Association of Pharmaceutical Manufacturers in Estonia

CODE OF CONDUCT OF ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS IN ESTONIA

Adapted and adopted by the Association of Pharmaceutical Manufacturers in Estonia on the basis of the EFPIA code[1]

[1] The code adopted by the APME General Assembly of 29.05.2008, with supplements adopted at the APME General Assembly of 28.05.2009, 11.06.2010, 09.12.2010, 03.06.2011, 07.06.2012, 06.12.2013, 19.06.2014, 09.06.2016, 08.06.2017, 12.12.2019, 07.06.2022, 08.12.2022 and 08.06.2023.

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INTRODUCTION

This code of conduct of the Association of Pharmaceutical Manufacturers in Estonia (APME Code) is based on the Code of Practice (EFPIA Code) of the European Federation of Pharmaceutical Industries and Associations (EFPIA) , which was adopted by the EFPIA General Assembly on 27 June 2019.

The EFPIA is the representative body of the pharmaceutical industry in Europe. Its members are the national industry associations of thirty European countries (member associations) and over forty leading pharmaceutical companies. The EFPIA's primary mission is to promote the technological and economic development of the pharmaceutical industry in Europe and to assist in introducing to the market medicinal products that improve human health worldwide.

The Association of Pharmaceutical Manufacturers in Estonia (APME) is a non-profit organisation, which represents research-based and generic pharmaceutical manufacturers operating in Estonia, whose production is meant for sale on the basis of prescriptions and over-the-counter medicines or under the control of healthcare professionals and who follow ethical principles in their operation.

The following is important to the EFPIA and its members: (i) provision of accurate, fair and objective information on medicinal products to promote their rational use; (ii) ethical cooperation with healthcare professionals, healthcare organisations and patient organisations, which is of key importance in the improvement of the quality of treatment of patients; and (iii) increasing the transparency of the relationships between the pharmaceutical industry and healthcare professionals, healthcare organisations and patient organisations.

With this in mind, the EFPIA has adopted the EFPIA Code, which reflects the requirements of Council Directive 2001/83/EC, as amended, relating to medicinal products for human use (the Directive). The EFPIA Code fits into the general framework established by the Directive, which recognises the role of voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies when complaints arise.

The APME supports competition among pharmaceutical companies. The APME Code is not intended to restrain the promotion of medicinal products to, or limit interactions with, healthcare professionals, healthcare organisations or patient organisations in a manner that is detrimental to fair competition. Instead, the code seeks to ensure that pharmaceutical companies conduct such promotion and interaction in a truthful manner, avoiding deceptive practices and potential conflicts of interest with healthcare professionals, and in compliance with applicable laws and regulations. The APME Code thereby aims to foster an environment where the general public can be confident that choices regarding their medicines are being made on the basis of the merits of each product and the healthcare needs of patients.

Healthcare professionals and healthcare organisations give the pharmaceutical industry valuable and independent expert knowledge, which are based on their clinical and

scientific experience. This expert knowledge is important, because it helps the pharmaceutical industry improve treatment quality, which benefits individuals as well as the whole of society. Healthcare professionals and healthcare organisations are entitled to be fairly remunerated for the expert knowledge shared with and the service provided to the pharmaceutical industry.

The EFPIA believes that the cooperation between member companies and healthcare professionals has a significant positive impact on treatment quality and the value of further research and development. However, the independence of the treatment decisions made by healthcare professionals is one of the foundations of the health system. The EFPIA is aware that the cooperation between the pharmaceutical industry, healthcare professionals and healthcare organisations may lead to a potential conflict of interest. Therefore, professional and industry associations, including the EFPIA and its member organisations, have adopted codes and guidelines to ensure that such cooperation complies with high ethical standards as expected by patients, governments and other stakeholders.

Self-regulation must comply with the increasing demands of society in order to guarantee its continued success. The EFPIA is aware of the increasing expectations that the relationships of the pharmaceutical sector with members of society must not only be honest, but also transparent.

The pharmaceutical industry also cooperates in the same manner with patient organisations in order to learn from their life experience and knowledge of what a patient's life with a specific disease is like, how it is treated, how it affects the patient's life, career and family, and how medicinal products and other treatment methods can improve the patient's quality of life and meet their needs.

Patient organisations have an extremely important role in helping identify, design and develop solutions that would benefit patients the most. Member companies disclose the payments made to patient organisations within the scope of such cooperation.

The EFPIA firmly supports public scrutiny. Disclosing and understanding the cooperation described above increases the confidence of stakeholders in the pharmaceutical industry.

Member companies should always look to disclose and to encourage healthcare professionals to agree to individual disclosure. Member companies are also permitted to disclose data on a broader scale than expected.

