GENAS - Association for Generic and Biosimilar Medicines

Code of Conduct

Chapter 1 - Introduction

1. GENAS - Association for Generic and Biosimilar Medicines (hereinafter referred to as "GENAS Association" or "GENAS") brings together manufacturers, marketing authorisation holders and suppliers of generic and biosimilar medicinal products operating in Slovakia (the Association was established in 2000). GENAS represents the pharmaceutical industry operating in the Slovak Republic and supports its social position and development. The members of GENAS (hereafter also referred to as the "Company or "Companies") are committed to common ethical standards that govern the industry's relationships with healthcare providers and that promote transparency in the pharmaceutical sector. The aim of the GENAS Association is, in addition to ensuring affordable and sustainable treatment, especially for chronically ill patients, to actively and in the long term contribute to the development of ethical standards of pharmaceutical companies operating in Slovakia.

2. GENAS is committed to ensuring the general acceptance and adherence to high legal and ethical standards in the advertising of medicinal products for human use. This Code of Conduct for GENAS Members (the "Code") sets out a framework of principles and standards that promote trust, responsible behaviour and respect between pharmaceutical companies and healthcare professionals, including healthcare organisations, patients and patient organisations. The Code of Conduct is adopted and implemented in cooperation with other associations of pharmaceutical companies in Europe, primarily in accordance with the Code of Conduct of Medicines for Europe.

3. Medicines for Europe is a non-profit, non-governmental organisation representing pharmaceutical associations and companies across Europe. Its members are committed to common ethical standards that regulate relations with the healthcare community in this area and promote transparency in the pharmaceutical sector. GENAS is a national member association of Medicines for Europe.

4. Acceptance of and adherence to the Code is a condition of membership of GENAS, and a member must submit to both the word and spirit of the Code. GENAS has made it mandatory for its members that all employees and/or agents acting or acting on their behalf undergo certification confirming that they have the necessary level of understanding and knowledge of the rules set out in the Code, as well as related topics (e.g. anti-corruption principles, etc.). The certification will be provided by GENAS in terms of content and technical support through an online learning tool. Members must ensure that all employees and/or agents acting on their behalf, including all their branches and subsidiaries, are fully aware of and comply with the provisions of this Code and that all employees and/or agents acting on their behalf are certified.

5. Members must also ensure that their marketing activities comply with all relevant legislation governing the advertising of medicinal products. In the event of a conflict between the Code and a statutory provision governing rights and obligations in the field of advertising of medicinal products, the wording of the statutory provision shall prevail. It shall not be deemed to be such a conflict if the Code imposes more stringent obligations on a member than those imposed by statutory provision.

6. Members are responsible for fulfilling the obligations imposed by this Code, including where they engage third parties (e.g. medical representatives, vendors, consultants, market research companies, advertising agencies) to design, implement or engage in activities governed by this Code on their behalf. In addition, Members shall at all times take the necessary steps to ensure that any third party they have commissioned to design, implement or engage in activities governed by this Code but who is not acting on behalf of the Member (e.g. joint ventures, licensed persons) complies with the provisions of this Code.

7. Generic pharmaceutical companies that are not members of GENAS are hereby invited to also adopt and comply with this Code and/or the Medicines for Europe Code.

8. GENAS is committed, with regard to the legislation in force, to helping its individual members to be aware of the obligations arising from this Code and to educate themselves about their content; GENAS is committed to achieving this objective by providing advice to its members in order to prevent breaches of the provisions of this Code.

9. Compliance with the Code is supervised by the Ethics Committee. The Ethics Committee may from time to time issue interpretations intended to interpret certain parts of the Code. The Ethics Committee shall ensure that all employees and/or agents acting on behalf of members have successfully completed certification. Complaints of suspected breaches of the Code shall be made to the Ethics Committee.

10. Failure to comply with the Code will result in sanctions to be imposed in accordance with the Code of Administrative Procedure adopted by the Ethics Committee. Compliance with this Code shall in no way diminish the obligations of members to comply with generally applicable law.

11. The basic guiding principle of the Code is that whenever an advertising claim is made with respect to a medicinal product, it must include information about the product in the Slovak language.

12. Advertising and other activities that take place within Europe must comply with the applicable laws of the country in which the advertising or other activity takes place, as well as with the national code of the Medicine for Europe member association of that country.

Chapter 2 - Definitions

Medical community

Healthcare professionals, health organisations, patients and patient organisations.

This includes any other person or organisation involved in the regulation, approval, control or supply of medicines, or who communicates about medicines at a professional level with healthcare professionals, healthcare organisations or patient organisations (e.g. journalists covering healthcare issues, but does not include representatives of member companies).

Health Care Professional (HCP)

A member of the medical, dental, pharmaceutical or nursing healthcare profession or any other person who, in the course of his or her professional activities, may prescribe, dispense, purchase, supply, recommend or administer medicines.

It also includes any agent or employee of a government agency or other organization (whether in the public or private sector) who may purchase, supply, recommend, or administer drugs. This includes all employees of pharmaceutical companies whose main job is to carry out professional medical activities. Excludes other employees of pharmaceutical companies and wholesalers or distributors of medicines.

Health Care Organisation (HCO)

A medical or scientific association or organisation active in the field of healthcare (regardless of legal or organisational form), such as a hospital, an ambulance service, a non-profit-making organisation (such as a foundation), a university or other educational institution or a professional society. Also, any entity through which one or more health care professionals provide health care.

Wholesalers, distributors and similar commercial intermediaries are not considered to be health organisations.

Pharmacies are always healthcare organizations, even if they are retailers, regardless of their ownership and ownership structure.

Patient organisation

A non-profit, patient-focused organisation in which the majority of the governing body is made up of patients or persons providing care to patients (carers).

Third party

A natural or legal person distinct from a GENAS member, usually with the status of a member of the healthcare community, who, for example, is the organiser of a professional event or provides services within the healthcare sector.

Fair Market Value (FMV)

The amount to be paid for goods or services that can be expected as a result of negotiations between independent and informed parties.

The FMV calculation takes into account:

- the nature and quality of the goods or services provided and the nature of the market;
- the quality and experience of the provider;
- the geographical location where the goods and services will be provided;
- prevailing commercial rates for similar goods and services in the provider's country.

If the individual or his/her employer/organization is to be reimbursed for the time during which he/she rendered services, the FMV must take into account the regular rate in the country where the individual is primarily based, even if the service was rendered elsewhere.

Transfer of values

Any value, including monetary payments or non-monetary benefits, provided by the company to the recipient directly or through third parties (hereinafter referred to as "intermediary" or, in the plural, "intermediaries").

