GENAS Code of Ethics – **Association for Generic and Biosimilar drugs**

The Code of Ethics came into effect on September 1, 2017. Its updated version adopted by VZ GENAS on December 10, 2018 comes into effect on 1.1.2019.

The change of name in the Code of Ethics was adopted at VZ GENAS on November 21, 2019, comes into effect on 1.1.2020.

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PREAMBLE

A. The purpose of this Code stems from the GENAS commitment to ensure the general acceptance and adherence to high standards in the marketing of human medications that require prescription.

B. This Code lays down ethical rules for the advertisement of human prescription medications with respect to healthcare professionals as well as advertising activities and communication towards healthcare professionals, as well as relationships between healthcare professionals and pharmaceutical companies. This Code sets ethical rules for the relationships between members and patient organizations and decision-makers.

The purpose of this Code is not to establish rules for providing non-promotional medical, scientific and factual information, nor to control or regulate activities towards general public that are related exclusively to non-prescription medications.

D. This Code does not apply to the following:

- labeling of medications and patient information leaflets;
- mailing inserts that may contain non-promotional materials, needed for clarification of particular question about specific medication;
- factual, informative notices and reference materials related to re-packaging, warnings of adverse effects, provided that they do not contain any statements about medications;
- non-promotional information related to human health or diseases;
- activities exclusively related to non-prescription medicines;
- non-promotional general information about companies (such as information addressed to investors or current or potential employees), including financial data, descriptions of research and development programs, and discussions on the development of legislation affecting the company and its medicinal products.

E. Adoption and adherence to the Code is a prerequisite for membership in GENAS, and the member must comply with both the wording and the spirit of this Code. Members must ensure that all employees and/or representatives acting on their behalf, including all branches and subsidiaries, are fully familiarized and comply with the provisions of this Code. Members must ensure that all relevant legislation regulating the advertising of medicinal products, such as Act No. 147/2001 Coll. on Advertising, or Act No. 308/2000 Coll. on Broadcasting and Retransmission, is adhered to in their marketing activities. In the event of a conflict between the Code of Ethics and the legal regulation governing the rights and obligations regarding the advertising of medicinal products, the wording of the legal regulation shall prevail. If the Code of Ethics imposes stricter obligations on a member than it is imposed by a legal regulation, it is not considered as a conflict.

F. Members are responsible for fulfilling the obligations imposed by this Code, even in situations, where they authorize third parties (such as medical agents, dealers, consultants, market research companies, advertising agencies) to design, implement or engage in the activities regulated by this Code on their behalf. In addition, members should at all times take the necessary steps to ensure that any third party that is authorized to design, implement or engage in activities governed by this Code, but not acting on behalf of a Member (e.g. joint ventures, licensed entities) complies with the provisions of this Code.

G. Pharmaceutical companies producing generic drugs, that are not members of GENAS, are hereby invited to adopt and comply with this Code.

H. Supervision with regard to compliance with the Code is carried out by the Ethics Committee. The Ethics Committee may continually issue interpretations that are intended to interpret certain parts of the Code. Complaints in case of suspected violation of the Code should be reported to the Ethics Committee.

I. The basic guiding principle of the Code is that whenever a promotional claim* is made with respect to a medicinal product, it must include the Slovak product information*.

J. Failure to comply with the Code will result in sanctions being imposed according to provisions of the Complaints Procedure. In any way the compliance with this Code does not reduce the obligations of members to comply with Slovak legislation and codes. The law prohibits the advertising of prescription medicinal products to the general public.

K. GENAS must, with due regard to applicable legislation, help individual members to become aware and educate themselves about the content of this Code, which also includes providing of consultations to members to prevent violations of the provisions of this Code.

L. Advertising and interactions that take place within Europe, must comply with applicable law and the national code of member association in force in the country, where the advertising or interaction took place.

Note: A glossary of defined terms used in this Code is attached to the Code. The first use of a term in the Code defined in the dictionary is always indicated by an asterisk (*).

PROVISIONS OF THE CODE

1. NATURE AND AVAILABILITY OF INFORMATION AND CLAIMS

1.1. Responsibility

It is the responsibility of members, their employees and their medical or technical advisers to ensure that medical content* contained in all advertising materials* is true, correct*, accurate, current, verifiable and fully supported by drug information, literature* or archived data*, and that newer information does not contradict the earlier information without being supported by new scientific knowledge. The activities of company representatives* must always be in compliance with the Code.

NOTES

1.1

This responsibility applies not only to the medicinal product, which is the subject of advertising, but also to any information provided or claims made with respect to other medicinal products.

Any claim must be consistent with the Slovak product information, regardless of the source on which the claim is based.

1.2. Providing data for justification

In addition to the mandatory or generally available information, the manufacturer shall, upon justified request, provide the healthcare professionals further accurate and relevant information on the medicinal products it offers on the market.

The substantiating information may not consist solely of archived data.

The sources, from which the data in the promotional materials are cited to support the claims, including archived data or data from printed media, must be made available to healthcare professionals and companies on request.

NOTES

1.2
(a) All data supporting the claims must be easy to find, so that they can be provided on request within 10 working days.
(b) The data contained in the application for drug registration may be used to substantiate claims. In the case of a request to substantiate the claim, such data must be provided in detail. Statement that the data is "confidential" will not be permitted.
(c) If the information, on which the claim is based, may not be disclosed, for example an article "in print", which is subject to confidentiality provisions, such information cannot be used to support a claim for the purpose of adhering to the requirements of this article.
(d) Data on cost-effectiveness of a medicinal product may be used to substantiate advertising claims, but such data must comply with Articles 1.1, 1.2, 1.3, 1.5 and 1.7 of this Code.

1.3. False or misleading claims

Information, medical claims* and graphical representations must be up-to-date, accurate and balanced and must not mislead, either directly or indirectly or by omission.

The information, claims and graphical tools* must be justifiable*, and such justification shall be provided without unnecessary delay upon request by healthcare professionals.

NOTES

1.3
Examples of situations, when advertising material may violate the Code. This list is not exhaustive and is based on the experience of the Ethics Committee.

(a) References to literature or citations selected from the study or studies and citations of opinions of individuals that are significantly more favorable or unfavorable than indicated by clinical evidence or experience. It is unreasonable to cite the results of a disproportionately favorable study (or disproportionately unfavorable in relation to a comparable drug) in a way that indicates that these results are typical and thus can be misleading.
(b) Information or conclusions of a study, whose design, scope or execution are apparently insufficient to support such information or conclusions.
(c) Citation of previously valid data, which has been deemed as obsolete or incorrect as a result of the evaluation of new data.
(d) Suggestions or representations of uses, doses, indications or any other aspect of the product information that have not been registered*.
(e) Shortening of the approved indication (in a subtitle, for example) by removing the qualification or restriction of the indication.
(f) Use of data obtained from animal experiments or laboratory data to directly support clinical claims.
(g) Presentation of information in such a way, for example font size* and graphical layout, which might give the average reader a false expectation. The font size used for qualified opinions must not be smaller than 2 mm. A qualified opinion must not be included in other reference material, but must be placed on the same page as the initial opinion. The initial opinion and the qualified opinion must be linked together using an asterisk or a similar symbol.

(h) Opinions related to competing medicinal product, negative opinions, in particular, that are not balanced by the corresponding information about the medicinal product being advertised.
(i) Shortening the title of a graphical representation that is reproduced from literature in a way that alters the author's original meaning.
(j) Use of foreign product information to support the claims, if this information does not match the Slovak product information.
(k) Literal or implied claims that any parameter in the product information that is subject to a warning, caution, or adverse reaction, is not a reason for concern.
(l) Insufficient justification of non-medical or non-scientific claims. This relates to information or claims about marketing parameters, such as pricing or market share. Care should be taken when extrapolating the prescription practice from sales data.
When animal data or laboratory data are used, there must be a prominent statement on the same page marking those data as such, and it should be done at a reasonable distance from those data in a manner, which does not obscure the marking by other material.

1.3.1. Unapproved medications and indications

Medicinal products that do not have a valid authorization, must not be advertised. This prohibition also applies to unapproved indications for authorized medicinal products.

1.4. Good taste

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

1.5. Unjustified superlatives

Unjustified superlatives must not be used. Claims must not create an impression that the medicinal product or its active ingredient is unique* or that they have any particular advantage, quality or property unless it can be proved. The word "safe" must never be used without justification. It must not be stated that the medicine has no side effects, that there is no risk of poisoning or the forming of addiction or dependence.

1.6. New medications

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

1.7. Comparative statements

Comparisons of medical products must not be misleading or abusive. It must be factual, honest, based on the relevant and comparable properties of the medicinal products and must be justified and substantiated with the reference to the source. When making comparisons, care must be taken to ensure that the comparison does not mislead by bias, inappropriate emphasis or otherwise. Comparative comparisons that only claim that the drug is better, stronger, more frequently prescribed and so on, must not be used.

If archived data are used to justify comparative statements, these must comply with the requirements of article 1.2 above.

NOTES

1.7
The comparative claim on efficacy or safety should not be based solely on the comparison of the summary of drug characteristics* (SPC), as these documents are based on different databases and are not directly comparable. This applies to both Slovak and foreign information about medicinal products.
Claims of comparative efficacy or safety should be justified with regard to all aspects of efficacy or safety. Where a comparative claim relates to a specific parameter, it must be clear from all claims that it relates only to that parameter.
The accepted level of statistical significance is $p < 0.05$. When comparative data that are not statistically significant are used, such data must be in compliance with the following conditions:

- the data must be clearly labeled as such with a statement and not solely by indicating the p value
- these data may not be used to generalize or imply higher or lower quality.

The statement that the claim is not statistically significant must be linked in some way to the initial claim presented on the same page and in a reasonable proximity to the initial claim in such a way that it is not covered by other material using a font size not smaller than 2 mm.

1.8. Imitations

Advertising information should not imitate the means, copy slogans or general design chosen by other manufacturers in a way that could easily mislead or confuse.

1.9. Medical ethics

Doctors' names or their photos must not be used in a way that is contrary to medical ethics.