SCOPE OF THE APME CODE

The APME Code regulates:

- the promotion of prescription-only and non-prescription medicinal products to healthcare professionals;

- cooperation between manufacturers of medicinal products and healthcare professionals, healthcare organisations and patient organisations;
- disclosure of the payments made by manufacturers of medicinal products to healthcare professionals, healthcare organisations and patient organisations;
- the procedure for proceedings concerning breaches of the APME Code.

The APME Code applies to APME member companies, their subsidiaries, and any companies affiliated with APME member companies or their subsidiaries if such affiliates have agreed to be bound by the APME Code (Member Companies).

Member Companies shall be responsible for the obligations imposed under any relevant Applicable Code (defined below) even if they authorise third parties (defined below) to design, implement or perform activities covered by the Applicable Code on their behalf. In addition, Member Companies shall take reasonable steps to ensure that any other parties that they authorise to design, implement or perform activities covered by the Applicable Code but that do not act on behalf of the Member Company (e.g. joint ventures, licensees) comply with Applicable Codes.

The APME Code covers all methods of promotion such as oral and written promotional activities and communication, journal and direct mail advertising, the activities of Medical Sales Representatives (defined in Section 20.01), the use of the digital communications methods and channels (e.g. websites and social media), the use of audio-visual systems (films, video recordings, data storage services and the like). The APME Code also regulates the distribution of informational and educational materials as well as items meant for medical utility, the provision of hospitality related to events and distribution of samples of medicinal products, and stipulates the prohibition on giving gifts.

The APME Code also regulates cooperation between Member Companies, healthcare professionals and healthcare organisations including, but not limited to, those in the context of research or contractual arrangements (including certain aspects of clinical trials, non-interventional studies and consultancy and advisory board meetings). The APME Code also regulates cooperation with patient organisations.

The APME Code is not intended to restrain or regulate the activities directed towards the general public that relate solely to non-prescription medicinal products.

The APME Code does not cover the following:

- the labelling of medicinal products and accompanying package leaflets, which are subject to the provisions of Title V of the Directive;
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;
- factual data and reference material relating, for example, to package changes, adverse-reaction warnings as a part of general precautions, trade catalogues and price lists, provided they include no product claims;
- activities that relate solely to the promotion of non-prescription medicinal products to the general public and are governed by legislation;

- non-promotional, general information about companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programmes, and discussions on regulatory developments affecting a company and its products.

Attached to the APME Code is: Annex A Data disclosure form.

APPLICABILITY OF CODES

The APME Code sets out the minimum standards considered to be applicable by the APME. In a manner compatible with their respective national laws and regulations, Member Associations must, at a minimum, adopt in their national codes provisions that are no less rigorous than the provisions contained in the EFPIA Code.

Promotion and interaction that take place within Europe must comply with applicable laws and regulations. "Europe" as used in the EFPIA Code includes those countries in which the EFPIA Member Associations' codes of practice apply. Member Companies must proceed in their activities from the "Applicable Code" as follows:
(a) in the case of promotion or interaction that is undertaken, sponsored or organised by a Member Company in Estonia, this APME Code, and
(b) in the case of promotion or cooperation that is undertaken, sponsored or organised by a Member Company in a foreign country, also the national code of the Member Association of the respective country.

In the event of a conflict between the provisions of the Applicable Codes set forth above, the more restrictive of the conflicting provisions shall apply (excl. in respect of the monetary threshold of meals arising from the Host Country Principle).

Member Companies must comply with all Applicable Codes and any laws and regulations to which they are subject.

In order to establish adequate procedures to ensure compliance with the APME Code, APME will be required, among other things, to introduce appropriate complaint procedures and sanctions for breaches of the Applicable Codes. Additionally, any relevant local subsidiary shall be notified of all international events (as defined in Section 10.02 of the EFPIA Code) or, alternatively, local advice must be taken. Both the spirit and the form of the provisions of the EFPIA Code have been adhered to.

ETHICAL PRINCIPLES

In order to improve healthcare and the quality of life, manufacturers of medicinal products cooperate with several stakeholders including healthcare professionals, healthcare organisations, patient organisations and their representatives, the authorities, governments and the general public.

As manufacturers of medicinal products, we believe in our activities and acknowledge that the health and wellbeing of patients depends directly or indirectly on our activities.

We aim for an environment where our stakeholders and the general public see manufacturers of medicinal products as trustworthy partners.

In addition to compliance with the different and extensive laws and regulations applicable to the pharmaceutical industry (e.g. the laws and regulations that cover medicinal products, competition, intellectual property and are anti-bribery and corruption), the pharmaceutical industry has undertaken to comply with the additional standards arising from self-regulation and joint declarations.

