Meeting, the GENAS Secretariat shall prepare the full text of the Code and have it signed by the Chairman of the Ethics Committee.
2. The alleged non-compliance of the member's conduct with the Code shall be assessed according to the wording of the Code in force at the time of the member's conduct, this shall not apply if the wording of the Code valid at the time of the member's conduct assessment is more advantageous to him.

16. FINAL PROVISIONS

1. The Code of Ethics was adopted by the GENAS General Meeting on June 27, 2017 and enters into force on 1.9.2017.
2. Amendments to the Code of Ethics were adopted by the General Meeting on 10 December 2018, and their wording in the form of the full wording of the Code of Ethics shall enter into force on 1 January 2019.
3. Amendments to the Code of Ethics were adopted by the General Meeting on 11 November 2019, and their wording in the form of the full wording of the Code of Ethics shall enter into force on 1.1.2020.
4. On June 25, 2020, the GENAS General Assembly adopted a comprehensive amendment to the Ethical Code, which, in the form of the full text of the Code, enters into force on 1.7.2020.

ANNEX 1. CODE OF ETHICS

DICTIONARY

A

"Archived data" is a collection of unpublished clinical or scientific information held by the company. They do not contain the evaluated data submitted to the State Institute for drug control (ŠÚKL) in accordance with Slovak legislation on drug registration or previous legislation.

"Association" means the GENAS Association for Generic and Biosimile Medicines.

U

"Usual price" means the average price at which it is / was possible at a given time and at a given time and territory to obtain a service or performance similar to that which it is interested in obtaining, or for the provision of which pays / collects some kind of retribution.

M

"Magazine" means a periodical publication whose distribution is limited to members medical professions.

“Therapeutic class number” means the labeling system used in the approved reference manual.

"Article ordered by the Company" means an article or series of articles for which the publication shall be paid for by the member or their publication shall be otherwise arranged or arranged.

“Member” means a legal entity that has been a decision of the GENAS General Assembly accepted as a member of GENAS.

D

"Dialogue" means all types of oral and written communication that led by Representatives of the member with Persons with decision-making authority.

E

"External Consultant" means a third party acting on behalf of a Member in a dialogue and negotiations with Decision-Makers. Such an external consultant can be, for example, a PR agency or a communication agency, a lawyer, etc.

"Extravagant place" or "place famous for its entertainment facilities" means facilities whose main operational purpose is entertainment, recreation and sports and the public generally knowns this fact and for that reason they are also sought after by the public. For an extravagant location is also considered a hotel with 5 or more stars, if any does not apply the exclusion set out in the Code. For the purposes of assessing extravagance, it plays a role
for example:
the annual period in which the professional event or other activity supported by the member organizes, if this fact has the effect of increasing the attractiveness of the facility and is therefore capable of significantly influencing the decision of the addressees of the activity to participate,
the real intention and purpose which is pursued by the member and how much the place of the professional event, resp. influence the choice of such a place was influenced by other objective facts (eg unavailability of suitable facilities that do not have extravagant elements, or historical experience of organizing a specific event by a professional company in the same place for several years) than the invitation to such activity communicated to the addressee (information about the device and its equipment? and the like was collected).

Even a place considered extravagant based on certain features can meet the requirement adequacy if e.g. generally considered appropriate for the organization of professional events and if the use of its premises is one of the main purposes of its usual use, and is well equipped for such activities.

G

"Graphic means" means the use of any pictorial or graphic representation in promotional materials including photographs, drawings, X-rays, graphs and bar graphs diagrams, but excluding all related ad text.

"GENAS" means the GENAS Association for Generic and Biosimile Medicines.

M

"The main program of patient organizations" means the work activities of members, artistic activity, sports and physical activities, rehabilitation stays, counseling and defense of patient rights, lectures and educational activities, participation in seminars and congresses concerning the physical and mental health of patients, active participation in legislation the process of patients' rights.

I

"Information" means educational facts about the properties of a medicine.

“Medicinal product information” means information on the properties of a medicinal product that corresponds to the valid summary of product characteristics. The product information may be complete or abbreviated.

"INN" means an international non-exclusive name.

"Member's Website" means a website that is created by a Member, or is created on the basis of his order and whose content is directly or indirectly designated by the member.

U

"Unique" means the first, different from everything else and the only one of its kind on the Slovak market.

K

A "clinically significant change" is any change to the product information that could change decision to prescribe or not to prescribe a medicinal product and may consist of the following:

(a) approved indications for use,
(b) precautions for use,
(c) contraindications,
(d) warnings,
(e) adverse reactions and interactions,
(f) available dosage forms,
(g) dosing regimens and routes of administration;
(h) the potential for dependence,
(i) a reference to a specific group of patients (if necessary).