1.10. Distinguishing of advertisement material

The advertising material must be clearly distinguishable.

NOTES

1.10.
Ads in journals* should not be designed to resemble editorial articles unless clearly marked as advertising. See also articles 3.2 and 3.3.

2. DRUG INFORMATION

All types of advertising material described in article 3 must include either complete or abbreviated product information, which must include the following required details:

- the date the product information was approved and/or last updated
- the way how the medicine is dispensed

Whenever required, the product information must appear printed with a font size of not less than 2 mm and sufficiently contrasted from the background to be legible. The main headings should be easily identifiable.
The information about the medicinal product must not be overprinted or covered by

advertising phrases or graphic elements and must clearly indicate any latest clinically significant change*.

NOTES

2.
This rule also applies to the shortened product information.

2.1. Complete drug information

Complete or abbreviated drug information must be attached to all advertising materials in the Slovak Republic.

2.2. Abbreviated drug information

The abbreviated drug information can be used in medical publications.

2.2.1.

The abbreviated drug information must accurately reflect the complete drug information and may be a paraphrase or a summary of the full product information.

2.2.2.

Under the heading "Abbreviated drug information", the following must be included:

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

2.3. Clinically significant changes

1.3.2.

If a clinically significant change related to the safety of the medicinal product is included in the product information, it should be included in all drug information statements for a period of 12 months from the date of this change with an asterisk(s) on the footnote with the font size not smaller than 2 mm with the following text: "Please note the change (changes) in the product information."

2.3.2.

The full wording of the amended section should be included in any abbreviated drug information during this period.

2.3.3.

If a member does not actively promote the medicinal product, the relevant healthcare professionals must be notified in writing about the change to the product information.

3. ADVERTISING MATERIAL*

3.1 Admissibility and legality of advertising

3.1.1

Members must adhere to a high ethical standard at all times. The ad must have the following properties:

- never discredit or lower the credibility of the pharmaceutical industry;
- to recognize by its very nature the special character of medicines and the professional reputation of its recipients;
- is not offensive.

3.1.2

Except as expressly provided otherwise in this Code, a medicinal product may not be advertised prior to the marketing authorization that would permit its sale or supply, or which would go beyond its approved indications.

3.1.3

Advertising must be accurate, balanced, honest, objective and sufficiently complete to enable the recipient to form their own opinion on the therapeutic value of the medicinal product, which is the subject of the advertising. It should be based on an up-to-date evaluation of all relevant evidence and clearly reflect it. It must not mislead by misrepresenting, exaggerating, inappropriate emphasis, omission or otherwise.

3.1.4

Advertising must promote the responsible use of medicines by presenting them objectively and without exaggerating their features. Claims must not suggest that the medicinal product or its active substance has a particular advantage, quality or property unless it can be proved.

3.1.5

Advertising must always be consistent with the information provided in the summary of product characteristics.

3.1.6

Any advertising or information about the medicinal product addressed to members of the healthcare professional community (hereinafter referred to as "providing information to the medical professionals") may be performed or provided only by qualified persons designated by the holder of marketing authorization. When providing information to the healthcare

professionals, the above mentioned persons are also obliged to submit or make available a summary of the characteristics of the medicinal product, price information for the medicinal product and the amount of its reimbursement by the health insurance company. When providing information to the healthcare professionals, it is forbidden to donate, offer or promise a monetary or material advantage to healthcare professionals and their relatives.

3.1.7

According to Slovak legislation, any advertising of prescription medicinal products to the general public, except for vaccination campaigns organized by the marketing authorization holder or a representative of the marketing authorization holder, if authorized by the Ministry of Health (Section 8 (5) (a) of Act No. 147/2001 Coll. on Advertising as amended), is prohibited.

3.1.8

At all times any advertising material must comply with all the requirements for the admissibility and legality of the advertising referred to in this article 3.1.

3.1.9

Advertising must not be broadcasted by an automatic telephone calling system, telefax, e-mail, text messages and other electronic data forms of communication, if it is refused by the healthcare professional.

3.2. Advertisement in journals

Advertising in journals must comply with the requirements of one of the following categories. The required information must appear in each publication, printed in a font size of not less than 2 mm, and must be sufficiently distinguished from the background in order to be legible.

NOTES

3.2.
Care should be taken to ensure that where advertising is on both sides or where a multiple-page copy is involved, the information contained on each individual page is not false or misleading when read separately.

3.2.1. Full advertisement*

3.2.1.1.

Full ad must include the following within its ad content:
(a) trademark of the drug,
(b) INN* of an active substances (substance),
(c) the name of the marketing authorization holder and his postal address in the Slovak Republic,
(d) complete or abbreviated product information.

3.2.1.2.

Full ad is required to advertise all new chemical substances* or new indications over the period of 12 months from the date of their first advertisement in medical publications or longer, at the discretion of the advertiser.

3.2.1.3.

The product information should be placed next to the body of the ad. If this is not possible, the ad must include a statement printed in a font size of at least 2 mm with the following wording: "Please read the product information before prescribing. In this publication, you will find the product information on on page ... ".

At this point the page number in the publication is inserted, where the information is located, or a reference to the appropriately cited product information section or advertiser index.

The product information should always be a fixed part of the magazine.

NOTES

3.2.1.1.
(b) The INN should appear next to the most prominent presentation of the business name.
(d) See articles 2.1, 2.2 and 2.3.

3.2.1.3.
The wording used to direct the reader to the location of the drug information may vary, but must include guidance to read the information about the drug before prescribing.
Inserts do not meet the requirements of this article.

3.2.1.4.

The abbreviated product information should be placed next to the body of the ad. If this is not possible, the ad must include a statement printed in a font size of at least 2 mm with the following wording: "Please read the product information before prescribing. In this publication, you will find the product information..."

At this point .... the page number in the publication is inserted, where the information is located, or a reference to the appropriately cited product information section or advertiser index.

The product information should always be a fixed part of the magazine.

3.2.2. Short ad

3.2.2.1.

Short ad is intended to remind the prescribing doctor of the existence of a medicinal product and must not contain promotional claims. The exclusive use of short advertising within any one issue of a publication is not permitted before the period of 12 months after the first publication of the advertisement for a new chemical substance has passed or 12 months after a clinical significant change recorded in the summary of medicinal product characteristics

3.2.2.2.

A short ad must contain:

(a) trademark of the drug,
(b) INN of an active substances (substance),
(c) the name of the marketing authorization holder and his postal address in the Slovak Republic,
(d) statement that further information can be obtained on request from the supplier.

3.2.2.3.

A short ad can contain:

(a) up to 5 words describing therapeutic class*, but without advertising phrases,
(b) graphical elements,
(c) statement of available dosage forms,
(d) statement referring to the location of the product information in the reference manual.

No other material or information is allowed.

NOTES

3.2.2.2.
(b) INN should appear next to the most prominent presentation of the business name.

3.2.3. Articles ordered by the company

3.2.3.1.

Articles ordered by the company must be identifiable by a font size of not less than 2 mm.

3.2.3.2.

The member responsible for publishing an article ordered by the company must be clearly identified, either above or below the article ordered by the company, with a font size of at least 2 mm. Articles ordered by the company may not be presented as or to remind an independent opinion of a third party and/or editorial material.

3.2.3.3.

Articles ordered by the company must comply with all relevant provisions of articles 1 and 3.1 of this Code. The articles ordered by the company must also comply with the requirements of articles 3.2.1 and 3.2.2 of this Code.

NOTES

3.2.3.
Sponsoring companies should ensure that third party statements cited in articles ordered by the company meet these requirements.

Independently edited inserts published by the Almanac of a recognized congress* are not considered as articles ordered by the company. It is recommended that if a company sponsors such insert, this should be clearly stated in the insert.

3.3. Materials for use by medical representatives*

The main guiding principle of this Code is that whenever a promotional claim is made about a medicinal product, it must be accompanied by the product information in terms of article 3.1 of this Code. If it is intended to distribute multiple forms of promotional items at the same time, the product information must appear at least once in all forms.

3.3.1. Printed promotional material

3.3.1.1.

All printed materials of a member must include the following information:

(a) trademark of the drug,
(b) INN of an active substances (substance),
(c) the name of the marketing authorization holder and his postal address in the Slovak Republic,
(c) complete or abbreviated product information,
(e) the date of issue or revision of printed advertising material.

3.3.1.2.

If it is impractical to print the product information on the main part of the advertising material, the advertising material must include the following statement printed in a font size of at least 2 mm: "Please read the product information before prescribing. The product information is attached to this item."
The item must then be accompanied by a document containing full or abbreviated product information.

3.3.1.3.

Any original material, including charts, illustrations, photographs and tables used from published studies that are part of the advertising material, should:

(a) clearly indicate the exact source(s) of the original material;
(b) be faithfully reproduced except where adaptation or modification is necessary for compliance with any applicable code(s), in which case it must be clearly stated that the template has been adapted and/or modified.

Special care needs to be taken to ensure that the original material contained in the advertisement is not misleading with regard to the substance of the medicinal product (for example, whether it is suitable for children) or with regard to making claims or comparisons (for example using incomplete or statistically irrelevant information or unusual units of measures).

NOTES

3.3.1.
This article applies to devices, leaflets, posters and other materials being prepared based on available literature, that are intended for distribution to members of the healthcare professional community and are containing promotional claims.

3.3.1.1.
(b) INN should appear next to the most prominent presentation of the business name.
(d) See articles 2.1, 2.2 and 2.3.

3.3.1.2.
The wording used to direct the reader to the location of the drug information may vary, but must include guidance to read the information about the drug before prescribing.

3.3.2. Audiovisual promotional material

3.3.2.1.

Each audiovisual material must be accompanied by a document containing the following information:

(a) trademark of the drug,
(b) INN* of an active substances (substance),
(c) the name of the marketing authorization holder and his postal address in the Slovak Republic,
(d) complete or abbreviated product information.

3.3.2.2.

If the audiovisual item is presented, after the presentation the product information must be passed on to the person who watched the advertising material or the presentation should be offered to the audience, if this presentation was watched by group of people.