To the EFPIA as well as its members, self-regulation means full dedication to the definition and enforcement of and compliance with the highest ethical standards via the EFPIA Code as well as the national codes, in the case of which breaches are not tolerated. Manufacturers of medicinal products continuously seek to exceed the expectations of society and openness regarding suggestions from others on how we might further strengthen confidence in our industry. The stakeholders that share the values and principles expressed in this self-regulation document are also invited to follow these rules.

Our commitment is expressed by the following ethical principles:
Firstly, THE INTERESTS OF PATIENTS ARE AT THE CORE OF OUR ACTIVITIES. Our goal is to ensure that everything we do ultimately benefits the patients. High-quality medicinal products and the desire to promote their appropriate and reasonable use in the care pathway constitute our contribution to society.

We are HONEST in our activities. We cooperate responsibly and want to ensure that our messages to stakeholders are accurate, legitimate and balanced. We take responsibility for our decisions, activities and communications, and encourage others to adhere to ethical standards that are equally high.

We treat all of our stakeholders with RESPECT. We communicate with our stakeholders in a manner that is open, accepting, constructive and learning, and based on mutual trust. It is important to us that the stakeholders make independent and evidence-based decisions that consider the needs of patients. We notice the expectations of society and adapt our activities accordingly. We also comply with applicable legislation and ethical principles in personal data processing.

We are committed to ensuring TRANSPARENCY. We disclose our activities and cooperation relationships and encourage our stakeholders to operate with similar openness as well.

DEFINITIONS

The following terms used in the APME Code have the following meaning (irrespective of the use of capital initials):

Contribution to Costs related to Events: means support providing or covering the costs of meals, travel, accommodation and/or registration fees to support the attendance of an individual healthcare professional or patient organization

representative to an Event organised or created by a Member Company and/or a Third Party.

Donations and Grants means financial resources, assets or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient to provide goods or services to the benefit of the donor in return.

Events means all professional, promotional, scientific or educational meetings, congresses, conferences, symposia and other similar events (including, but not limited to, meetings of the advisory board, visits to research and production institutions, the planning, training and investigator meetings of clinical trials and non-interventional studies), which are organised or sponsored by or on behalf a Member Company.

Healthcare organisation means any legal entity: (1) that is a healthcare or medical or scientific association or organisation such as hospital, clinic, university or a professional society whose headquarters or place of business is in Europe; or (2) through which one or more healthcare professionals provide services. Patient Organisations are not considered as Healthcare Organisations.

Healthcare professional means any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his/her professional activities may prescribe, purchase, supply, recommend or administer a medicinal product and whose place of business is in Europe. The term "healthcare professional" also covers: (i) any official or an employee of a government, government agency or other organisation (both in the public and the private sectors) who may prescribe, buy, supply, recommend or administer medicinal products; and (ii) any employee of a Member Company who mainly acts as a practising healthcare professional (excl. all other employees of the Member Company and wholesalers or resellers).

Host country principle means the monetary threshold of meals established by the Member Association of the respective country in the national code. The monetary threshold of meals of the country of location of the event must be taken into account.

Informational or educational material means inexpensive material directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients.

Item of medical utility means items directly related to the education of healthcare professionals enhancing the provision of medical services and patient care and that do not offset routine business practices of the healthcare professionals and that is inexpensive.

Location means the country or city where an event takes place.

Member Association means, pursuant to the EFPIA Statutes, an organisation that represents the interests of the manufacturers of medicinal products at the national level and whose members include, among others, research-based companies.

Member Company's staff means the employees of a Member Company or persons acting on behalf of the Member Company on the basis of a contract entered into with a third party and whose activities are in the scope of the APME Code.

Medical Education means education related to human health and diseases and the specific non-promotional training related to medicinal products.

Medicinal products means, pursuant to Article 1 of the Directive: (a) any substance or combination of substances presented for treating or preventing disease in human beings; or (b) any substance or combination of substances that may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Medical sales representative means an employee of the Member Company or a person acting on behalf of the Member Company on the basis of a contract entered into with a third party, who interacts with healthcare professionals and/or healthcare organisations for purposes related to the promotion of medicinal products.

Medical Sample means, within the meaning specified in the Directive, samples of medicinal products provided free of charge to persons qualified to prescribe or supply them so that they can familiarise themselves with new products and acquire experience in dealing with them.

National code means the code of practice or code of conduct adopted by a specific Member Association.