Chapter 3 - Scope of the GENAS Code of Conduct (the "Code")

Scope of Obligations to Comply with the Code

The standards and requirements of the Code are binding on all GENAS members.

Members must not use their corporate structure to deliberately avoid their obligations under this Code or the Medicines for Europe Code of Conduct.

Where national general mandatory legal requirements differ from the rules and requirements set out in this Code, the more stringent requirements shall always apply.

Product Scope

This Code **governs and applies to:**

a) ethical rules for the advertising of prescription-only medicinal products for human use (hereinafter referred to as "medicinal product"), including innovative, generic and biosimilar medicinal products;
b) ethical guidelines for advertising to and communicating with healthcare professionals, as well as for interactions between members and healthcare professionals;
c) ethical rules for interactions between members and patient organisations;
d) ethical rules for interactions between members and decision-makers.

This Code **does not apply** to the following:

a) advertising of over-the-counter (OTC) medicines;
b) interactions with healthcare professionals and healthcare organisations, which only apply to over-the-counter medicines;
c) labelling of medicines and package leaflets;
d) correspondence, possibly supplemented by enclosed material of a non-advertising nature, necessary to answer a specific question about a particular medicine;
e) providing non-advertising medical, scientific and factual information to both the professional and lay public;
f) factual, informative notices and reference material relating to, for example, repackaging, adverse reaction warnings, provided, however, that they do not contain any statements about the medicinal product;
g) non-promotional information relating to human health or disease;
h) activities relating exclusively to non-prescription medicines;
i) non-promotional general information about the companies (such as information directed to investors or current/potential employees), including financial data, descriptions of research and development programs, and discussions of regulatory developments affecting the company and its drugs.

Work Interactions

The Code deals with any professional interaction with any person who may prescribe, dispense, purchase, supply, recommend or administer a prescription medicinal product in the course of their business.

To the extent that they prescribe, dispense, purchase, supply, recommend or administer prescription-only medicinal products, professionals such as veterinarians, opticians, podiatrists, midwives, laboratory managers, biomedical experts, physiotherapists, nutritionists and the like are also covered by the scope of this Code.

Other employees of pharmaceutical companies and wholesalers and distributors of medicines do not fall under the category of healthcare professionals.

Chapter 4 - Policies

Medicines for Europe has adopted the European Commission's "List of Guiding Principles Promoting Good Governance in the Pharmaceutical Sector". GENAS also recognises that adherence to these principles can have a significant positive impact on healthcare policy and practice and ultimately on patient health. The basic principles are:

Integrity

Stakeholders should consistently apply their standards, values and practices and communicate them accordingly.

Respect

Stakeholders should foster an attitude and environment of mutual respect for other stakeholders, different cultures, socio-economic backgrounds, different views, different working practices and decision-making processes of the relevant authorities.

Ability to respond

Stakeholders should clearly identify how they will work with other stakeholders and who is responsible for this within their organisation. They should also be prepared to answer questions responsibly and accurately in context and to identify a reasonable timeframe in which to expect a response.

Responsibility

Stakeholders should seek to identify those most likely to be affected by their decisions and, where possible, make their intentions known to them and, where appropriate, initiate an exchange of views with them. They should also defend their objectives and accept responsibility for the foreseeable and/or real consequences that arise from them, whether they relate to activities, products or processes.

Collaboration

Where possible, stakeholders should seek to work with other stakeholders to achieve the objectives, for example through public-private partnerships. Public-private partnerships should be based on clear, transparent and sound governance principles. Within these partnerships, participants should share information on their objectives where appropriate.

Transparency

In order to build public trust, the pharmaceutical industry is committed to working with all stakeholders to develop a clear approach to full transparency of financial transactions (including in-

kind benefits) and declarations of potential interests. Companies must provide relevant, full, transparent and complete information to the competent authorities.

CHAPTER 5 - STANDARDS

These standards apply to all activities conducted by companies that fall within the scope of this Code, including interactions with healthcare professionals, company-organized meetings, including virtual meetings, use of online platforms, and other types of interactions with the healthcare community that are not specifically described in Chapter 6. Companies are also responsible for activities carried out on their behalf by agencies or consultants and must ensure that they comply with the same standards and requirements.

5.1 Prohibition of Advertising to the General Public

5.1.1 In accordance with EU and national legislation, prescription-only medicines must not be promoted to the general public.

5.2 Independence of Healthcare Professionals

5.2.1 Pharmaceutical companies must respect the independence of healthcare professionals and must not interfere with the relationships and trust that exist between patients and healthcare professionals.

5.3 Promotional and Non-promotional Materials and Information

5.3.1 Companies can promote pharmaceutical products by providing relevant information to healthcare professionals to help them make decisions. The materials and information must comply with Slovak legislation, the instructions of the State Institute for Drug Control and the instructions of other competent regulators.

5.3.2 In accordance with EU and Slovak legislation, promotional communications outside the recommended use of the medicinal product are prohibited. Companies can only promote their products with specific information that is included in the relevant Summary of Product Characteristics (SPC).

5.3.3 Claims and comparisons made in the context of promotion must always be scientifically up-to-date, supported by references, clinically relevant and in accordance with the registered indication and prescribing information in the Slovak Republic.

At international congresses, including virtual international congresses, companies must clearly indicate the country in which the summary of product characteristics used as the basis for the promotional material is used and remind participants to familiarise themselves with the prescribing information applicable in their country.

5.3.4 All promotional material and information (printed, digital or verbal) must be clear, legible, accurate, up-to-date, balanced, objective and sufficiently complete to enable the recipient to form their own opinion. They must not be misleading and must promote the judicious use of medicines by presenting them objectively and without exaggeration.

5.3.5 Companies should bear in mind that digital platforms are also a communication channel and that the requirements applicable to physical meetings or other forms of communication media apply equally to digital and virtual interactions. Companies must ensure that their representatives use only company-approved materials, whether the interaction is in a traditional format or online.

5.3.6 Companies must not promote prescription-only medicines to patients or any other person who is not legally entitled to receive such information.

The company's website and other digital channels must clearly indicate which content is intended only for healthcare professionals and, to the extent required by Slovak law, access to such content must be restricted to the relevant target group.

Companies may advertise their corporate brand, their company or their industry in general to the public to the extent permitted by Slovak law.

5.4 Social Media

5.4.1 Social media posts must meet the standards set out in clause 5.3. Where required by law, pharmaceutical companies must ensure that materials and information are available only to the relevant recipients and that each contribution itself complies with the principles of the Code and the law, even if read in isolation without related communications.