NOTES

3.3.2.
This article applies to audio and video cassettes for private use by healthcare professionals or for demonstration to groups of healthcare professionals.

3.3.2.1.
(b) INN should appear next to the most prominent presentation of the business name.
(d) See articles 2.1, 2.2 and 2.3.

3.3.3. Medical literature and reprints

3.3.3.1.

The main content of any reprint of magazine articles, symposium proceedings* or summary of literature used in advertising must be consistent with the product information.

3.3.3.2.

Citations from medical and scientific literature or personal communications must be faithfully reproduced, accurately reflect the author's opinion and the significance of the study, and accurately identify the sources.

NOTES

3.3.3.3.
Healthcare professionals may request literature regarding the facts that are not captured in the product information, such as non-approved indications. It is not acceptable for such literature to be widely distributed without request. It is acceptable to provide such information upon request by authorized persons.

The reprint does not need to be accompanied by the product information, but the product information must be attached to any accompanying material (letter, for example) or presentation that contain promotional claims.

Citations related to medicinal products that are exempt from public distribution or private events, such as medical conferences or symposia, should not be reproduced without the written consent of the cited person unless they are immediately published. Care should be taken not to attribute unpublished claims or opinions about medicinal products that are subject to medical prescription, to authors, if such claims or opinions no longer represent or may not represent the current opinion of the author.

3.3.4.Computer-based advertising material

3.3.4.1.

Computer-based advertising materials must comply with all applicable provisions of this Code.

3.3.4.2.

When advertising an individual drug, the person watching the advertising material easily accessible via the computer or offered to the audience in a group situation, must get the relevant information about the drug right after the presentation has finished.

3.3.4.3.

If the drug information is inserted into an interactive data system, the instructions for making it accessible must be clearly showed.

NOTES

3.3.4
This article covers at least the following:
Advertising material created by members in order to advertise their medicinal products directly to the healthcare professionals, including advertising tools such as software programs used by medical representatives in professional communication with healthcare professionals.
Use of externally developed computer programs by members to advertise their medicinal products, including programs, such as software for prescribing and dispensing medications.
Use of links on the Internet by members. Members using the Internet should be aware of Slovak law, which prohibits the advertising of medicinal products subject to medical prescription to the general public.

3.4. Mailings*

3.4.1.

Mailings must comply with all relevant provisions of articles 1 and 3.1 of this Code.

3.4.2.

As needed, full or abbreviated product information must be included in all mailings that contain advertising claims.

3.4.3.

Mailings should be sent only to those categories of healthcare professional who may reasonably be expected that they require or are interested in obtaining such information. Requests for removal from the mailing directory must be fulfilled promptly, and no name may be renewed without a separate request or written consent.

3.4.4.

Unprotected shipments, including postcards, envelopes or packaging, may not carry content that could be considered as advertising to the general public or which could be considered inappropriate for public viewing.

NOTES

3.4.1
Envelopes implying urgent attention should only be used for matters related to the withdrawal of medicinal products or important safety information. Envelopes that contain words suggesting that the content is non-promotional should not be used for sending promotional material. Unsolicited reprints of magazine articles must be in accordance with the product information and any cover letter should be in accordance with articles 1 and 3.1 of this Code.

3.5.Media used to transfer documents

Unsolicited electronic transfers or replies may not be used for advertising purposes. Electronic media may be used to transfer permitted advertising in accordance with applicable laws.

4. MEDICAL REPRESENTATIVES

4.1.

Medical representatives must only use advertising material that complies with the provisions of article 3 of this Code. Verbal statements about the medicinal product must comply with the provisions of article 1 of this Code.

4.2.

Members are responsible for maintaining high standards and continuous training of their medical representatives.

4.3.

Medical representatives should have sufficient professional knowledge to present the company's information about their medicinal products accurately, up-to-date and in balance

and must be familiar with all provisions of this Code. Each member must ensure that their medical representatives, including employees contracted from the third party, as well as any other company representatives who are in contact with healthcare professionals regarding the advertising of medicinal products, are aware of the applicable requirements of this Code and all applicable legislation and that they are adequately trained and have enough scientific knowledge to provide accurate and complete information about the medicinal products they promote.

4.4.

Medical representatives must adhere to a high standard of ethical conduct while performing their duties. All medical representatives of GENAS member companies must be trained and certified with regard to knowledge and application of this Code before commencing to work independently as a medical representative. Certification is valid for 3 years, unless otherwise specified by the Ethics Committee. Certificate is issued by GENAS office.

4.5.

Medical representatives may not use any fraudulent tactics or incentives or excuses with the intention to meet a healthcare professional. During the meeting or when negotiating the date of the meeting, medical representatives must take appropriate measures from the beginning in order to ensure not to mislead with regard to their identity or the company they represent.

4.6.

Medical representatives should ensure that the frequency, timing and length of meetings with the healthcare professional as well as the way they are conducted are not disturbing. Medical representatives must adhere to the organization rules applicable in a particular facility. Medical representatives may not visit doctors authorized to prescribe medicines during their office hours if their purpose is to advertise medicines.

4.7.

Telephone advertising must not be used to advertise medicinal products if the healthcare professional refuses it.

4.8.

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

4.9.

Under no circumstances may a medical representative pay to gain an opportunity to meet a healthcare professional.

4.10.

Each company must establish a scientific service, which will be in charge of information about its medicinal products. This scientific service must include a doctor or pharmacist who will be responsible for approving any advertising material before it is published. This person must confirm that he/she has reviewed the final form of the advertising material and that, in

his/her opinion, it complies with the requirements of this Code and any applicable legislation, is consistent with the Summary of product characteristics and is a fair and truthful representation of the facts about the medicinal product.

4.11.

Each company must appoint at least one employee who will be responsible for overseeing that the company and its subsidiaries ensure compliance with the standards of the applicable code (codes).

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.

NOTES

4.
Members must ensure that medical representatives are made aware of the provisions of this Code. Particular attention should be paid to article 3.3 about the materials used by medical representatives, article 5 about the samples and article 6 about the exhibitions at scientific and professional events.

4.5, 4.6
Medical representatives may be used to gather information for surveys in accordance with article 8 of this Code. However, it is necessary to avoid that the survey is used as an excuse to prolong the meeting and advertise the medicinal product.

5. DRUG SAMPLES

Members must ensure that the distribution of samples is carried out in an appropriate manner and in accordance with applicable law. Samples may not be provided for the purpose of encouraging referral, prescription, purchase, delivery, sale or administering of products.

5.1.

Marketing authorization holder may only provide samples of medicinal products upon written request to a person authorized to prescribe medicinal products, and in the range of two samples of the smallest package of the authorized medicinal product per year, which is marked "FREE MEDICAL SAMPLE - NOT FOR SALE" and it must also include a summary of product characteristics.

5.2.

Sample packages must be clearly identifiable and must be labeled in the following way to indicate that they are medical samples, free of charge and are not intended for sale: "Free medical sample - not for sale."

5.3.

Medical representatives must take appropriate precautions to ensure the safety of the samples they carry. Members must have an appropriate mechanism of control and traceability of the samples they provide and for all products handled by their medical representatives. Members should set up an appropriate registration system so that in case the product needs to be recalled, the relevant samples are also recalled.

5.4 .

Donations to hospitals should be at an appropriate level and information about the donation should be publicly available.

5.5.

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

5.6.

No samples of the following medicinal products may be provided: (a) medicinal products containing substances classified as psychotropic or narcotic by an international treaty, such as the 1961 and 1971 United Nations Conventions; and (b) any other medicinal products for which it is inappropriate to provide samples in terms of the applicable decisions of the relevant authorities.

NOTES

5.
Members should ensure that they are informed of any changes to the Slovak legislation related to providing samples.

5.4
Public accessibility means that there is a written contract that is available upon request.

6.EHHIBITIONS AT PROFESSIONAL, SCIENTIFIC AND EDUCATIONAL EVENTS

Exhibitions are important to share the knowledge and experience among healthcare professionals. The only aim of organizing such exhibitions is to increase knowledge in the field of medicine. If hospitality is associated with professional exhibitions, it must always be secondary to the main purpose of the exhibition.

6.1.

The exhibitions must be intended only for healthcare professionals.

6.2.

The exhibition must have the name of the sponsoring company clearly displayed on a visible place.

6.3.

Exhibitors must respect all requirements of the organizer with regard to installation and execution of the exhibition.

6.4.

A summary of the product characteristics for a product that is subject of the study must be available at the exhibition kiosk.

6.5.

All materials used in trade shows must comply with the requirements of articles 1.3.1 and 3.3 of this Code.

NOTES

6.
All materials used in trade shows must comply with the requirements of article 3.3 of this Code. However, with regard to type of participants at international congresses organized in the Slovak Republic, it is acceptable to exhibit or provide educational materials for a medicinal product that is not authorized in the Slovak Republic or an indication that has not been approved for a medicinal product already authorized in the Slovak Republic, provided that each exhibited material or educational material used clearly indicates that it relates to a medicinal product or indication that has not been approved in the Slovak Republic and that the medicinal product or indication is approved in other countries. Any appropriately formulated indication placed in a clearly visible place shall be considered sufficient for that purpose. This label must clearly inform that it is a medicinal product or an indication that is not authorized in the Slovak Republic. Information concerning such medicinal products must be in accordance with the approved summary of product characteristics in the country, in which the medicinal product is authorized. Such product information must be available and distributed according to the principles outlined in this Code.

6.6

See also article 3.1 of this Code.

7. EDUCATIONAL ACTIVITIES

7.1.

Pharmaceutical companies that are members and that sponsor delegates traveling from or within the Slovak Republic to symposia and congresses. are subject to the following: All scientific or professional meetings, congresses, conferences, symposia and other similar events (hereinafter referred to as "the event") organized or sponsored by a member must be held in an appropriate place that corresponds to the main purpose of the event and the hospitality services can be offered only if it is proportionate and also in other respects complies with the provisions of this Code. No member may organize or sponsor an event taking place outside the Slovak Republic unless:

(a) the majority of the invited participants is not from abroad and, given the origin of the majority of the participants in the event, it makes more sense with regard to logistics to organize the event in another country; or
(b) considering the location of the relevant resources or expertise that is the object or intention of the event, it makes more sense in terms of logistics to organize the event in another country.