Non-interventional study means a study whereby a medicinal product is/medicinal products are prescribed in the usual manner according to the conditions of the marketing authorisation. The assignment of a patient to a particular therapeutic strategy is not decided in advance with the study plan, but it takes place within the scope of the regular practice and the prescription of the medicinal product is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures are applied to the patients and epidemiological methods are used to analyse the collected data.

Patient Organisation means a non-profit organisation (incl. umbrella organisation) whose membership consists mainly of patients and/or their carers and that represents and/or supports the needs of patients and/or their carers and whose headquarters or primary place of business is in Europe.

Personal health data means any information related to the physical, mental health or to the inherited or acquired genetic characteristics of an identified or identifiable natural person, including the provision of health care services, which reveal information about his or her physiology or health status.

Promotion/advertising means any activity undertaken, organised or sponsored by a Member Company, or with its authority, promoting the prescription, supply, sale,

administration, recommendation or consumption of its medicinal product(s). The words "promotion" and "advertising" have the same meaning in the APME Code.

Representative of Patient Organisation means a person authorised to represent and express the collective views of the Patient Organisation in relation to a particular issue or disease area.

Sponsorship means the support provided by a Member Company or on its behalf to sponsor an activity (incl. event) organised by a healthcare organisation, patient organisation or third party.

Third party means a natural person or legal entity that represents a Member Company or communicates with other third parties on behalf of a Member Company or in relation to a medicinal product marketed by the Member Company, such as a reseller, wholesaler, consultant, contract research organisation (CRO), professional event organiser, contracted sales representative, market research company, advertising agency, provider of services related to events, provider of public relations services, provider of non-clinical trials or non-interventional study management services.

Venue means the exact place chosen for the event (e.g. hotel, conference centre).

PROVISIONS OF THE APME CODE
SECTION 1 – ADVERTISING OF MEDICINAL PRODUCTS

1 GENERAL PRINCIPLES

1.1 A medicinal product must not be promoted prior to the grant of the marketing authorisation or outside of its approved indications.

1.2 Promotion must be consistent with the particulars listed in the summary of product characteristics of the medicinal product and comply with the other requirements set forth in the Medicinal Products Act.

1.3 In the context of the promotion of prescription-only medicinal products, the term "healthcare professional" only means persons qualified to prescribe medicinal products, pharmacists and assistant pharmacists, because prescription-only medicinal products may only be promoted to them pursuant to the Medicinal Products Act.

1.4 The requirements established in the section also apply to the promotion of non-prescription medicinal products if this is aimed at healthcare professionals.

2 INFORMATION TO BE MADE AVAILABLE

2.1 Pursuant to the additional requirements provided for by law, all promotional material aimed at healthcare professionals must include the following information clearly and legibly:

a) information required in the Medicinal Products Act that is consistent with the summary of product characteristics, specifying the date on which such information was generated or last revised;
b) classification of the medicinal product as a prescription-only or non-prescription medicinal product.

2.2 Pursuant to the Medicinal Products Act, advertising the name of a Medicinal Product as a reminder without additional information is not permitted in Estonia.

3 PROMOTION AND ITS SUBSTANTIATION

3.1 Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the healthcare professional to form his/her own opinion of the therapeutic value of the medicinal product concerned. It should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It must not mislead by distortion, exaggeration, undue emphasis, omission or in any other way.

3.2 Promotion must be capable of substantiation, which must be promptly provided in response to reasonable requests from healthcare professionals. In particular, promotional claims about side effects must reflect available evidence or be capable of substantiation by clinical experience. Substantiation need not be provided, however, in relation to the validity of elements approved in the marketing authorisation.

3.3 Promotion must encourage the rational use of medicinal products by presenting them objectively and without exaggerating their properties. Claims must not imply that a medicinal product, or an active ingredient, has some special merit, quality or property unless this can be substantiated.

3.4 When promotion refers to published studies, clear references should be given.

3.5 Any comparison made between different medicinal products must be based on relevant and comparable aspects of the products. Comparative advertising must not be misleading or disparaging.
3.6 All artwork, including graphs, illustrations, photographs and tables taken from published studies and included in promotional material, shall:

a) clearly indicate the precise source(s) of the artwork;
b) be faithfully reproduced; except where adaptation or modification is required in order to comply with any Applicable Code(s), in which case it must be clearly stated that the artwork has been adapted and/or modified.

Particular care must be taken to ensure that artwork included in promotional material is not misleading regarding the nature of a medicine (for example whether it is appropriate for children) or a claim or comparison thereof (for example by using incomplete or statistically irrelevant information or unusual scales).
3.7 The word "safe" must never be used to describe a medicinal product without proper justification.
3.8 The word "new" must not be used to describe any medicinal product or presentation (pharmaceutical form, strength, method of administration, pack size) that has been generally available for more than one year, or any therapeutic indication that has been generally promoted for more than one year.
3.9 It must not be stated that a product has no side effects, toxic hazards or risks of addiction or dependency.