5.4.2 Companies must have appropriate social media activity policies in place for their employees to ensure that individual employees' activities on company social media (including forwarding, sharing, commenting or "liking") do not make content visible to inappropriate audiences.

5.5 Approval and Withdrawal of Materials for External Use

5.5.1 Companies must ensure that all materials and information intended for use outside the company are reviewed and approved by competent persons prior to use and dissemination. The processes for approval and identification of competent persons should be in accordance with Slovak standards and relevant rules and requirements.

5.5.2 Companies must regularly review and, where necessary, update their materials to ensure that they remain relevant and consistent with current scientific knowledge.

5.5.3 Companies must have processes in place that comply with Slovak standards and relevant rules and requirements and that ensure that outdated materials are withdrawn and prevent their reuse.

5.6 Location and Venue

5.6.1 Events should be held at the location that makes the most logistical sense given the location from which the participants come or the resources required for the event. The venue could therefore be major transport hubs and cities with adequate infrastructure.

5.6.2 The event may be held outside Europe in certain circumstances, e.g. if the majority of the non-pharmaceutical company participants are resident or based outside Europe.

5.6.3 The venue must be suitable and help to fulfil the main purpose of the event. Suitable locations may be spaces in clinical, laboratory, educational, conference or healthcare facilities, such as business hotels or conference centres. Luxury hotels, resorts, places known for their entertainment and recreational value or extravagant places are not suitable in any case, regardless of amenities or price.

5.7 Hospitality

5.7.1 Pharmaceutical companies may provide transportation, hotel accommodation, food and beverages (collectively, the hospitality) in connection with the event, provided that the hospitality is necessary, incidental, reasonable and secondary to the main purpose of the event.

5.7.2 Hospitality must be reasonable and justified, never ostentatious or luxurious:
- Accommodation shall be in accordance with clause 5.6.3;
- Flights are to be booked in economy class. Business class flights can only be reimbursed by airlines in exceptional cases and where justified.

5.7.3 Travel should, wherever possible, be by the most direct and logical route, taking into account the cost to the company. If logistically possible, arrivals and departures should coincide with the start and end of the event. Companies may not finance or authorise stopovers (except where logistically necessary), recreation, excursions or extended stays.

5.7.4 Companies should apply limits on hotel and meal expenses in accordance with the standards and requirements of the relevant country in which the hotel or meal is provided.

5.7.5 Hospitality may only be offered to persons who meet the eligibility criteria (hereinafter referred to as “Invited Guest”). Companies must not offer, fund or facilitate “companionship” to any member of the medical community, or provide anything of value to such uninvited guests, except in very exceptional circumstances where the service provider requires the disabled person to have a companion with them when travelling. Companies should actively discourage participants from travelling with uninvited guests on trips funded by pharmaceutical companies.

5.7.6 Companies shall not provide or fund any separate hospitality that is not related to or necessary for the Professional Event. Providing or financing entertainment is not permitted under any circumstances.

5.7.7 Companies may not provide or fund any food or beverages for individual participants in virtual events.

If pharmaceutical companies sponsor or organise an event where some attendees and/or representatives of pharmaceutical companies participate virtually, the companies may provide or fund appropriate snacks or beverages only for those healthcare professionals who are physically present in mass at the event site.

5.8 Fair Market Value

5.8.1. Remuneration to the health care community for the provision of services shall be at fair market value, taking into account the skills, experience, job title, importance, status, and place of employment of the individual performing the service.

5.8.2 Where a pharmaceutical company sponsors an activity, the amount paid must be at fair market value, taking into account the nature and scale of the activity and any commercial benefit accruing to the pharmaceutical company.

5.8.3 Where a pharmaceutical company makes a contribution to support the activities of a health or patient organisation, the amount must represent fair market value, taking into account the market prices of the goods and services being funded.

5.8.4 The principle of fair market value also applies generally to other transfers of value to members of the healthcare community.

5.9 Cross-border Activities

5.9.1 When using services or transferring value to a member of the healthcare community from another country, companies must ensure that all relevant requirements of the country in which the individual is primarily based (or where the organisation receiving the value is based), as well as the requirements of the Slovak Republic, are complied with.

5.9.2 Where hospitality is provided to a member of the medical community from his/her own country and the person is travelling to another country, the rules of the host country (in which the event is being held) shall apply in respect of hotels and meals, unless the laws or Code of the individual's country provide otherwise.

5.10 Planning and Documentation of Activities

5.10.1 In order to respect the time and professional priorities of professionals and to ensure compliance with this Code, pharmaceutical companies should have procedures and processes in place to facilitate the review of activities well in advance.

5.10.2 Companies must adequately document their interactions with the healthcare community and enter into contracts or written agreements where appropriate. They must keep adequate records and evidence of activities and commitments, such as copies of contracts, meeting reports, proof of services rendered, invoices, travel receipts and requests for donations and other support.

5.10.3 Companies should consider whether additional internal agreements or safeguards would be appropriate for activities where pharmaceutical company representatives, speakers from the medical or healthcare community, or event attendees are not physically present, such as virtual events. This could include control measures to ensure that only appropriate attendees are at the event, or addressing data protection risks in digital interactions.

5.11 Transparency and Disclosure

5.11.1 Transparency in the relationships and interactions between pharmaceutical companies and the healthcare community helps to prevent unethical and illegal behaviour. Companies must therefore comply with all disclosure requirements in the countries in which they operate. Disclosures must always comply with data protection and competition laws.

5.11.2 Companies should disclose details of commitments and transfers of value to healthcare professionals and healthcare organisations that could potentially present a conflict of interest, and should encourage recipients of transferred value to also disclose where this is in the best interests of patients or the public. Examples of good practice (and in some cases required by law) are that organisations disclose details of pharmaceutical industry support on their websites and that healthcare professionals declare conflicts of interest as part of their presentation.

Disclosure procedures for transfers of value by companies within the scope of this Code are set out in Chapter 7 of this Code.

5.11.3 Activities that fall outside the scope of this Code, e.g. trade discounts for pharmacies or hospitals, must always comply with the relevant rules and requirements, but due to their nature this Code does not require disclosure of any information about them.

CHAPTER 6 - REQUIREMENTS FOR SPECIFIC TYPES OF COMPANY ACTIVITIES

All activities of member companies subject to the Code, including those not specifically described in this chapter, shall be carried out in accordance with the relevant standards set out in Chapter 5.

Meetings between companies and healthcare professionals (including employees of healthcare organisations) can be mutually beneficial. Meetings may be held for educational, scientific research or promotional purposes, but meetings and other activities of the company must never be used to unduly influence any member of the medical community.