All international events must be announced to the relevant member's subsidiary or branch in that country (if established), or consultations must be requested at the national level, except for events organized by professional societies.

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.

The decision on who will be invited must be based on objectively defined criteria that are directly related to the educational needs of the beneficiary and the educational value of the program.

All forms of hospitality offered to healthcare professionals must be reasonably and strictly limited to the main purpose of the event. The general rule is to provide such hospitality that the participant (healthcare professional) would be willing to pay for himself/herself. Hospitality must not include organizing or sponsoring entertainment events (such as sports or recreational events). Members should avoid places primarily known as entertainment facilities, which are prohibited. The itinerary and the program of events must be approved by the CEO of a particular member. Attendance at an event must not be conditioned on a request for prescription of a specified quantity of a particular medicinal product.

7.2.

Financial support must not be offered as a substitute for the time spent by medical professionals' at the event.

7.3.

All events must be focused on scientific, professional or educational purposes and hospitality must always be only secondary to the main purpose of the event. Independent hospitality or entertainment not associated with any business or related meeting is prohibited.

NOTES

7.1
A suitable center is an international standard generally accepted by the medical audience. An appropriate location is the Slovak Republic in case the event is organized by the local representation of the company in Slovakia (international and domestic). The location is not limited in cases of international events organized by international medical companies and separate symposia of companies with significant international participation. International events organized by the "parent" company from other country must be governed by applicable local legislation and the Code of Ethics. This procedure is intended to protect the company from being ignorant of a violation of law or code.

7.4 Visits to production facilities

Visiting and inspecting the company's production, research and development facilities helps healthcare professionals better understand the efficiency and quality of the company's products and operations. This helps to build understanding and trust in generics and biosimilar medications and helps healthcare professionals to make decisions for the benefit of patients and the public.

Visits to company facilities must have an educational value and must never be provided as a means of inappropriate influencing of healthcare professionals. Healthcare professionals should only be taken to a logistically most appropriate premises that can demonstrate the main production capabilities or technology that is essential for educational purposes.

All visits to production facilities must have a specific and complete program. In general, such visits should be time-limited in order to match the purpose and must not include any secondary activities, such as trips, extensions, stopovers, recreation or entertainment. The arrival and departure of the participants should coincide closely with the beginning and end of the meeting.

8. RESEARCH

The following provisions apply to all research activities related to financial remuneration that are carried out and/or sponsored by the pharmaceutical industry, with the exception of the clinical trials defined and regulated in Section 29 - Section 44 of Act No. 362/2011 Coll. on Medicines and Medical Devices and on amendments to certain laws, whether carried out by the manufacturer or by an organization acting in accordance with or following the instructions of the manufacturer.

Research is:

(a) non-interventional clinical investigation as defined in Section 45 of Act No. 362/2011 Coll. on Medicines and Medical Devices and on amendments to certain acts,
(b) other studies and research where data collection is not directly linked to the prescription of a particular drug (e.g. epidemiological studies, marketing surveys).

For the avoidance of doubt, any unrestricted contributions to health organizations that are not linked to a specific project or activity are prohibited.

NOTES

Sponsored research means financial and other remuneration for the information provided.

8.1. Non-interventional clinical trials (NCT)

8.1.1.

The aim of NCT is to obtain scientific and professional information defined in the NCT protocol. The purpose of the NCT must be to obtain an answer to a scientific question, which has not yet been answered.

When carrying out NCT, the provisions of Act No. 122/2013 Coll. on the Protection of Personal Data, as amended, must be observed.

NCT must not constitute an encouragement to recommend, prescribe, buy, supply, sell or administer a particular medicinal product.

8.1.2

NCT is defined by Section 45 of Act No. 362/2011 Coll. on Medicines and Medical Devices and on amendments to certain laws.

NCT may be performed only with the prior written consent of the health insurance company of the NCT participant on the basis of the NCT protocol submitted by the scientific supervisor.

8.1.3

Each NCT must have a formal protocol containing the following information:

(a) first and last name of the NCT sponsor,
(b) home or business address of the NCT sponsor,
(c) name of NCT,
(d) goal of NCT,
(e) start date and end date of NCT,
(f) first and last name of scientific supervisor,
(g) methods of data analysis in NCT,
(h) date, form and time period for publishing of results from NCT, which must not be less than two months since the NCT end date,
(i) financial compensation for scientific supervisor of NCT.

Each NCT must contain its own code on each protocol sheet and questionnaire to identify the NCT.

The protocol must be approved by the member's scientific service, which is also required to supervise the implementation of the NCT, as well as by the health insurance company of each NCT participant.

The sponsor is obliged to send the NCT protocol approved by the health insurance company of the NCT participant to the National Health Information Center, which will publish it within three days of its delivery at its website.

The sponsor sends a copy of the processed NCT results to the health insurance company of the NCT participant and to the National Health Information Center, which will publish it within three days of its delivery at its website.

NOTES

8.1.3
c) Name
It should describe the essence of NCT in one sentence.
d) Goal/goals
Description of what the NCT sponsor intends to accomplish and, if possible, formulating hypotheses.
f) First and last name of scientific supervisor
Name of expert (medical doctor) in the field in which NCT is performed. He/she should guarantee the professional level of the NCT. He/she must not be full-time employee with the

sponsor of NCT.
g) Design of the trial
It should contain at least the following information:
number of centers,
number of patients,
number of doctors,
form of evaluation (questionnaire, for example),
statistical analysis of NCT.
The number of participating patients and doctors must not exceed the number that is absolutely necessary to answer the question arising from the NCT's purpose.
g) Method of NCT data processing
Statistical methods to be used for evaluation of collected data.
g) Form of reporting of adverse reactions
To whom and how the adverse reactions are reported to.
h) Expected date and form of publication of the results
Publication means the presentation of results to the professional community. The form may be a presentation or a poster or publication in a professional journal.

8.1.4

The protocol must be submitted to each NCT examiner at the start of his collaboration with the NCT.

In addition, a written agreement must be signed with each examiner, which specifies the terms of cooperation and rewards.

8.1.5

The distribution of drug samples must not be part of the NCT. Encouragement to initiate or change treatment with the medication of the NCT sponsor is prohibited.

8.1.6

The investigator's compensation for cooperation on the NCT must be in accordance with the work performed, must be the usual price and must not exceed an amount equal to 1/10 of the minimum monthly wage* per hour.

8.1.7

NCT results must be published within 12 months after the end date of data collection in domestic professional journals or the results will be presented at national congresses and conferences.

8.1.8

Medical representatives are excluded from the following stages of NCT:

- formal processing of the agreement (filling out the required forms, etc.),
- agreement on the compensation for cooperation,
- the payment of any compensation.

Under no circumstances may medical representatives motivate investigators to recruit patients to an NCT. Any visit of a medical representative to a physician involved in the trial and related to NCT must not be associated with any promotional activities.

NOTES

Before starting NCT, medical representatives must be notified about the reporting of adverse reactions and must also be informed about the contact person at the Slovak branch of the company or at the head office.
Medical representative can only hand over a contract that is already prepared by the sponsor and, if signed by the doctor, will bring it back to the sponsor.
Medical representatives distribute protocols, questionnaires and agreements and, if not done by postal service, they also collect questionnaires.

8.1.9

Each NCT must be reported to the office of GENAS Association before beginning of its implementation. The NCT notification to the GENAS Association should contain complete documentation.

If a complaint is filed, the Ethics Committee will request the GENAS office for complete trial documentation.

The mandatory notification must include the following details:

- name and goals of the trial,
- identification of the organization or sponsor that organizes and/or carries out the NCT,
- time schedule - the estimated start and end dates for data collection,
- number of patients/centers involved,
- expected date and form of publication of the results,
- complete protocol and documentation for testing, including the approval of the relevant Ethics Committee pursuant to Section 2 para. 12 and Section 5 of Act No. 576/2004 Coll. on Health Care, as amended, and the financial conditions under which the examination is carried out, including a draft financial agreement with a doctor.

8.2 Other studies

8.2.1

The aim of other studies conducted and/or sponsored by the pharmaceutical industry (hereafter referred to as “other studies”) may be, in addition to obtaining scientific and professional information, also obtaining information for the sponsor.

NOTES

8.2.1

Some examples of other studies:

- marketing surveys to determine the status of the drug with regard to other drugs in the same group,
- marketing surveys to find out the quality of the work performed by sponsor (medical representatives, marketing, etc.),
- marketing surveys to identify therapeutic practices of physicians,
- epidemiological surveys to detect the occurrence of a particular disease.

8.2.2

An offer to cooperate on other studies must not be associated with the prescription of any medicine.

8.2.3

The investigator's compensation for cooperation on other studies must be in accordance with the work performed, must be the usual price and must not exceed an amount equal to 1/10 of the minimum monthly wage* per hour.

8.2.4

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

- formal processing of the agreement (filling out the required forms, etc.),
- agreement on the compensation for cooperation,
- the payment of any compensation.

NOTES

Medical representatives can only hand over a contract that is already prepared by the sponsor and, if signed by the doctor, will bring it back to the sponsor.
Medical representatives distribute protocols, questionnaires and agreements and, if not done by postal service, they also collect questionnaires.

8.2.5

Any other study must be reported to the GENAS office before commencing. If a complaint is filed, the Ethics Committee will request the GENAS office for complete study documentation. The mandatory notification must include the following details:

- name and goals of other study,
- identification of the organization or sponsor that organizes and/or carries out other study,
- time schedule - the estimated start and end dates for data collection,
- if publication of the results is planned - expected date and form,
- if publication of the results is not planned - justification.

8.3 Reporting

Any trials and studies needs to be reported to GENAS office. Only authorized staff of the GENAS office and members of the Ethics Committee have access to the report if a complaint is pending.