4 USE OF QUOTATIONS IN PROMOTION

4.1 Quotations from medical and scientific literature or from personal communications must be faithfully reproduced (except where adaptation or modification is required in order to comply with any Applicable Code(s), in which case it must be clearly stated that the quotation has been adapted and/or modified) and the precise sources identified.

5 ACCEPTABILITY OF PROMOTION

5.1 Member Companies must maintain high ethical standards at all times. Promotion must: (a) never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry; (b) be of a nature which recognises the special nature of medicines and the professional competence of the target group of the promotion; and (c) not be likely to cause offence.

6 DISTRIBUTION OF PROMOTION

6.1 Promotion should only be directed at those whose need for, or interest in, the particular information can reasonably be assumed.
6.2 Mailing lists of healthcare professionals must be kept up-to-date. Requests by healthcare professionals to be removed from promotional mailing lists must be complied with.
6.3 Unless otherwise provided for by law, the use of faxes, e-mails, automated calling systems, text messages and other digital methods of communications for promotion is prohibited except with the prior permission, or upon the request, of the recipient.

7 TRANSPARENCY OF PROMOTION

7.1 Promotion must not be disguised.

7.2 Clinical assessments, post-marketing surveillance, and experience programmes and post-authorisation studies (including those that are retrospective in nature) must not be disguised promotion. Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose.

7.3 Where a Member Company purchases, orders or otherwise arranges the publication of promotional material in newspapers and journals, such promotional material must not resemble independent editorial matter.

7.4 Material, which is sponsored by a Member Company financially or non-financially and relates to medicinal products and their uses, whether promotional in nature or not, must clearly indicate the fact that the Member Company has sponsored the material.

7.5 The publications that are prepared and/or sponsored by a Member Company shall indicate the date of its completion as well as the name of the relevant Member Company clearly and in a distinguishable manner.

8 PROMOTION WITHIN INTERNATIONAL EVENTS

8.1 Promotional information that appears on exhibition stands or is distributed to participants at international events may, unless prohibited or otherwise regulated by local laws and regulations, refer to medicinal products (or indications) that are not registered in the country where the event takes place, or that are registered under different conditions, so long as (i) any such promotional material is accompanied by a suitable statement indicating countries in which the product is registered and clarifying that the product or indication is not registered locally, and (ii) promotional material that refers to the prescription information (indications, warnings, etc.) authorised in a country or countries where the medicinal product is registered, is accompanied by an explanatory statement indicating that registration conditions differ internationally.

8.2 In Estonia, the promotion of medicinal products without marketing authorisation or indications not yet registered is also prohibited within international events.

9 NO ADVICE ON PERSONAL MEDICAL MATTERS

9.1 In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer should be advised to consult a healthcare professional.

SECTION 2 – COOPERATION WITH HEALTHCARE PROFESSIONALS, HEALTHCARE ORGANISATIONS AND PATIENT ORGANISATIONS

10 EVENTS AND HOSPITALITY

10.1 All events must be held in an "appropriate" location and venue that are conducive to the main purpose of the event. In this context, APME considers venues equipped with conference rooms to be "appropriate". Member Companies should avoid using venues that are "renowned" for their entertainment facilities or that are "extravagant".

10.2 No Member Company may organise or sponsor an event that takes place outside its home country, unless:

a) most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the event in another country; or
b) given the location of the relevant resource or expertise that is the object or subject matter of the event, it makes greater logistical sense to hold the event in another country (an "international event").

10.3 Hospitality extended in connection with events shall be limited to travel, meals, accommodation and registration fees. The provision, sponsorship or organisation of entertainment (e.g. sports, cultural and leisure events) as separate events or as a part of another event is not allowed.
10.4 Hospitality may only be extended to persons who qualify as participants in their own right. As an exception, a participant with special needs may be accompanied by a support person, whose participation is also subject to the conditions stipulated in this article. All forms of hospitality offered to healthcare professionals, members of healthcare organisations and representatives of patient organisations shall be "reasonable" in level and strictly limited to the main purpose of the event. As a general rule, the hospitality provided must not exceed what the participants would normally be prepared to pay for themselves. Providing meals (food and beverages) to healthcare professionals, members of healthcare organisations or representatives of patient organisations is allowed on the condition that the value of such a meal (food and beverages) in Estonia does not exceed the monetary **threshold of 80 euros with VAT per person**. The monetary threshold for meals (food and beverages) outside of Estonia is the threshold set by the country (i.e. the Host Country Principle must be followed).
10.6 Below, the APME shall provide guidance on the meaning of the terms "**reasonable**", "**appropriate**", "**renowned**" and "**extravagant**" as used in this article. The provided hospitality is reasonable if its costs remain within the average limits that the invitees would be prepared to pay for themselves. The prerequisite for an appropriate venue is the availability of conference rooms; it is also important that the invitees not participate because of the venue and that they not use the entertainment options (even if the venue does include such additional options). Since in Estonia, most venues for holding conferences are renowned as places of entertainment in one way or another, then it must be considered that the venue itself or the services it provides, except for the conference service in itself, must not be the motivation for attending the event. A venue is extravagant if its uniqueness can be considered as motivation for attending the event.