"Congress" means an event sponsored and / or organized by a company, a faculty, university, or other entity that is not a business.

L

The "general public" or "the public" is usually made up of people who do not have status

a healthcare professional; to distinguish the general public from the medical public is the essential real objective which the member pursues in that communication to that public.
“Substance” means any substance, whatever its origin, which may be (i) human, (ii) animal, (iii) vegetable or (iv) chemical.
“Medical Representative” means a person who is openly employed by a the purpose of this employment is to promote the company's medicines to members of the professional medical community.
"Drug" means any substance or combination of substances intended for treatment or prevention of human diseases. Any substance or combination of substances which may be administered to human beings with a view to determine the therapeutic diagnosis, or to restore, modify or alter the physiological functions of humans is also considered a drug.
"Treatment" means any officially approved method of administration.
"Literature" means a collection of those published trials, discoveries, and reviews that are found in professional and scientific publications.
M
“Medical Content” means that portion of promotional material that expresses medical statement.
"Medical claims" means any statement which expresses the attributes of a medicinal product with respect to
its therapeutic use, that is to say, for or in connection with:
(a) the prevention, diagnosis, treatment or relief of disease, injury or human injury;
(b) influencing, suppressing or modifying a physiological process in human;
(c) testing a human's susceptibility to a disease or illness; or
(d) the eradication or control of micro-organisms which may be of human concern harmful.
"International Congress" means a congress that takes place in the Slovak Republic, at which a company or university of another country actively participates and manages it jointly with a Slovak company or university.
A "minor violation" is a violation of the Code that has no security implications with regard to the health of the patient, but may affect how the medicine will be made by individuals authorized to prescribe medicines prescribed (for example, advertising and promotional claims giving the impression of a broader indication, unsubstantiated allegations, inaccurate disclosure of data on value transfers and the like).
“Minor violation” is a violation of this Code that has no security implications on the patient's sense of health and will have no greater effect on how medical he or she will prescribe drug.
"New chemical" means a medicine containing an active substance that has not been used before in a medicinal product approved in the framework of the registration of a medicinal product in the Slovak Republic for use in humans, including new combinations, salts or esters of substances previously sold on the market.
“New indication (s)” means another indication for a medicinal product that has been approved by the State Institute for Drug Control (SUKL) or the European Medicines Agency (EMA) after the initial registration of this medicinal product.

P

"Commercial package" means a package of a medicinal product sold by a member.
"Professional event" means an event which is intended exclusively for a professional, scientific event or an educational purpose for healthcare professionals. They can be a part of such an event, to an appropriate extent, accompanying activities, the time scale of which does not exceed 20% of the total time range of the professional event and which must not be in conflict with the law on advertising. The time required for travel and overnight stays is not included in the total time range of the professional event.
"Professional public" or "professionals" means a healthcare professional who is authorized to prescribe or dispense medicinal products in accordance with the relevant legal regulations.
"Repeat violation" means when a member advertises any of their products repeatedly commits the same infringement within 12 months.
"Repeat of a previous infringement" means that the same thing has happened repeatedly or a similar infringement in the advertising of a particular medicinal product to a company which has been recognized guilty of violating the Code in the previous 24 months.
"Patient organization" means entities primarily established for purposes other than business (usually in the legal form of a civic association, a non - profit organization providing services of general interest, foundations, etc.) aimed at addressing patient issues
(e.g. concerning the patient 's position in the treatment of his illness and his rights under healthcare delivery system) composed mainly of patients;
including their umbrella organizations in which they are incorporated.
"Decision-maker" means a Politician or an employee of public authority with decision-making power

P

"Politicians" means persons who are members (or candidates for) of the National Council of the Slovak Republic,municipal council (or city council), higher council
territorial unit or to the European Parliament.
“Post-Termination Violations” means more serious violations of this Code in which: completed the advertising activity before the violation was detected.
"Healthcare provider" means a natural or legal person who is authorized under the legislation to provide healthcare.
"Post-marketing observational studies" means research aimed at generating data on authorized medicinal product in accordance with the approved product information.
"Postal Items" means promotional material that is intended for distribution
through the postal system or by private means.
"Working time" means the usual 8-hour working day.
"Rules" means the currently effective rules of the Association.
"Industry" means the members of GENAS.
"Market research" means the collection of data on the extent or dimensions of the market and its components, including the needs of customers in this market.
"Reasonable market value" as well as the usual price means the value at which they must all services, sponsorship or contribution and reward may be provided. Reasonable market the value is the value that would be provided as a result of the agreement in good faith between well-informed counterparties in a normal transaction involving the provision of goods or services. This value must take into account the nature or quality of the goods or the services provided, the qualifications and experience of the provider, the geographical location where

the goods or services to be provided, the nature of the market for the goods or services provided, and prevailing prices applied to similar goods or services.
"Reasonable level of hospitality" means the hospitality at which the participant would normally be willing to pay for the event himself/ herself.