9. RELATIONSHIPS WITH HEALTHCARE PROFESSIONALS

Members may choose to financially or otherwise support professional activities. Such support must successfully pass through detailed scrutiny by the public and professionals, and must comply with professional standards of ethics and good taste. Members may not provide sponsorship to fund or subsidize recreational or entertainment activities to healthcare professionals. .

9.1 Hospitality

Hospitality offered to healthcare professionals must be appropriate and always secondary with regard to the educational content and corresponding to the occasion and meeting.

Depending on the nature of the meeting, an appropriate hotel accommodation, food and drinks may be a necessary part of the hospitality. Hospitality and entertainment without any connection to business meetings is prohibited.

The meeting should take place in location, which is the most logical in terms of the location, where the participants or the resources necessary for particular meeting come from. Such places are the main transport hubs and the cities with appropriate

Locations of meetings must be adequate and serve the main purpose of the meeting. Suitable locations include clinical, laboratory, educational, conference or medical premises, or business premises, such as business hotels or conference centers. Luxury hotels, upscale resorts, places known for their entertainment or recreation value or extravagant places are never adequate.

The travel route should follow the most straightforward and logical route, taking into account the costs of the pharmaceutical company. Stopovers, side trips, excursions and trip extensions funded or made available by the company are prohibited. Arrivals and departures should, if logistically possible, correspond to beginning and end of the meeting. Flights should be booked in economy class, the higher class can only be compensated under special circumstances, if it is justified.

9.2 Medical educational materials

9.2.1

The materials provided for the training of doctors must be authorized or include the name of the manufacturer or sponsor and his postal address in the Slovak Republic.

9.2.2

The material provided by the physician may contain promotional claims and/or statements, but in this case it is not educational material and in any case it must be in accordance with the article Advertising material* of this Code.

9.3 Payments for services

Any remuneration for the services provided should not exceed what is appropriate for the services supplied. Contracts between members and institutions, organizations or associations of healthcare professionals, under which these institutions, organizations or associations provide any type of service to members (or any other type of funding not defined in article 9.5 Gifts and grants supporting healthcare and research or in other provision of this Code) are permitted only if such services (or other funding):

- are provided for the purpose of promoting health care or health research or education
- they do not constitute an encouragement to recommend, prescribe, buy, supply, sell or administer a particular medicinal product.

9.4 Gifts and incentives

When medicinal products are promoted to medical professionals, such persons shall be prohibited from supplying, offering and promising gifts, monetary or material benefits.

It is also prohibited to deliver, offer and promise any gifts, monetary or material benefits to medical professionals in order to encourage recommendations, prescription, purchase, delivery, sale or administration of particular medicinal product. Gifts for the personal benefit of healthcare professionals (such as entertainment tickets) may not be offered or provided.

9.5 Gifts and grants supporting healthcare or research

Gifts, grants and material benefits to institutions, organizations or associations that consist of healthcare professionals and/or provide health care or conduct research (not otherwise defined in this Code) are permitted only if:

(i) are provided to support health care or research;
(ii) are documented and tracked in records of donor or grant provider; and
(iii) do not constitute an encouragement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product.

Gifts (unless they meet the terms defined in clause 9.4) and grants to individual healthcare professionals are prohibited by this article.

The sponsorship of healthcare professionals by companies for the purpose of their participation on international events is defined by article 7. Members are encouraged to disclose information on donations, grants or material benefits in terms of article 9.5 Gifts and grants supporting healthcare or research.

9.6 Gifts

Both cash and non-cash donations must be limited to non-profit (non-profit-making) organizations and state hospitals. Private healthcare providers (physical and legal entities) must be excluded from donations. Healthcare professionals, who are employees of a state hospital, can only accept gifts through their employer. Healthcare professionals, who are employees of a private healthcare provider, may not receive any gifts from pharmaceutical companies*.

NOTES

9.6
Donations of medicines are only permitted for charitable reasons.
The determination of the nature of the organization as non-profit (non-profit-making) must always be made with regard to objective pursued by the organization, which is usually set when the organization is established. The legal form of the organization is secondary (for example, a joint stock company [a.s.] or a limited liability company [s.r.o.] can also be established and registered as a non-profit (non-profit-making) company under the Commercial Code.

9.7 Prohibition of rentals

Fake or fraudulent rental of premises at the healthcare provider's premises, whether free of charge or at a symbolic price, is prohibited.

9.8 Use of consultants

9.8.1.

It is permitted to use the services provided by health professionals as consultants and advisors, whether in group or on an individual basis, such as lecturing or supervision of events, engagement in medical/scientific studies, clinical trials, training, attending advisory committee meetings and participation in market research, if such participation involves remuneration and/or travel. Agreements governing such actual consulting activities or other services must, to the extent relevant to the individual agreement, meet all of the following requirements:

a written contract or agreement shall be concluded prior to the commencement of the provision of the services, which defines the nature of the service provided and, with reference to (g) below, the title for payment for these services; ;
a clear legitimate service requirement has been clearly defined before requesting services and before concluding an agreement with potential consultants;
the criteria for the selection of consultants are directly related to the identified requirement and people responsible for the selection of consultants have the professional experience necessary to assess whether individual healthcare professionals meet these criteria;
the number of contracted healthcare professionals is not higher than the number reasonably required to implement the identified requirement;
the contracting member shall keep records of the services provided by the consultants and uses those services in an appropriate manner;
contracting healthcare professionals to provide relevant services does not constitute an encouragement to recommend, prescribe, purchase, deliver, sell or administer any particular medicinal product; and
the remuneration for the services provided is reasonable and corresponds to the actual market price of the services provided. Considering the above mentioned points, the symbolic remuneration arrangements for the consultancy services should not be used to reward healthcare professionals.

9.8.2

Members are strongly encouraged to include provisions in their written agreements with the consultants regarding the consultant's obligation to declare that he/she provides consultancy to that member whenever he/she publicly writes or speaks about the facts that are subject to the agreement or about any other matter concerning that member. Similarly, it is strongly recommended that members, who offer part-time employment to healthcare professionals,

who still have their practice, should ensure that such persons are obliged to declare their working relationship with a member whenever he/she writes publicly or speaks about the facts that are subject to his/her working relationship or about any other matter concerning that member.

9.8.3

Small market surveys, such as one-off telephone conversations or postal/ e-mail/internet questionnaires, are not subject to the provisions of article 9.7, but only if the healthcare professional does not provide consultancy repeatedly (either with regard to the frequency of telephone calls in general or phone calls regarding the same research) and that the remuneration is minimal.

NOTES

9.8.3
Minimal remuneration means the remuneration not exceeding 1/3 of the monthly minimum wage per doctor, company and year.

9.8.4

If healthcare professional attends an event (international or other event) as a consultant or advisor, the relevant provisions of article 7 shall apply.

10. RELATIONSHIPS WITH PATIENTS ORGANIZATIONS

1. A collection of generic pharmaceutical industry principles in Slovakia associated in GENAS regarding the relationships between pharmaceutical companies and patient organizations (“Code of Practice”) was created to ensure an ethical and transparent relationships between the pharmaceutical industry and patient organizations. The independence of patients' organizations with regard to their political views, attitudes and activities will be promoted.

2. All partnerships between patient organizations and pharmaceutical companies will be based on mutual respect, and each partner's views and decisions will be given equal importance.

3. Pharmaceutical companies will not demand and patients' organizations will not commit themselves to advertising individual prescription medicinal products.

4. The objectives and scope of any partnership will be transparent. Cash and non-cash support provided by pharmaceutical companies will always be sufficiently transparent.

5. Pharmaceutical companies will welcome the possibility of funding patient organizations from various sources.

NOTES

"Patient organizations" means non-profit entities (including umbrella organizations, to which they are incorporated) that consist primarily of patients and/or healthcare providers expressing and/or supporting the needs of patients and/or healthcare providers.
For the avoidance of doubt, the term "pharmaceutical company" as used in this chapter means any legal entity or third party authorized by this entity that provides funding or

engages in activities with patient organizations and has its registered office in the Slovak Republic or in Europe, whether such an entity is a parent company (e.g. a head office, residence of a board of directors or a managing organization of a business entity), subsidiary or any other form of company or organization.
"Activity" means any interaction that is covered by this Code, including the provision of funds.

10.1 Written agreements

When pharmaceutical companies provide financial support, significant indirect support and/or significant non-cash support to patient organizations, such support must be the subject of written agreements. The agreement must specify the amount of financial support and its purpose (e.g. unlimited subsidy, specific event or publication, etc.). It must also contain a description of significant indirect support (for example, donations in the form of PR agency involvement) and significant non-cash support. Each member should have an appropriate approval process for such agreements.

NOTES

Any aid to an individual entity in excess of cumulative amount of €4,000 per calendar year is considered as significant support.

Any written agreements must include the following:
A) Name of the activity;
B) Names of partner organizations (pharmaceutical companies, patient organizations and, where necessary, third parties participating in the activity under mutual agreement between the pharmaceutical company and patient organization);
C) Type of activity (for example, whether the agreement is related to unlimited support, a specific event, a publication, etc.);
D) Objectives;
E) Agreed roles of the pharmaceutical company and patient organization;
F) Time frame;
G) Amount of funding;
H) Description of substantial indirect/non-cash support (e.g. donation in the form of public relations agency involvement, free training courses);
I) A statement that all parties are aware that sponsorship must be clearly confirmed and apparent from the beginning;
J) Applied codes;
K) Names of signatories to the agreement;
L) Date when the agreement was signed.
Measures regarding transparency of the details of activities are subject to agreement, but their minimum scope must meet the requirements of this Code.

10.2 Use of logos and materials

Members must seek written permission from patient organizations to publicly use their logos and/or materials owned by patient organizations. The request for permission must clearly state the specific purpose and way in which the logo and/or materials owned by the patient organizations shall be used.

10.3 Editorial censorship

Members may not attempt to influence the texts in materials sponsored by patient organizations in a manner that would promote their commercial interests. However, this principle does not prevent members from editing incorrect data.