6.1 Sponsorship of Third Party Activities

6.1.1 Companies may sponsor meetings, events or projects (hereinafter referred to as the "Event") aimed at healthcare professionals if they are related to the therapeutic area in which the company is engaged or to the company's business interests. Sponsorship may be direct, through the provision of funds to an organizing member of the medical community (hereafter referred to as the "Organizer"), or indirect, through an agency of such organizer. Examples of event sponsorship might be paying for an exhibition table or stand or funding catering at an event.

6.1.2 In return for sponsorship, the company generally receives commercial benefits such as advertising opportunities, exhibition stand or space, distribution of promotional materials, display of the company's logo on banners or materials or similar forms of promotion. The company must consider the appropriateness of sponsorship benefits and ensure that they are proportionate to the scale of the sponsorship and the size and nature of the event.

6.1.3 Before committing to sponsor any event, the company should ensure that it has sufficient information about the nature of the event, the content of the programme and any associated hospitality. Companies are required to ensure that their sponsorship is used only for the purposes specified and does not subsidise activities that do not meet the standards and requirements of the Code.

6.1.4 Companies are prohibited from independently providing hospitality and entertainment to members of the medical community; therefore, company sponsorship may not directly or indirectly fund or subsidize recreational or entertainment activities for participants. The event organiser must fund any cultural or social aspects of the event programme from its own resources and not from sponsorship donations from pharmaceutical companies.

6.1.5 A professional event shall prominently display the name of the sponsoring member.

6.1.6. Accompanying promotional activities (e.g. in the form of exhibition stands) may be part of the professional event to a reasonable extent, provided that they do not exceed 20 % of the total duration of the professional event and that they do not contravene the law. Travel and accommodation time is not included in the total duration of the professional event.

6.1.7. The summary of product characteristics (hereinafter referred to as the "SPC") presented as part of the authorised promotional activities at a professional event must be available at all times.

6.1.8 Transfers of values to organisers under clause 6.1 must be disclosed in accordance with Chapter 7 of this Code.

6.2 Supporting the Education of Healthcare Professionals

6.2.1 Companies may support the scientific, medical, pharmaceutical and professional education of individual healthcare professionals by funding their attendance at meetings and conferences that educate them in areas related to their specialty. Educational support may be provided through attendance at appropriate events organised by the company as well as congresses and conferences organised by third parties. Meetings, congresses and conferences can be face-to-face, virtual or combined.

6.2.2 All meetings, whether face-to-face or virtual, in which the company encourages participation by healthcare professionals must:

6.2.2.1 have primarily scientific, educational and professional content;

6.2.2.2 be related to the professional specialty in which the healthcare professional is primarily working at the time; and

6.2.2.3 be directly related to the field of medicine in which the company operates.

6.2.3 Companies may cover the cost of event registration, travel, accommodation and reasonable refreshments, all of which must meet the standards set out in Chapter 5 of this Code, including provisions relating to venue conditions, hospitality and rules on cross-border activities.

6.2.4 The decision on who receives training support must be based on objective criteria related to the educational needs of the recipient and the educational value of the event programme. Selection criteria may include, for example:

6.2.4.1 existing knowledge and experience of the healthcare professional and relevant training needs;

6.2.4.2 reputation and standing of the healthcare professional in the scientific and professional community, and the likelihood that he/she will willingly and effectively share his/her acquired knowledge with other healthcare professionals;

6.2.4.3 resources of the institution employing the healthcare professional;

6.2.4.4 location and accessibility of the event in relation to the healthcare professional's usual place of work;

6.2.4.5 in the case of meetings abroad, whether an alternative event in the healthcare professional's home country could offer similar learning opportunities; and

6.2.4.5 potential impact on the quality of patient care.

The healthcare professional's experience with the products of the company making the decision to provide support may be taken into account, but not their prescribing behaviour.

6.2.5 No compensation or benefit, monetary or non-monetary, shall be provided to a member of the medical community for time spent at a professional event.

6.2.6 The Code prohibits the company from funding the attendance of individual healthcare professionals on courses certified by accredited further education institutions (e.g. MSc, Asthma Diplomas) or modules leading to postgraduate qualifications, as these are not educational meetings

or conferences and such support would constitute a significant personal benefit to the individual concerned.

This provision does not preclude the funding of relevant educational grants and scholarships to health care organizations, provided that the company does not have the opportunity to participate in the selection of individual recipients. Companies must not actively engage with individuals who benefit from such support during their studies, or subsequently distinguish them unreasonably from other healthcare professionals on the basis of the grant/scholarship they have received.

6.2.7 Transfers of value to healthcare professionals under 6.2 shall be disclosed in accordance with Chapter 7 of this Code.

6.3 Visits to Premises

6.3.1 A tour of the company's manufacturing, distribution or research and development facilities (the "Facilities") can help healthcare professionals better understand the company's core manufacturing capabilities, technologies and operations that support their decision-making. Visits to premises must be purely educational and should not be organised as a promotional activity.

6.3.2 All visits to the premises must have a specific and detailed programme that is consistent with the defined learning objectives. This agenda should include a complete timetable, a sufficient description of the content of each session, the title of each presentation and, if possible, the names and job titles of all presenters.

6.3.3 Companies should only invite healthcare professionals to visit those premises that are logistically best suited to meet the training objectives. If it is absolutely necessary for the company to organise visits to premises outside the home country of healthcare professionals, this is only permitted provided that everything is organised in accordance with the relevant rules and requirements, including the standards set out in this Code.

6.3.4 It is rarely acceptable for companies to organise visits to premises as "supplementary" to attending a congress or to organise an advisory committee meeting in conjunction with a visit . Participants in each individual activity must be suitable and therefore selected according to the same criteria as would be applied to a stand-alone event.

6.3.5. Transfers of value to healthcare professionals under clause 6.3 shall be disclosed in accordance with Chapter 7 of this Code.

6.4 Payments for Services and Consultations

6.4.1 Expert advice and support from healthcare professionals, healthcare organisations and patient organisations (for the purposes of clause 6.4 these are referred to as "experts") helps the pharmaceutical industry to make decisions that are ultimately beneficial to patient care. Companies may work with relevant healthcare professional experts who:

6.4.1.1 serve as experts on advisory boards;

6.4.1.2 provide lectures and presentations;

6.4.1.3 participate in research;

6.4.1.4 are part of a market survey, or

6.4.1.5 train and educate on products.

6.4.2 The company must have a legitimate business need for the particular service and intend to make proper use of it. This need for the service must be identified and documented before the company begins to provide the service. A company shall not create appointments or work for the sole purpose of maintaining engagements with members of the medical community as a means of rewarding them.