R

"Reference material" is a periodical or monographic publication compiled by the publisher to provide information in order to readily refer to pharmacological or therapeutic data.
“Registration” is the issuance of a decision on the registration of a medicinal product by the State Institute for Drug Control
(ŠÚKL) or the European Medicines Agency (EMA) which is a precondition for drug on the market in the Slovak Republic.
“Advertising”, “Advertising”, or “Advertising Claim” means the presentation of the Drug in each form in order to apply it on the market. It also includes any form of door-to-door information, agitation activities or incentives to promote the prescription, extradition, sales or consumption of medicines, as well as statements regarding efficacy, the rate of side effects or other warning aspects of the medicinal product and comparative information.
"Advertising material" means any statement relating to the attributes of a medicinal product, expressed by any means necessary to encourage the use of the medicinal product.
"Company Representative" means an employee of a Member or an external employee consultant working for a member.
"Respondent" means a person who has the necessary information about him or her interest of the contracting authority and which it wants to obtain from the respondent through the implementation of another study.
"Negotiations" means a situation in which the Member's Representative has a dialogue with the Person with decision-making power in order to reach an agreement on a particular requirement, or proposal of a member or obtaining support for him.

S

A "software application" is any type of software solution that enables electronic communication, including a solution enabling the reception / sending of SMS messages.
"Sponsored Symposium" means scientific meetings sponsored by a member as independent event or as a satellite event to a congress.
"Correct" means a balanced representation of all available data.
"Summary of Product Characteristics" means the written document that meets the conditions legislation, which was approved by the State as part of the registration dossier of Institute for Drug Control (ŠÚKL) or the European Medicines Agency (EMA), valid for the territory of Slovakia, unless otherwise stated in the specific text of the Code

T

"Therapeutic class" means the classification system used to define a grouping of medicinal products in an approved reference manual.

F

"Full advert" means an ad that requires the inclusion of a full or abbreviated ad information on the medicinal product as provided for in the relevant articles of the Code.

"Officials" means all those who are employees of the public authority in possession of regulatory or similar powers. Officials are, for example, employees:
ministries, supervisory authorities, national agencies and directorates and institutes, councils and committees,
in conjunction with the above;
Local authorities and municipal councils;
various private associations and companies of which members or owners are part public sector and have decision-making competencies. This applies, for example, to employees and elected representatives of local governments and municipalities;
EU Commission or other EU administration.

F

"Font size" means the height of the lower case letter "o" with a height of not less than 2 mm.
"Suitable place" for the purpose of organizing events for patients means the standard generally accepted for patients. The adequate location is the Slovak Republic in case that it is an event organized by the local representation of the member in Slovakia (international, etc.)
domestic). Location is not limited in cases of international events organized international companies and separate symposia of members with significant international participation.
"Executive Officer" means the person designated to manage the affairs of the Association in accordance with the rules ofassociations.
"Manufacturer" includes the manufacturer, importer or Slovak distributor of the medicinal product.
"Exhibition at a professional, scientific or educational event" means a demonstration or issuing educational material on the product or medicines.
"Educational Material" means any statement or literature intended
provide information about a disease or therapy that does not contain any specific advertising claims.
"Samples" means a certain amount of medicine provided free of charge by a doctor.

M

"Member's Representatives" are those persons, including medical representatives, whom the Member has authorized to dissemination of information on the medicinal product to members of the healthcare community.
“Serious violation” is a violation of the Code that may have security implications p with regard to the patient's health and / or may affect how the medicine will be made by individuals prescribers and / or may adversely affect reputation
pharmaceutical industry (for example, unsubstantiated claims concerning the safety of a induction of prescription, concealment of data or non - disclosure of value transfer data a Similarly)
"Rationale" means the provision of reasonable grounds in support of an advertising claim. The supporting information should comply with the requirements of the article False or misleading claims and must not be limited to archived data.
"Health Organization" means a legal entity operating in the field of biomedical research, the health system, science, research and education in the field of health through which one or more healthcare professionals provide healthcare
care; for the purposes of the Code, they are also considered to be a healthcare organization health care providers as defined in Act no. 578/2004 Coll. about
health care providers, health care workers, staff

organizations in health care and amending certain laws.
"Healthcare professional" means a natural person who carries out the medical profession and meets for its performance the conditions set out in Act no. 578/2004 Coll. about providers health care, health care workers, professional organizations in health care and amending certain laws
"Medical community" means organized (for example, through professional Slovak Medical Society) as well as unorganized persons with the status of medical professional.