10.4 Transparency

10.4.1

Each company must publish at least once a year before March 31 of the following year on its website or website of the relevant association, the list of patient organizations to which it provides financial assistance and/or indirect/non-cash assistance. This includes a description of the nature of the support, which is sufficiently detailed to allow the average reader to understand the importance of such support. The description must include the monetary value of the financial support and the invoiced costs. For significant non-cash support that cannot be assigned a meaningful monetary value, the description must clearly state the non-monetary benefit that the patient organization will receive. This information may be provided at national or European level and shall be updated at least once a year.

10.4.2

Companies must ensure that their sponsorship is clearly confirmed and evident from the beginning.

10.4.3

Each company must publish a list of patient organizations that it has involved in the provision of significant contractual services. This will include a description of the character of the services, provided that they are sufficiently completed to allow the average reader to understand the origin of the agreement without disclosing any confidential information. Companies must also disclose the total amount they paid to each patient organization during the reporting period.

10.5 Exclusive funding by members

No member may request to be an exclusive sponsor of a patient organization or any of its major programs.

NOTES

The main programs of the patient organizations are: members' business activities, artistic activities, sport and physical activities, recreational trips, consultancy and advocacy of patients' rights, lecturing and educational activities, participation in seminars and congresses about physical and mental health of patients, active participation on the legislative process related to patients' rights.

10.6 Events and hospitality

10.6.1

All events sponsored or organized by a member or on behalf of a member must take place in an appropriate venue that corresponds to their primary purpose. They should not take place in an “extravagant” locations or those that are known as entertainment facilities.

10.6.2

All forms of hospitality provided by members to patient organizations and their members should have an appropriate standard and should always be secondary to the main purpose of the event, regardless of whether the event is organized by a member or a patient organization.

NOTES

10.6.1
A suitable location is a standard venue generally accepted for patients. An appropriate location is the Slovak Republic in case the event is organized by the local representation of the company in Slovakia (international and domestic). The location is not limited in cases of international events organized by international companies and separate symposia of companies with significant international participation.

Renowned and extravagant venues are centers, where their main business purpose is entertainment, relax and sport.

10.6.2
The reasonable level of hospitality is a hospitality, which the participant wouldnormally be willing to pay for him/herself.

10.6.3

The hospitality provided in connection with events should be limited to travel costs, meal, accommodation and registration fees.

Hospitality can only be extended to persons who are qualified participants. In specific cases, for example in case of apparent medical situations (e.g. disability), travel costs, meal, accommodation and registration fees of the accompanying person are also justified. All forms of hospitality offered to patient organizations and their representatives will be 'proportionate' to the given level and strictly limited to the purpose of the event.

Hospitality does not include sponsorship or organization of entertainment events (e.g. sports or leisure events).

10.6.4

No member may organize or sponsor an event taking place outside the country in which it is established, except where:

A) the majority of invited participants are from a country other than their home country and if it is more reasonable to organize an event in another country with regard to providing an accommodation for invited participants;
B) regarding the location of relevant resources or expertise that is the subject or topic of the event, it is more reasonable to organize the event in another country with regard to arranging an accommodation for invited participants.

10.7 Contractual services

Contracts between companies and patient organizations, under which they provide any kind of services to companies, are only allowed if such services are provided to support healthcare or research.

It is permitted to hire patient organizations as experts and advisors for services such as attending meetings of the advisory board and spokesman services. Agreements that cover consultancy or other services must meet the following criteria to the extent that corresponds to a specific agreement:

a) a written agreement must be concluded in advance, specifying the nature of the services provided and, subject to clause (g) below, the basis for payment for such services;
b) the justified need for such services is clearly identified before requesting such services and concluding an agreement;
c) the criteria for the choice of services are directly related to the identified need and the persons responsible for the choice of the service have the expertise necessary to assess whether specific experts and advisers meet these criteria;
d) the range of services is not greater than reasonably necessary to meet the identified need;
e) the contracting company keeps records about the services in question and uses then as appropriate;
f) the involvement of a patient organization must not serve as an encouragement to recommend any particular medicinal product;
g) The remuneration for these services is reasonable and does not exceed the acceptable market value of the services provided. In this respect, agreements related to symbolic counseling may not be used as a reward for patient organizations;
h) Companies are strongly encouraged to include provisions in their written agreement with patient organizations that specify the obligation of patient organizations to declare that companies have provided paid services, either in writing or orally, and that they talk about the matter that is subject to an agreement or any other matter related to such company;
i) Every company must make available to the public a list of patient organizations it hired to provide paid services - see section 10.4.3 and above and the explanatory notes.

11. RULES FOR COMMUNICATION AND NEGOTIATIONS WITH DECISION MAKERS

11.1 General terms

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.

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

A) "Politicians" means persons who are members (or candidates) of the National Council of the Slovak Republic, municipal council (or city council), local government or the European Parliament.

B) "Officials" are all employees of a public authority with regulatory or similar powers. Officials are, for example, employees of:

- ministries, regulatory authorities, national agencies and headquarters and institutions, councils and committees, in connection with above stated;
- regional councils and municipal councils;
- various private associations and companies, whose members or owners are from public sector. This applies, for example, to employees or elected representatives of regional councils or municipalities;
- European Commission or other administrative body of the EU.

C) The term "Decision-maker" means a Politician or an Employee of a public authority with a decision-making power (see letters A and B above).
D) "Pharmaceutical Company" means GENAS member companies or their representatives.
E) "External Consultant" means a third party acting on behalf of the Pharmaceutical company in dialog and negotiations with Decision-makers. External consultant can be, for example, a PR agency or a communications agency, a legal representative, etc.
F) "Company Representative" means an employee of the Pharmaceutical company or an external consultant working for the company, see letters D and E above.
G) The personal scope of this chapter also includes: doctors, dentists, veterinarians, pharmacists, nurses, veterinary nurses, pharmacoeconomists and students in these fields.
H) "Dialog" means all types of oral and written communication conducted by Company representatives with Decision-makers.
I) "Negotiations" means a situation in which a Company representative conducts a dialog with a Decision-maker in order to reach an agreement on a particular request or proposal of a company or to obtain support for it.
(J) "Fair Market Value" means the value at which all services, sponsorship or contribution, remuneration and compensation must be provided. Fair market value is the value that would be provided as a result of a good faith agreement between well-informed contractual parties in a normal transaction involving the provision of goods or services. This value must take into account the nature or quality of goods or services provided, qualifications and experience of the provider, geographical location where the goods or services are to be provided, the nature of the market of goods or services provided and the prevailing rates applied to similar goods or services.

11.3. Scope

11.3.1

Ethical rules represent a minimum set of rules that are binding for GENAS members.

Therefore, pharmaceutical companies may also have their own sets of rules that go beyond these rules.

11.3.2

The ethical rules apply to the Dialog and Negotiations of Company Representatives with decision-makers (Politicians and Officials) at international, national, regional or local level.

11.3.3

If an External Consultant is involved in the Dialog or Negotiations with the Decision-Making Officials, it is the duty and responsibility of the Pharmaceutical Company to ensure that the External Consultant fully complies with ethical standards.

11.4 Transparency

11.4.1

There must be complete openness about who and what interests a particular Company Representative represents. Representatives of companies are therefore obliged, right at the beginning and without asking, to clearly state their name and to indicate the name of the Pharmaceutical Company they work for. This also applies in cases, when the interests of several companies in the same case are represented by an External Consultant.

11.4.2

The pharmaceutical company is obliged to demonstrate and ensure full openness in cases when it pays compensations to the decision maker, compare the exceptions in clauses 11.8.3 A, B and C.

11.4.3

All pharmaceutical companies 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.

With regard to timing, disclosure must be made without unnecessary delay after concluding the agreement with the External Consultant and must be published on the public domain over the period when the project is in progress for at least three months.

This document of Pharmaceutical Company published on its website must explicitly state that the Pharmaceutical Company has informed the External Consultant about the current rules of this Code and that the Pharmaceutical Company accepts responsibility for ensuring the compliance with this Code by third party.

11.5 Information requirements

11.5.1

The information passed to Decision-makers must be up-to-date and complete and must not contain erroneous or misleading information.

11.6 Decent behavior

11.6.1

Dialogs and Negotiations with decision-makers must respect good behavior, which includes:

A) Honor of the Decision-makers must not be challenged by the Company Representative.
B) No misleading, incorrect, damaging or discriminatory suggestions or references may be

made with regard to third parties.
C) Insignificant personal information must not be used in an intimidating or coercive manner.

11.7 Confidential information

11.7.1

The company representative must always act with confidentiality and fully respect information obtained confidentially from the Decision-maker, unless it is illegal. Confidentiality must also be respected in cases where confidential information is acquired accidentally or by mistake. Efforts to obtain confidential information by dishonest means are prohibited.

11. 8 Independence

11.8.1

Any form of financial dependence between the Pharmaceutical Companies and Company Representatives (medical representatives) on the one hand and the Decision-maker on the other hand, is prohibited. Similarly, a Company Representative may not act in a way that would give a reason to suspect a bribery.

11.8.2

Company representatives may not in any way provide financial support or sponsorship to Officials or Politicians individually or through organizations/associations (such as political parties, election funding, etc.)

A) However, pharmaceutical companies may sponsor specific professional activities, campaigns and similar events organized by a public authority.

11.8.3

Neither the Pharmaceutical Companies nor the Company Representatives may not in any way provide rewards to Officials or Politicians performing official duties, influencing which may be in the direct interest of the Pharmaceutical Company. However, the following is exceptionally permitted in the case of:

A) Decision-maker primarily in a position of permanent employee of the Pharmaceutical Company, whose remuneration is exclusively related to that primary job. If the Pharmaceutical Company has employed a Decision-maker who is responsible to lead a Dialog and Negotiations with the Decision-makers on behalf of that particular Pharmaceutical Company (e.g. employees responsible for public and external affairs) as his/her main occupation/area of responsibility, the Pharmaceutical Company is particularly responsible for ensuring:

a) that legal rules and principles regarding conflict of interest are always respected at least to a minimum;
b) that the person leading the Dialog and Negotiations with other Decision-makers is always and without exception fully transparent with regard to the nature of his or her work (compare Article 6 and 7), in order to avoid any doubts with regard to conflict of interest.