Market research must not be used as a mechanism to channel undisclosed payments to a particular group of healthcare professionals. If a company provides an agency with a list of potential targets/respondents (e.g. a customer satisfaction survey conducted with pharmacies), this cannot be considered truly anonymous if a significant proportion of them will be identifiable respondents.

6.4.3 Experts shall be selected and hired as service providers only on the basis of their qualifications, expertise and ability to provide services. The company personnel responsible for selecting the expert must have the expertise necessary to assess whether the proposed experts are suitable for the specific needs identified.

6.4.4 Where companies combine payment for services with attendance at a convention or a visit to the premises, participants in each activity must be selected according to the same criteria that would apply to separate events.

6.4.5 Companies should only work with as many experts as is strictly necessary and only for as long as is reasonably necessary to achieve the identified business need.

6.4.6 Companies must be mindful of the reputation of experts and must not work with any person at a frequency that would be considered excessive, as it must be remembered that alternative experts are usually available.

6.4.7 All engagements must be confirmed in writing with clear details of the services provided and the amount of remuneration.

6.4.8 Where possible, the expert should be contractually bound to:

6.4.8.1 declare that he/she is providing a paid service to the company whenever he/she speaks or writes publicly about the subject matter of the contract or about any topic relating to the company; and

6.4.8.2 notify these commitments to his/her employer, if appropriate.

6.4.9 In accordance with the principles in Chapter 5 of this Code, companies must not pay more than fair market value for services and may only pay for the actual service provided. If it was not possible for the expert to perform all the services agreed in the contract, the company may only pay fair market value for those contractual services that were actually performed.

6.4.10 Expert that provide services may ask that the remuneration for their services be donated to charity. It is forbidden for companies to comply with this request.

6.4.11 Value transfers for experts under clause 6.4 shall be disclosed in accordance with Chapter 7 of this Code.

6.5 Educational Materials, Medical Devices, Promotional Items and Gifts

6.5.1 Companies may provide the following educational materials from time to time:

6.5.1.1 materials provided for the education of healthcare professionals must be authorized or contain the name of the manufacturer or company and its mailing address in the Slovak Republic;

6.5.1.2 material provided to a healthcare professional may contain advertising claims and/or statements, but in this case it is no longer educational material but advertising material which must comply with the terms of this Code (paragraph 5.3).

6.5.2 When medicines are promoted to persons authorised to prescribe medicines and persons authorised to dispense medicines, such persons shall be prohibited from supplying, offering or promising gifts, pecuniary or material benefits or advantage.

6.5.3 The prohibition set out in clause 6.5.2 does not preclude that, in the event of a need for medical devices in crisis situations that could help protect public health or assist in disaster relief, companies may provide such support in the form of reasonably necessary medical devices, but only to the extent consistent with generally applicable law. Such assistance must be documented by the company and the recipient should generally be health organizations or government agencies rather than individual healthcare professionals.

6.6 Samples

6.6.1 The purpose of providing samples of medicines is to help prescribers to become more familiar with specific medicines and to gain experience of their use. Samples of medicinal products may only be provided to persons authorised to prescribe them.

6.6.2 Samples may only be provided at the written request of the persons authorised to prescribe medicinal products.

6.6.3 Companies may only provide samples of medicinal products on an exceptional and occasional basis and always in accordance with generally applicable legislation governing the quantity and frequency of the provision of such samples.

6.6.4 Samples must not be resold by the prescriber and the packaging of the medicine must clearly state that it is a sample. Disclosure of the provision of samples of medicinal products is not required by this Code.

6.6.5 Companies must establish and maintain an appropriate control system for the distribution of samples. The organisation of supplies must comply with generally binding legislation.

6.6.6 It is not permissible to provide samples of medicinal products containing narcotic drugs or psychotropic substances.

6.7 Charitable/Social Contributions

6.7.1 Companies can contribute to communities, through donations in cash or kind to health and patient organisations to support health objectives. Legitimate purposes are defined as support for:

6.7.1.1 scientific research;

6.7.1.2 health education;

6.7.1.3 patient education;

6.7.1.4 patient access to healthcare and

6.7.1.5 overall development of health systems.

6.7.2 The company may also support community and eleemosynary initiatives. Contributions may also be made to recognised charities, civic associations or non-profit organisations.

6.7.3 The principal object of all such beneficiaries must be eleemosynary and philanthropic.

A profit-making health organisation may be granted a contribution only if it pays all of its profits to the state or a public institution. Companies may not support or contribute to the profitability of a private enterprise, so donations are prohibited if:

6.7.3.1 the organisation has private shareholders; or

6.7.3.2 the donation would financially benefit any healthcare professional.

6.7.4 Contributions must never be made to or for the benefit of specific individuals.

The requirements set out in clause 6.7.3 do not preclude the company from, for the purpose of achieving any of the objectives specified in clauses 6.7.1.3 to 6.7.1.5 (e.g. screening and similar primary care activities), provided that this is permitted by generally applicable law (and provided that there is no direct financial or non-financial benefit to the healthcare professional or health organisation), to organise and/or pay the costs of an activity pursuing one of the objectives specified in clauses 6.7.1.3 to 6.7.1.5. This type of support should be disclosed as an in-kind donation to the healthcare organisation in collaboration with which the support was made.

Please note that research grants and sponsorship of healthcare professionals education are not considered “contributions” for the purposes of this provision.

6.7.5 Companies may only make contributions on the basis of an independent request from a potential recipient without any prior inducement from the company, i.e. a request that comes from an organisation without any inducement from the company. This requirement is met by the charity’s public appeal.

In exceptional circumstances, companies may actively donate if:

6.7.5.1 all other requirements in clause 6.7 are met; and

6.7.5.2 the donating company does not have, and is not reasonably likely to have, any business interest in the activities of the recipient.

An exception to this provision for the purposes of dealing with public health emergencies or disaster relief may only be granted by GENAS if permitted by generally binding legislation.

6.7.6 Unrestricted contributions to health organisations, i.e. donations that are not linked to a specific project or activity, are prohibited. The company must therefore ensure that it has sufficient information on how the funds will be used. The application must include a detailed description of the needs of the organization, program or project and the total budget, as well as the amount requested by the company. This requirement is deemed to be met if the company is responding to a public appeal by a charity with a national or international reputation.

6.7.7 Companies should give due consideration to the proposed recipient and ensure that the recipient is legitimate, financially stable and that the contribution will not present a risk of conflict of interest.

6.7.8 Companies must have set a process for approving contributions. The approval process must be independent of any commercial aspects and must not involve the company's commercial department staff.