11 PROHIBITION OF GIFTS

11.1 No gift, item and souvenirs or pecuniary advantage in cash or benefit in kind or services (such as tickets to entertainment events, trips, gift cards, stationery, notepaper, etc.) may be directly or indirectly supplied, offered or promised to a healthcare professional, member of a healthcare organisation or representative of a patient organisation. This prohibition does not cover the informational or educational materials, items meant for medical utility and samples consistent with the conditions of Article 17 of this Code and hospitality related to events consistent with the conditions of Article 10 of this Code as well as support provided for participation in the medical or pharmaceutical events specified in subsection 86 (2) of the Medicinal Products Act.

12 DONATIONS AND GRANTS THAT SUPPORT HEALTHCARE OR RESEARCH

12.1 Donations and Grants (in cash or in kind or otherwise) to healthcare organisations and/or patient organisations are only allowed if: (i) they are made for the purpose of supporting healthcare, research or respective training activities; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

12.2 Donations and Grants to individual healthcare professionals are not permitted, excl. for participation in the medical or pharmaceutical events specified in subsection 86 (2) of the Medicinal Products Act. The conditions of sponsorship of healthcare professionals to attend international events is covered by Article 13.

13 CONTRIBUTION TO COSTS RELATED TO EVENTS AND SPONSORSHIP

13.1 Member Companies must comply with criteria governing the selection and sponsorship of healthcare professionals or representatives of patient organisations to attend events as provided in, or in connection with, Applicable Code(s). Funding must not be offered to compensate merely for the time spent by healthcare professionals or representatives of patient organisations in attending events.

13.2 The public use of a logo or material (intellectual property) belonging to a healthcare organisation or patient organisations by a Member Company is subject to the relevant written permission of such organisation. The organisation must be clearly informed about the exact purpose and manner of use of the logo or material when such permission is requested.

13.3 Member Companies must guarantee that the sponsorship provided by them to healthcare professionals and patient organisations is clearly declared and transparent.

14 FUNDING BY MEMBER COMPANY

14.1 A Member Company may not demand to be the only supporter or sponsor of a healthcare organisation or patient organisation or their programmes. Member Companies welcome broad-based funding and sponsorship of healthcare organisations and patient organisations from different sources.

15 CONTRACTUAL SERVICES

15.1 Contracts between Member Companies and healthcare professionals, healthcare organisations, patient organisations or representatives of patient organisations under which such persons and entities provide any type of services to Member Companies (which are not otherwise covered by the APME Code) are only allowed if such services: (i) are provided for the purpose of supporting healthcare, research or educational activities; and (ii) do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

15.2 It is permitted to enter into contracts with healthcare professionals or representatives of patient organisations, whether in groups or individually, for the provision of consultancy services, such as speaking at meetings as a lecturer, moderations of meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research where such participation involves remuneration and/or hospitality. The

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

a) a written contract is entered into in advance of the commencement of the services to specify the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;
b) a legitimate need for the services has been clearly identified and documented in advance of requesting the services and entering into a contract for this;
c) the criteria for selecting consultants are directly related to the legitimate need for the services and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular consultants meet those criteria;
d) the number of consultants retained and the scope of the service is not greater than the number reasonably necessary to achieve the legitimate need specified in the clauses above;
e) the Member Company maintains records concerning, and makes appropriate use of, the services provided by consultants;
f) the entry into a contract with a consultant to provide the relevant service is not an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product; and
g) the compensation for the services is reasonable and reflects the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensations to healthcare professionals or representative of patient organisations.