B) Decision-maker who also acts as a healthcare professional and who exclusively performs professional services for the Pharmaceutical company. The remuneration may only be granted in respect of such professional services and must otherwise be adequate to the services provided.

C) Decision-maker who provides specific, limited services to the Pharmaceutical company in connection with teaching, lecturing and so on. The remuneration may only be granted in relation to teaching/lecturing services and must be adequate to the services provided.

11.8.4

Neither the Pharmaceutical companies nor the Company representatives may in any other way offer or provide gifts or other non-monetary benefits of financial value to Decision-makers, and which have no professional purpose, such as private gifts, tickets to sporting events, cultural or entertainment events, travel, holidays, extravagant restaurant visits, and so on.

A) Despite the above mentioned limitations, Company representatives may provide professional information materials (reports, books, analyses, films) that Pharmaceutical company created to provide appropriate information and which also server as a natural and transparent part of the Pharmaceutical company's Dialog with Decision-makers.

11.8.5

The Company representative may provide relevant hospitality at direct meetings between the Company representative and the Decision-maker or when attending specialized events, conferences, etc. organized and funded by the Pharmaceutical company. This does not apply if such a meeting would involve advertising medicinal products. As part of the above mentioned meetings, the Company representative may reimburse travel and accommodation costs to the Decision-maker.

(A) The above-mentioned food, travel and accommodation costs must be adequate, subject to rule of willingness to pay for these cost individually by the participant.
B) Permitted level for the above costs must be governed by the same strict framework related to food, accommodation and travel expenses as the one applied to relationships of Pharmaceutical companies with professionals.

11.9 Legislation

All activities related to the Dialog and Negotiations with Decision-makers must comply with the applicable legislation. If a opposite party suggests activities or quid pro quo that are against the law, they must always be rejected.

A) Company representative is always obliged to actively intervene against the violation of the law if he/she is made aware that this is happening or that it is planned by a third party.

12. PUBLIC AND MEDIA RELATIONS

The information provided to the public must be used exclusively to improve public awareness in the area of medicine and healthcare. Such information about new chemical substances, new medicines* and treatments made available to the public and the media must be:

- truthful, verified, complete, clear and comprehensible;
- they must not contain any unsubstantiated assumptions and expectations;

- they must not give the patient a false idea of the effectiveness of the treatment or the unverified hope for some improvement of their health;

- must not have the intention of deceiving a patient or journalist or deliberately harming a competitor.

Media representatives must not be subject to coercion to publish supplied information. They must be free to decide how to use the information according to their professional opinion and the interests of the reader. Media should not be financially motivated by advertisement or barter to publish certain information about prescription medications. This is an advertisement that is prohibited by law.

12.1 No consultancy with regard to personal medical issues

In the case of individual requests from the general public for advice on personal medical matters, the requester should always get the recommendation to consult an expert.

12.2 Press release

Press releases must comply with all of the rules outlined in this article (Public and media relations). The content of press releases must use proven facts without references to advertisement.

12.3 Press conferences

The information provided to journalists must comply with all of the rules outlined in this article (Public and media relations). It is recommended that medical professionals, who are not employees of the company, are used as those who provide medical information, information about treatment methods and drug information. Hospitality must be appropriate and adequate to the occasion. Press releases must be a standard part of press conferences.

12.4 Radio and television

Radio and television broadcasts must adhere to all of the rules outlined in this article (Public and media relations).

12.5 Hospitality and incentives

The hospitality provided to journalists should be appropriate and adequate to the occasion and must not motivate or bind journalists to publish the information supplied by the company in its desired way.

Journalists are invited by the company for stays abroad or stays within Slovakia only for educational purposes or for professional reasons and hospitality should be secondary to the main purpose of the event.

NOTES
It is not possible to use the name of the medicine or the name of the active substance in the communication of pharmaceutical companies to the general public.

13. MARKETING OF PHARMACEUTICAL PRODUCTS ON THE INTERNET - RULES FOR INTERNET WEBSITES FOR HEALTH PROFESSIONALS, PATIENTS AND PUBLIC

General rules:

- All internet communications regarding the presentation of members and their medicinal products on the internet must comply with the provisions of this Code.

- In connection with marketing and advertising activities, the internet is considered as an information and advertising medium for the general public as well as healthcare professionals.

13.1 Transparency of the origin, content and the purpose of the internet sites

Each website site must clearly identify:

a) identity, postal and email address of the sponsor of the website;
b) the source of all information used on the website, the date of its publication and identity, together with the recommendations (including the date on which it was received) of all information providers used on the website;
c) the procedure for selecting the content of the website;
d) target audience of the website (e.g. health professionals, patients, public or combination); and
e) the purpose or goal of the website.

13.2 Content of websites

(a) The information provided on the website must be regularly updated and the date of the last update of the page and/or article must be clearly displayed.
(b) Examples of information, which may appear on a individual or shared website are: (i) general information about the company; (ii) health education information; (iii) information intended for medical professionals, including any promotion; and (iv) non-promotional information for patients and general public.

(i) General information about the company. The website may contain information that might be of interest to investors, the mass media and the public, including financial data, research and development programs, information for prospective employees, etc.
(ii) Health education information. The website may contain non-promotional information about health education regarding disease characteristics, methods of prevention, screening and treatment, or other information to promote public health. Websites containing health education information must always advise individuals to consult further information with a specialist.
(iii) Information intended for medical professionals. Any information intended for healthcare professionals that are part of the promotion, must comply with applicable legislation and any other regulations governing the content and form of advertising and the promotion of medicinal products. Such information must be clearly labeled as 'information for healthcare professionals', without being password-protected or otherwise restricted.
(iv) Non-promotional information for patients and general public*. Under the conditions specified by the applicable legislation, the websites may contain an up-to-date list of medicinal products manufactured or distributed by the member. For each product, a complete and up-to-date Summary of product characteristics (SPC) and package information leaflet (PIL) must be provided.

13.3 Questions via e-mail

The website may contain a contact e-mail address for healthcare professionals, patients or the general public. This will allow communication via e-mail to obtain further information (for example, feedback regarding the website). The member may answer the questions in the same way (by e-mail) as he would answer telephone inquiries, questions received by regular mail or otherwise. Personal medical questions should be avoided when communicating with patients or the general public. If such information are disclosed, they should be treated as confidential. Where necessary, the answers must provide recommendation to seek an advise from an expert on any further questions.

13.4 Links from other websites

Links to a website sponsored by a member may be created on a website sponsored by other persons, but members may not create links on websites intended for the general public that link to a website sponsored by a member that are intended for healthcare professionals. In the same way, links may be created to other websites, including those sponsored by members or other persons. Links should normally link to the homepage of the website or otherwise ensure that the reader is aware of the identity of the website.

13.5 Websites on the packaging

Considering the legislation in force, the web addresses (URL) of a website sponsored by member that comply with these rules, may be displayed on the packaging of medicinal products.

13.6 Scientific reviews

Members should ensure that all scientific and medical information intended for their websites are edited to comply with applicable regulations.

13.7 Privacy

The website must comply with applicable legislation and legislation governing privacy, security and personal information.

NOTES

General information about treatment must not be on the same website or linked directly to the SPC, PIL or price list of a particular medication.

14. TRANSPARENCY

Promoting transparent relationships or interactions between pharmaceutical companies and healthcare professionals helps to make informed decisions and helps prevent unethical and illegal behavior.

According to various rules and requirements in force, pharmaceutical companies must publicly disclose their engagement, reimbursement and other transfers to healthcare professional or to specific stakeholders. Pharmaceutical companies must therefore comply with all applicable rules and disclosure requirements.

Companies must disclose their engagement and value transfers that could potentially constitute a conflict of interest or should encourage recipients of value transfers to disclose them, if such disclosure would be in the best interests of patients or the public.

This disclosure also includes value transfers done by third party on behalf of the member and for the benefit of the recipient, where the member knows or is informed about the recipient, who will benefit from the value transfer.

The transfer of value may include anything that has a value, provided (or "transferred") by the member (directly or indirectly through a third party acting on his request) to the recipient, including cash payments or material benefits, such as catering, travel, hospitality, etc.

Value transfers must be published on an individual and name basis:

- Transfers of value to patient organizations in the form of cash and non-cash support, as well as remuneration for services provided to the patient organization, including a description of the nature of the value transfer (summer education camp, raising awareness, World Disease Day, information brochures, etc) and the amount that was provided. This does not impact the clause 10.4. of this Code of Ethics.

- Transfers of value to healthcare professionals, including remuneration for services and consulting. This includes cumulative remuneration (excluding the cost of food, beverages, travel and accommodation) provided to healthcare professionals for their services, such as participation in an advisory body, speech at educational event, participation in a working group, etc. Remuneration for services related to research activities and market research are excluded from this obligation.

In the context of disclosure of value transfers in the area of supporting of educational activities and visits in production sites, members may choose from the following disclosure options:

Option 1:

The total number (but not monetary value) of events, for which the healthcare professional received support (this may include payment of registration fees, travel and/or hotel expenditures). Support must be disclosed individually for each healthcare professional and classified into the following categories and subcategories:

- Sponsorship for participation at an event organized by third party, where the member pays registration fees, travel and accommodation. It should also be stated whether the event is domestic, taking place in Europe or outside Europe.
- Visits to production facilities
- Meetings organized by a member, where a healthcare professional is provided with hotel accommodation and/or air travel.