6.7.9 Transfers of value to beneficiaries under clause 6.7 shall be disclosed in accordance with Chapter 7 of this Code.

6.8 Interaction with Patients and Patient Organisations

6.8.1 In order to maintain its independence and credibility in relation to patient organisations, the company must not seek to be the sole founder of a patient organisation or any organisation with such an underlying agenda.

6.8.2 Companies must ensure that their sponsorship is always acknowledged and evident from the outset.

6.8.3 If requested by a patient organisation, the company may contribute to the development of materials from a fairness and balance perspective. Companies may also correct factual inaccuracies. However, companies must not have editorial control over the text of the materials of the patient organisations they support and must not seek to influence their content in a way that would benefit their own commercial interests.

6.8.4 Public use of the logo or materials owned by patient organisations by companies requires the written consent of that organisation. When obtaining permission, the company must clearly state the specific purpose and manner of use of the logo or other materials owned by the organization.

6.8.5 Where a company provides financial support, significant non-financial support (e.g. product or equipment) or significant indirect support (e.g. donating time to a PR agency) to a patient organisation, a contract must be drawn up which clearly states:

6.8.5.1 amount of funding;

6.8.5.2 purpose of the sponsorship, such as providing a grant, sponsoring a particular meeting or promoting a publication;

6.8.5.3 if relevant, a description of any non-financial support; and

6.8.5.4 if relevant, a description of any indirect support, including support of a specific nature involving another second party.

6.8.6 Sponsorship contributions and donations must comply with the requirements set out in clauses 6.1 and 6.7.

6.8.7 Companies may only accept services from patient organisations for the promotion of healthcare and healthcare research. For example, patient organisations can provide experts to attend advisory body meetings or to speak at educational sessions. Payment for the provision of the service shall be in accordance with the requirements set out in clause 6.4.

6.8.8 Companies must have set processes for approving donations, sponsorship or contracted services in relation to patient organisations. The donation approval process must be independent of any commercial considerations and must not involve employees of the commercial department.

6.8.9 Transfers of value to patient organisations under clause 6.8 shall be published in accordance with Chapter 7 of this Code.

6.8.10 Patient support programmes (PSPs) are non-promotional, company-funded programmes designed to help patients or carers, with their consent, either directly or through healthcare professionals, to better understand and/or manage their illness. An example of a PSP might be the provision of nurses through third parties to assist patients with medication administration, on a patient helpline or provide regular contact to check medication adherence. A PSP organisation must comply with generally applicable laws and the requirements of this Code.

The selection and management of PSP suppliers and PSP decision-making is usually the responsibility of the company's medical department, with significant support from the pharmacovigilance department, and these processes must be independent of the company's sales and marketing department.

Chapter 7 - Procedures for Disclosure of Transfers of Value

This chapter applies to the disclosure of transfers of value made from 1 January 2023. The procedures for disclosure of transfers of value provided for in the Code do not relieve companies of obligations arising from their internal rules or from generally binding legislation, such as withholding tax reporting obligations or reporting on the company's marketing and advertising costs, medicines and monetary and non-monetary benefits provided in accordance with Act No. 362/2011 on Medicinal Products and Medical Devices and on Amendments to Certain Acts (hereinafter referred to as "Act No. 362/2011 Coll.").

7.1 Responsibility for Disclosure of Transfers of Value

7.1.1 Transparency in the interactions between pharmaceutical companies and the healthcare community helps to prevent unethical and illegal behaviour.

7.1.2 A company must disclose transfers of value made on its behalf by its intermediaries if the company knows or has access to the identity of the recipient(s). Such indirect transfers of value will be treated for disclosure purposes in the same way as if they had been made directly by the company.

The status and nature of the intermediary (e.g. travel agent, event management company or distributor) is irrelevant. If the transfer of value occurs as a result of an activity covered by this Code and is ultimately under the control of the pharmaceutical company, then the company must disclose this information. Companies should ensure that the obligation for intermediaries to provide data for disclosure is included in their contractual terms and conditions with each other.

7.1.3. A pharmaceutical company must disclose transfers of value arising from benefits provided within the scope of this Code that have been provided to healthcare professionals, healthcare organisations and patient organisations (hereinafter also referred to as the "Recipient"). Benefits provided to others do not have to be disclosed under this Code.

7.1.4 Where this chapter provides that the nature of the transfer of value must be described, that description must be sufficiently comprehensive to enable the public to understand what the arrangements are between the company and the transferee. However, it is neither necessary nor mandatory to disclose confidential information.

7.2 Scope of Disclosure

7.2.1 Companies must disclose details of the following transfers of value (whether funded directly or indirectly) to healthcare professionals, healthcare organisations or patient organisations:

7.2.1.1 **payments for services** (excluding related costs), excluding payments made in connection with research and development activities or anonymous market research;

7.2.1.2 **registration fees** for attending a third party congress/conference;

7.2.1.3 **travel and accommodation costs** provided to participants in connection with attendance at meetings, including meetings organised by third parties, meetings organised by the company and visits to the premises;

7.2.1.4 **financial and in-kind grants and donations** to organizations that are part of the healthcare community;

7.2.1.5 **sponsoring activities and events** of health and patient organisations.

7.2.2 The exemption from the obligation to disclose payments for research and development applies only to payments for services rendered. At the same time, there is no need to disclose data on equipment provided to health organisations, as long as this equipment is returned after the study is completed. If the equipment remains in the ownership of the healthcare organization, the data must be disclosed as a donation at the current market value of the equipment. Non-interventional clinical trials within the meaning of Act No 362/2011 Coll. are not considered to be research and development.

7.2.3 The exemption for disclosure of market research fees applies only to truly anonymous market research where the company cannot know or infer the identity of the respondents.

7.2.4 If there are no direct costs associated with the meeting (other than refreshments and beverages), there are no transfers of value to be disclosed. In the case of meetings organised by the company, items such as room hire or audio-visual support do not confer any personal benefit to individual participants and are not considered as transfers of value.

7.2.5. Transfers of values relating solely to over-the-counter products and other non-prescription medicines are outside the scope of this Code and therefore outside the scope of disclosure.

7.2.6 If a company's product portfolio includes not only prescription medicines but also over-the-counter medicines, then such meetings, activities and transfers of value that relate solely or in part to prescription medicines are covered by the disclosure obligations under this Code.

7.2.7 Activities outside the scope of this Code, such as discounts or the sale of advertising space that are unrelated to the sponsorship of materials, are inherently outside the scope of the disclosure obligation.

7.3 Period and Frequency of Disclosure

7.3.1 Pursuant to Act No. 362/2011 Coll. GENAS member companies are obliged to submit electronically to the National Centre for Health Information (NCZI) for the purposes of public control of the provision of monetary or non-monetary benefits, no later than 31 January and 31 July of the calendar year, a report on the expenditure on promotion, marketing and on monetary and non-monetary benefits for the previous calendar half-year.