15.3 Good practice foresees that Member Companies add to the written agreements with consultants' provisions regarding the obligation of the consultant to declare that he/she is a consultant to the Member Company whenever he/she writes or speaks in public about a matter that is the subject of the agreement or any other issue relating to that Member Company.
Similar to the previous sentence Member Companies that employ, on a part-time basis, healthcare professionals that are still practising their profession, are obligated to ensure that such persons have an obligation to declare their employment arrangement with the Member Company whenever they write or speak in public about a matter relating to their employment relationship or that Member Company. The provisions of this clause apply even when the APME Code does not otherwise cover non-promotional, general information about Member Companies (as discussed in the section "Scope of the Code" section).
15.4 Limited market research, such as one-off phone interviews or mail/e-mail/Internet questionnaires are excluded from the scope of this Section, provided that the healthcare professional, member of a healthcare organisation or representative of a patient organisation is not consulted with in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal. APME shall provide guidance on the meaning of "minimal" in connection with the Code. Minimal remuneration is one that corresponds to the time spent and the minimum wages of the doctor.
15.5 If a healthcare professional or representative of a patient organisation attends an event (an international event or otherwise) in the capacity of a consultant, the relevant provisions of Section 10 shall apply.

SECTION 3 – SPECIFIC REQUIREMENTS RELATED TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

16 MEDICAL EDUCATION

16.1 The purpose of medical education is to increase the scientific knowledge and competence of healthcare professionals in order to enhance medical practice and improve patient outcome. Member Companies may have activities in different types of medical education, but this may not constitute promotion/advertising.

If Member Companies finance independent medical education or organise medical education activities themselves or via a third party, they must declare their participation and role clearly and guarantee transparency. If Member Companies participate in the determination of the content of an activity, they are also responsible for the information communicated during the respective activity. Such information must be fair, balanced and objective, and allow for presentation of different theories and recognised opinions.

17 INFORMATIONAL AND EDUCATIONAL MATERIALS AND OTHER ITEMS OF MEDICAL UTILITY

17.1 The transmission of informational or educational materials is permitted, provided that all the following conditions are met:

(i) it is directly relevant to the practice of medicine or pharmacy;
(ii) it is directly beneficial to the care of patients; and
(iii) it is inexpensive.

17.2 Items of medical utility aimed directly at the education of healthcare professionals and patient care can be provided if they are inexpensive and do not offset routine business practices of the recipient. In defining the value of informational or educational materials and items of medical utility, the APME Code relies on the following principles:

(i) the value of informational or educational materials must not exceed the reasonable market price of creating similar materials:
(ii) the value of an item of medical utility must not exceed a price that is reasonably necessary for achieving or fulfilling the educational need related to the item.

17.3 Informational or educational materials and items of medical utility may not constitute a circumvention of the prohibition on gifts stipulated in Section 11 of the APME Code. Informational and educational materials and items of medical utility may not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific medicinal products.

17.4 Informational or educational materials and items of medical utility may bear the name of the Member Company, but they may not bear the product name or brand features (e.g. Trademark), unless this is permitted by legislation and the name of the medicinal product is essential so that a patient can use the material or the item correctly.

18 NON-INTERVENTIONAL STUDIES OF MARKETED MEDICINAL PRODUCTS

18.1 Non-Interventional Studies must be conducted with a primarily scientific purpose and must not be disguised Promotion.

18.2 Non-interventional studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study must comply with all of the following criteria:

a) the study is conducted with a scientific purpose;
b) there is a written study plan (protocol);
c) any remuneration provided is reasonable and reflects the fair market value of the work performed;
d) the study protocol should be submitted to the ethics committee for review;
e) applicable law and regulations on personal data privacy (including the collection and use of personal data) must be respected;
f) the study must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product;
g) the study protocol must be approved by the Member Company's scientific service and the conduct of the study must be supervised by the company's scientific service as described in Section 20.02(a);
h) the study results must be analysed by or on behalf of the Member Company and summaries thereof must be made available within a reasonable period of time to the Member Company's scientific service (as described in Section 20.02(a)), which shall maintain records of such reports for a reasonable period of time. The Member Company should send the summary report to all healthcare professionals that participated in the study and should make the summary report available to the Ethics Committee of the Association of Pharmaceutical Manufacturers in Estonia that is in charge of supervising or enforcing the APME Code upon their request. If the study shows results that are important for the assessment of benefit-risk, the summary report should be immediately forwarded to the relevant competent authority;
i) medical sales representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the Member Company's scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

18.3 To the extent applicable, Member Companies are encouraged to comply with Section 18.02 for all other types of non-interventional studies, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Section 15.01.

19 SAMPLES

19.1 Distribution of samples is an activity that may only occur in exceptional cases. Samples may not be provided as an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product, and they may not be given for the sole purpose of treating patients. Samples are provided to healthcare professionals so they can get to know a new medicinal product and gain experience in its use. In the context of distribution of samples, the term "healthcare professional" only means persons qualified to prescribe medicinal products, because samples may only be provided to them pursuant to the Medicinal Products Act.