Option 2:

The aggregate total amount of support provided to healthcare professionals at a particular conference or meeting, as follows:

- Sponsorship for the participation at an event organized by third party:
  - The name of the event,
  - The total amount of money spent on the event,

    - Number of participating healthcare professionals to whom sponsorship is granted.
- Visits to production sites:
    - Total amount spent on the event
    - Number of participating healthcare professionals to whom sponsorship is granted.
- Event organized by the company:
    - Total amount spent on the event
    - Number of participating healthcare professionals to whom sponsorship is granted.
- Transfer of values to healthcare professionals
    - Rewards for services and consulting. This includes cumulative remuneration (excluding the cost of food, beverages, travel and accommodation) provided to healthcare professionals for their services, such as participation in an advisory body, speech at educational event, participation in a working group, etc. Remuneration for services related to research activities and market research are excluded from this obligation.
    - The aggregate financial amount of grants and donations provided, including a brief description (e.g. research grant, donation of equipment, donation of product, etc.)

Under the above disclosure mechanisms, each member shall disclose a description of the methodology used to prepare and identify value transfers for each category. This will include sorting criteria and should also govern the way how multi-year contracts are accessed, tax and currency aspects, and other issues related to the time factor and the amount of value transfers. It is recommended that VAT and all other taxes required by the law are included in the amounts.

Each member must adhere to the applicable privacy regulations. To the extent necessary and in accordance with applicable personal data protection legislation, members should make an effort to obtain consent from individual healthcare professionals to disclose the value transfers that relates to them. If the healthcare professional refuses to provide the consent required under applicable privacy regulations, the pharmaceutical company will disclose the transfer of the values on an anonymous basis. If more than one healthcare professional refuses to grant consent, the transfer of values may be published as a summary, indicating the number of healthcare professionals concerned.

Members will disclose transfers of value in a way that will allow the public easy access to this information, that means through their website and/or on a central portal (operated by the state, a regulatory or professional institution). Members are not obliged to disclose transfers of value under the article 14 of this Code, if they are subject to disclosure obligation and they disclose the transfers to patients organizations, health professionals and healthcare organizations under (1) the transparency regime of other self-regulatory associations or (2) local legislation governing the transparency and disclosure of value transfers, if these alternative regimes require disclosure of value transfers at least to the extent that is required by this Code in Article 14, including the public availability of such data.

Disclosure must be made annually and each published period shall cover the entire calendar year. The first disclosed period will be the calendar year of 2017 and the first disclosure of the data will be made from January 2018. Members are advised to publish the relevant data as soon as possible, but not later than six months after the end of the relevant disclosure period.

15. FINAL PROVISIONS

The Code of Ethics was adopted by the GENAS general meeting on June 27, 2017 and comes into effect on September 1, 2017.

Changes to the Code of Ethics were adopted at the general meeting on December 10, 2018, and their wording in the form of the complete Code of Ethics comes into effect on January 1, 2019.

Changes to the Code of Ethics were adopted at the general meeting on 11/11/2019, and their wording in the form of the complete Code of Ethics comes into effect on 1/1/2020.

In Bratislava, 21. 11. 2019

Prof., PharmDr. Ján Klimas, PhD., MPH
Chairman of the Ethics Committee

APPENDIX 1. TO THE CODE OF ETHICS

DICTIONARY

A

“Archived Data” is a collection of unpublished clinical or scientific information stored by the company. They do not contain the analyzed data submitted to ŠÚKL in accordance with the Slovak legislation regarding the registration of medicinal products or previous legislation.
“Association” means the Association for Generic and Biosimilar Drugs (GENAS).

Č

"Journal" means a periodical publication which is distributed only to healthcare professionals.
“Therapeutic Class Number” means the labeling system used in the approved reference manual.
“Article commissioned by the company” means an article or series of articles when member pays for their publishing or otherwise arranges their publishing.

“Member” means any person, firm or company that has a full or affiliated membership in GENAS or as defined in the statute of the association.

G

“Graphic elements” means the use of any image or graphic display in advertising material, including photographs, drawings, X-rays, graphs and bar charts, but excluding any related advertising texts.

I

“Information” means educational facts about the properties of the medicinal product.
“Product Information” means a document containing the product information (Summary of medicinal product characteristics or patient information leaflet) compiled according to the ŠÚKL guidelines for the authorization of medicines or later revision. The product information may be complete or abbreviated (see the article Abbreviated drug information of this Code).
“INN” means international non-proprietary name.

J

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

K

"Clinically significant change" means any change in the medicinal product information that could change the decision to prescribe or not to prescribe the medicine and may include the following:
(a) approved indications for use,
(b) precautions for use,
(c) contraindications,
(d) warnings (cautions),
(e) adverse effects and interactions,
(f) available forms of dosage,
(g) dosage regimens and routes of administration,
(h) dependence potential,
(i) reference to particular group of patients (if necessary).
“Congress” means an event sponsored and/or organized by a company, faculty, university or other non-commercial entity.

L

"General public" are any persons other than the healthcare professionals.
"Substance" means any substance regardless of its origin, which may be (i) human, (ii) animal, (iii) vegetable or (iv) chemical.
"Medical Representative" means a person who is openly employed by the company and the purpose of this employment is to promote the company's medicinal products to healthcare professionals.
"Medicinal product" means any substance or combination of substances intended for the treatment or prevention of human diseases. Any substance or combination of substances that may be administered to humans for the purpose of making a therapeutic diagnosis or to restore, correct or alter the physiological functions of humans is also considered as medicinal product.
"Treatment" means any officially approved method of administration.
"Literature" means a collection of published trials, discoveries and reviews that appeared in professional and scientific publications.

M

"Medical content" means that portion of the advertising material that expresses a medical

claim.
"Medical claims" means any statement that expresses the attributes of a medicinal product with regard to its therapeutic use, which means its use for the purpose or in connection with:
(a) preventing, diagnosing, treatment or alleviating a disease, defect or injury of a human;
(b) influencing, inhibiting or modifying a physiological process in human;
(c) testing the susceptibility of a human to a disease or an ailment or
(d) destroying or inhibiting microorganisms that may be harmful to humans.
"International Congress" means a congress that takes place in Slovak Republic, where a company or university of another country actively participates and manages it together with a Slovak company or university.
"Monthly Minimum Wage" means the minimum monthly wage currently regulated by the Act No. 663/2007 Coll. on Minimum wage, as amended, or other generally binding legal regulation, which may replace this Act in the future.
"Moderate infringement" is a violation of the Code that has no safety implications with regard to patient's health, but may affect how the person authorized to prescribe the medication prescribes it (such as advertising or promotional claims that give the impression of a broader indication, unsubstantiated claims, inaccurate disclosure of value transfer data, etc.).

N
"Minor infringement" is a violation of this Code that has no safety implications for the patient's well-being and will have no major effect on how the medical professionals will prescribe the medication.
"New chemical substance" means a medication containing an active substance that has not been previously used in a medicinal product approved in the Slovak Republic for use in humans, including new combinations, salts or esters of substances previously sold on the market.
"New indication (indications)" means another indication for the medicinal product that has been approved by ŠUKL/EMA after the initial authorization of this medicinal product.

O
"Sales packaging" means the packaging of the medicinal product sold to members.
"Repeated violation" means a situation when a member repeatedly makes the same violation within 12 months when advertising one of their products.
"Repeat of previous violation" means that the same or a similar violation has occurred repeatedly in the advertising of a particular medicinal product of a company that was found guilty of having violated the Code over the period of last 24 months.

P
"Infringement after termination of activities" means more serious violations of this Code, where advertising activities were completed before the violation was detected.
"Post-marketing observational studies" means research aimed at generating data about the authorized medicinal product when used in accordance with the approved product information.
"Mailings" means advertising material intended for distribution through the postal system or privately.
"Working time" means the usual 8-hour working day.
"Rules" means the currently effective rules of the association.
"Industry"means GENAS members.
"Market research" means data collection about the size or dimensions of the market and its components, including customer needs on this market.

R
"Reference Manual" is a periodical or monographic publication compiled by the publisher to provide information in a categorized order for prompt reference to pharmacological or

therapeutic data
“Registration” is the issuing of a marketing authorization by the relevant authority (ŠÚKL, EMA) for launching a medicinal product on the market in the Slovak Republic.
"Advertisement", "Advertising" or "Advertising claim" means the presentation of the Medicinal product in any form for the purpose of marketing it. It also includes any form of door-to-door campaigns, promotional activities or encouragement to promote the prescription, supply, sale or consumption of medicinal products, as well as statements related to the efficacy, level of adverse reactions or other warning aspects of the medicinal product and comparative information.
"Advertising material" means any statement related to attributes of a medicinal product, expressed by any means, to encourage the use of the medicinal product.
"Company representative" means an employee of the Pharmaceutical company or an external consultant working for the company.

S
"Sponsored symposia or creative workshops" means scientific meetings sponsored by a member as an independent event or as a satellite event of a congress.
"Correct" means a balanced representation of all available data.

T
"Therapeutic class" means the classification system used to define and group medicinal products in an approved reference manual.

U
"Full advertisement" means advertisement that requires the inclusion of full or abbreviated product information as set forth in section Full Product Information of this Code.

V
"Font size" means the height of the lower case letter "o".
"Executive official" means the person designated to manage the affairs of the Association in accordance with the Association's rules.
"Producer" includes the manufacturer, importer or Slovak distributor of a pharmaceutical product.
"Exhibition at a professional, scientific or educational event" means the presentation or display of an educational material about the product or medications.
"Educational material" means any statement or literature intended to provide information about a disease or therapy that does not contain any specific promotional claims.
"Samples" means a certain amount of medication, provided free of charge by a physician.

Z
"Company representatives" are individuals, including medical representatives, who have been authorized by a member to distribute information about the medicinal product to healthcare professionals.
"Serious violation" means a violation of the Code that may have safety implications with regard to patient's health and/or affect how the drug will be prescribed by the person authorized to prescribe it and/or may have a negative impact on the reputation of the pharmaceutical industry (for example unsubstantiated claims regarding drug safety, induction of prescription, concealment of data or non-disclosure of data regarding value transfer, etc.)
"Justification" means providing reasonable arguments to support a promotional claim. Justification information should be in accordance with the requirements of the article False or misleading claims and must not be limited to archived data.
"Health care professions and healthcare professionals" include members of the medical,

dental, pharmaceutical or nursing professions and any other individuals who can prescribe, supply, dispense or administer a medicinal product as a part of their professional activities.