7.3.2 The reporting period is the calendar year. In the event of a difference in the required scope of value transfer disclosure between Medicine for Europe and the required content of the reports to NCZI, the company shall disclose the excess scope of value transfer no later than 30 June of the calendar year following the end of the calendar year in which the value transfer was made.

7.4 Procedures for Disclosure of Values Outside the Scope of NCZI Report - Healthcare Professionals

Payments for Services

7.4.1 Payments for services shall always be disclosed by name (unless the healthcare professional refuses consent to disclosure of personal information in accordance with clause 7.7.2 below).

7.4.2 The amount disclosed for each healthcare professional is the sum of all payments for the reporting period.

7.4.3 Expenses directly related to the performance of the contracted service (e.g. travel, accommodation and meals) do not need to be disclosed.

7.4.4 If the healthcare professional provides the services agreed in the contract through a consultancy or personal services company and that company is controlled by the healthcare professional or the healthcare professional's family, then for disclosure purposes the contractual commitment is treated as a transfer of value made to the healthcare professional (the transfer of value will be disclosed individually, to the healthcare professional, not to the healthcare professional's company).

7.4.5 If a company has a contractual relationship with an organisation providing services through a specialist healthcare professional with whom the organisation has a contractual relationship, then for disclosure purposes the contractual relationship is treated as a transfer of value to the individual, even if the individual does not receive remuneration directly for the services performed.

Encouraging Participation in Meetings

7.4.6 The "support" category includes transfers of value during the reporting period in the form of:

7.4.6.1 registration fees for participation in third party congresses/conferences, including virtual meetings;

7.4.6.1 travel and accommodation associated with attendance at meetings - including third party meetings, meetings organised by the pharmaceutical company and site visits.

7.4.7 Pharmaceutical companies must choose one of two disclosure options in this category:

7.4.7.1 Option 1: Disclosure of the number of meetings at which each named healthcare professional was supported to attend but without providing any financial information.

The information on the provision of the benefit to the healthcare professional must include:

a) name and surname of the healthcare professional;
b) number of third-party meetings attended in the country where he/she primarily operates (includes registrations provided for virtual meetings);
c) number of third-party meetings attended within Europe;
d) number of third-party meetings attended outside Europe;
e) number of premises visits attended in the country where he/she primarily operates;
f) number of site visits attended in Europe;
g) number of visits to premises attended outside Europe;
h) number of meetings organised by the pharmaceutical company and attended in the country where he/she primarily operates;

i) number of meetings organised by the pharmaceutical company and attended within Europe;
j) number of meetings organised by the pharmaceutical company and attended outside Europe.

7.4.7.2 Option 2: Disclosure of the total cost of each specific meeting and the total number of healthcare professionals whose attendance was supported, but without disclosing the specific names of participants .

The following shall be stated for each encounter:

a) name of the congress, meeting or premises visit;
b) total amount spent on registration fees (see clause 7.4.9 regarding the value of publishing "free" conference registrations), travel and accommodation for all healthcare professionals; and
c) number of healthcare professionals whose participation was financially supported.

7.4.8 The value of meals included in the "package" when registering for the conference is relatively insignificant and should not be deducted.

7.4.9 Where the company is provided with a number of complimentary conference registrations as part of a sponsorship package and donates these registrations to a healthcare professional, the transfer value will be deemed to be the price the individual recipient would have paid for themselves at the amount current at the time of donation.

7.5 Procedures for Disclosure of Values Outside the Scope of NCZI Report - Healthcare Organisations

7.5.1. Transfers of value to health organisations must be disclosed by name. The consent of the health organisation is not required.

Payment for Services

7.5.2. The amount disclosed for each healthcare organisation is the sum of all payments for the reporting period.

7.5.3 Expenses directly related to the performance of the contracted service (e.g. travel, accommodation and meals) do not need to be disclosed.

7.5.4 If a company contracts with an organisation to provide the services of one or more healthcare professionals employed by the organisation and there is no requirement for the service to be performed by specific individuals, then for disclosure purposes such a contractual obligation is treated as a transfer of value provided to the organisation.

Grants and Donations

7.5.5 The amount disclosed for each health care organization is the sum of all contributions made in accordance with clause 6.7 of this Code for the reporting period.

7.5.6 For each health organisation, companies must also provide a brief description of the nature of the contribution(s) (e.g. research grant, donation of equipment, donation of products) and, where this is not obvious, the purpose (e.g. "increase of lung cancer screening capacity" or "support of pandemic mitigation").

7.5.7 In-kind contributions to healthcare organisations must be disclosed at fair market value (FMV), even if the company has written off all or part of the value given in its accounts.

Sponsorship of Activities and Events

7.5.8 The amount disclosed for each healthcare organisation is the sum of all values of sponsorship contributions made in accordance with clause 6.1 of this Code for the reporting period.

7.6 Disclosure Rules and Procedures - Patient Organisations

7.6.1 Transfers of value to patient organisations must be disclosed by name. The consent of the patient organisation is not required.

Payment for Services

7.6.2. The amount disclosed for each patient organisation is the sum of all values for the reporting period.

7.6.3 Expenses directly related to the performance of the contracted service (e.g. travel, accommodation and meals) do not need to be disclosed.

7.6.4 For each patient organisation, companies must also provide a brief description of the nature of the services provided to them by the patient organisation.

Support in the Form of Grants, Donations and Sponsorship of Events

7.6.5 The amount disclosed for each patient organisation is the sum of all contributions and sponsorship support made in the reporting period in accordance with clauses 6.1 and 6.7 of this Code.

7.6.6 For each patient organisation, companies must also provide a brief description of the nature of the sponsorship or contribution(s) (e.g. funding for Disease Awareness Day, covering the cost of an information periodical or general support for the organisation's running costs).

7.6.7 In-kind contributions to patient organisations must be disclosed with an indication of the fair market value (FMV), even where the company has written off all or part of the value given in its own accounts.

7.6.8 Where, exceptionally, the company provides significant non-financial support for which it is not possible to place a meaningful monetary value, the non-monetary benefit to the patient organisation must be clearly described.

7.7 Procedures for Disclosure of Values Outside the Scope of NCZI Report - Privacy and Consent

7.7.1 Companies must ensure that disclosures comply with data protection requirements and other relevant generally applicable laws.

7.7.2 If the healthcare professional does not consent to the disclosure of his/her name, the company will disclose the details of the transfer in such a way that the person cannot be identified. If multiple

healthcare professionals refuse to consent to the processing of personal data in relation to the disclosure of a transfer of value, then transfers of value for their benefit will be included in the categories and the total number of recipients must be included in the aggregate category, as indicated in the disclosure document (Annex 1).

7.7.3 If a healthcare professional withdraws consent to the disclosure of his/her personal information, the reporting company must update the disclosure as soon as possible (within 30 days at the latest) and include the data relating to the transfer of value to that healthcare professional in the aggregate category as set out in clause 7.7.2.

7.8 Procedures for Disclosure of Values Outside the Scope of NCZI Report - Methodological Note for Companies

7.8.1. Along with the disclosure of the data, each pharmaceutical company must also disclose the methodology used in preparing the disclosure and in identifying the value transfers in each category. The methodological note should also explain how the company approaches issues related to:

7.8.1.1 multi-year contracts;

7.8.1.2 taxes, including whether or not VAT has been included in the published figures;

7.8.1.3 currency and, if applicable, the exchange rate;

7.8.1.4 issues relating to the timing and amount of transfers of value for disclosure purposes; and

7.8.1.5 the company's practice in cases where an activity has been performed during the reporting period (so that a payment obligation has arisen) but the contracted entity has not yet invoiced the company.

7.8.2 Companies must disclose the transfer values both with and without VAT in the reported data and explain their approach in a methodological note.

7.8.3 In general, if the transfer of values was not made in EUR (e.g. a fee paid to a speaker from another country, payment of an attendance fee in a foreign currency), the company should convert the reported amount into the currency used in the disclosure report and explain the approach in the methodology note.

7.9 Platform, Place and Format of Disclosure Outside the Scope of NCZI Report

7.9.1 The company must disclose transfers of value in a manner that makes the information readily available to the public. If required by generally binding legislation, this should be on a national platform designated by the government or the relevant regulatory authority. Another option is to publish the data on their own website.

In addition, companies may disclose data in the countries of their sales offices and/or in the country where their European regional office is located.

7.9.2 Companies must comply with the relevant national requirements in each country where they publish data, including the requirements of the GENAS Code.

7.9.3 It is advisable for companies to publish the transfer of value report in the form of a searchable database by name/recipient name and location or professional registration number/organisation identification number. “Place” means the municipality/city in which an individual carries out his/her professional activity or in which an organisation is registered or operates.

The results of the database search must include the recipient (in the case of a healthcare professional, to the extent that he/she has consented to the processing of personal data):

7.9.3.1 name of the recipient;

7.9.3.2 details of the recipient as specified in clauses 7.4, 7.5 and 7.6;

7.9.3.3 total volume of values transferred by type for all healthcare professionals, healthcare organisations or patient organisations.

When searching for a person whose name is not listed in a published report, summary information on healthcare professionals should be displayed.

7.10 Other Acceptable Forms of Disclosure

7.10.1 Pharmaceutical companies are not required to disclose transfers of value under this Code as long as they report a complete report of the same transfers of value in accordance with Act No. 362/2011 Coll. and/or the transparent reporting regime of another self-regulatory association (such as EFPIA or AIFP).

7.11 Data Retention Requirements Outside the Scope of NCZI Report

7.11.1 Companies are responsible for ensuring that information about their disclosures is available on the internet for at least one year.

Chapter 8 - Monitoring Compliance with the Code of Conduct

Member companies are responsible for addressing and correcting any violations of the Code and should report any violations.

The Code’s enforcement procedures are without prejudice to the rights of member companies and the ability of GENAS to bring relevant matters to the attention of the competent regulatory authorities. However, complainants should not initiate an enforcement process under this Code if a process under another relevant Code of Conduct has already been initiated in the same matter (e.g. by the AIFM or one of its member associations).

GENAS has procedures for complaints and enforcement of the Code set out in the Code of Administrative Procedure. Companies must comply with the enforcement procedures set

out in the GENAS Association's Code of Administrative Procedure. The GENAS Association may, in justified cases, refer requests for an assessment of a company's compliance with the GENAS Code of Conduct to the Medicines for Europe Secretariat.

If the company alleged to have breached this Code is not a member of GENAS but is (or its parent company is) a member of Medicines for Europe, it will be subject to Medicines for Europe's procedures.

Pharmaceutical companies that are not members of GENAS, as well as healthcare organisations, patient organisations, healthcare professionals, the public or other interested parties may lodge a complaint either under the applicable Slovak legislation (if applicable) or under the Code of Administrative Procedure of GENAS, in the manner and to the extent permitted by the Code of Administrative Procedure of GENAS.

Individual complainants who wish to remain completely anonymous should report their complaints to the relevant local regulatory authority or to the whistleblowing hotline of the relevant whistleblowing company.

Chapter 9 - TECHNICAL PROVISIONS

1. After the approval of the Code of Conduct or its amendments by the General Assembly, the GENAS secretariat shall prepare the full text of the Code and have it signed by the Chair of the Ethics Committee.
2. The alleged non-compliance of a member's conduct with the Code shall be assessed according to the version of the Code in force at the time of the member's conduct, except where the version of the Code in force at the time of the assessment of the member's conduct is more favourable to the member.

Chapter 10 - FINAL PROVISIONS

1. The Code of Conduct was adopted by the GENAS General Assembly on 27/06/2017 and enters into force on 01/09/2017.
2. The amendments to the Code of Conduct were adopted by the General Assembly on 10/12/2018, and their version in the form of the full version of the Code of Conduct will enter into force on 01/01/2019.
3. The amendments to the Code of Conduct were adopted by the General Assembly on 11/11/2019, and their version in the form of the full version of the Code of Conduct will enter into force on 01/01/2020.
4. On 25/06/2020, the GENAS General Assembly adopted a comprehensive amendment to the Code of Conduct, which in the form of the full version of the Code will enter into force on 01/07/2020.
5. On 20 September 2023, a comprehensive amendment to the Code of Conduct was adopted by the GENAS General Assembly, which replaces in its entirety the previous version of the Code of Conduct as amended and, in the form of a complete new version of the Code, shall enter into force on 21 September 2023 and shall become effective on 15 December 2023.
6. An amendment to the Code of Conduct was adopted by the GENAS General Assembly on 16 October and will enter into force on 16 October 2023 and take effect on 15 December 2023. GENAS shall ensure the publication of the full text of the Code containing the version adopted by the General Assembly on 20 September 2023, incorporating the amendments adopted on 16 October 2023.

Annex 1 - Example of the Data Publication Form

Name of the recipient	Place of organisation	Date	Place of operation	Purpose / description of the event	Details of expenditure	Total amount/value
Total						