19.2 Pursuant to applicable laws and regulations, a limited number of samples may be distributed in a limited period of time. As samples of medicinal products, one

healthcare professional can be provided with up to five packs in the smallest marketed pack size of a medicinal product with a marketing authorisation and the total of distributable samples is 300 packs a year for up to two years from distributing the first sample or from the approval date of a new indication. In this context, a new medicinal product is a product for which a new marketing authorisation has been granted, either following an initial marketing authorisation application or following an extension application for new strengths/dosage forms that include a new indication. Extensions of the marketing authorisation to additional strengths/dosage forms for existing indications or pack sizes (number of units in the pack) cannot be considered as new medicinal product.

19.3 Samples of a particular medicinal product may be provided on the basis of a written and signed application only to healthcare professionals who are qualified to prescribe that medicinal product. The time and place of providing a sample of a medicinal product, as well as the persons of the provider and the recipient shall be documented in two copies, one of which shall be kept by the provider and the other by the recipient, and the recipient of the sample shall confirm the receipt of the sample with his/her signature.

19.4 Member Companies must have adequate systems of control and accountability for samples that they distribute and for all medicines handled by their medical sales representatives.

19.5 Each sample of a medicinal product shall be marked with the words "Mitte müügiks" (not for sale), the package shall conform to the marketing authorisation, and each sample shall be accompanied by a copy of the summary of product characteristics. Samples of medicinal products shall not be sold or transferred for non-medical purposes.

19.6 Pursuant to the Medicinal Products Act, no samples of medicinal products containing narcotic drugs or psychotropic substances, or antibiotics may be supplied to any person.

20 MEMBER COMPANY STAFF

20.1 Each Member Company shall ensure that its Medical Sales Representatives are familiar with the relevant requirements of the Applicable Code(s), and all applicable laws and regulations, and are adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the medicinal products they promote.

a) Medical Sales Representatives must comply with all relevant requirements of all Applicable Code(s), and all applicable laws and regulations, and Member Companies are responsible for ensuring the compliance of their activities.
b) Medical Sales Representatives must perform their duties responsibly and ethically.
c) During each visit, and subject to applicable laws and regulations, Medical Sales Representatives must give the persons visited, or have available for them, a summary of the product characteristics for each medicinal product they promote.
d) Medical Sales Representatives must transmit to the scientific service of their company forthwith any information they receive in relation to the use of the company's medicinal products, particularly reports on side effects caused by the use of the medicinal product, use of the medicinal product outside the summary of product characteristics of the medicinal product or problems with the quality of the medicinal product.

e) Medical Sales Representatives must ensure that the frequency, timing and duration of visits to healthcare professionals, pharmacies, hospitals or other healthcare facilities, and the manner, in which they are made, do not cause inconveniences.
f) Medical Sales Representatives must not use any inducement or subterfuge to gain an interview. During an interview, or when seeking an appointment for an interview, Medical Sales Representatives must, from the outset, take reasonable steps to ensure that they are not misleading as to their identity or that of the Member Company they represent.
g) A pharmaceutical company is fully responsible for the prevention of conflicts of interest between the work of a Medical Sales Representative and the prescription of medicinal products. A Medical Sales Representative may not, at the same time, work in a position qualified to prescribe or dispense medicinal products.

20.2 All staff of the Member Company must be fully familiar with the requirements of the Applicable Code(s) and relevant laws and regulations.

a) Every Member Company must establish a scientific service in charge of information about its medicinal products and the approval and supervision of non-interventional studies. Member Companies are free to decide how best to establish such service(s) in accordance with Section 20.02 (i.e. whether one service in charge of both duties or separate services with clearly determined duties), taking into account the company's resources and organisation. The scientific service must include a medical doctor or, where appropriate, a pharmacist who will be responsible for approving any promotional material before release. Such a person must certify that he/she has examined the final form of the promotional material and that in his/her belief, it is in accordance with the requirements of the Applicable Code(s) and any applicable legislation, is consistent with the summary of product characteristics, and is a fair and truthful presentation of the facts about the medicine. In addition, the scientific service must include a medical doctor or, where appropriate, a pharmacist, who will be responsible for the oversight of any non-interventional study (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by Medical Sales Representatives). Such a person must certify that he/she has examined the protocol relating to the non-interventional study and that in his/her belief it is in accordance with the requirements of the Applicable Code(s) and legislation.
b) Each Member Company must appoint at least one senior employee who shall be responsible for supervising the Member Company and its subsidiaries to ensure that the standards of the Applicable Code(s) are met.
c) A representative of a Member Company must declare to the audience of the presentation which company and which position he/she represents, while Medical Sales Representatives with a medical degree (doctors, pharmacists, nurses, etc.) shall be obligated to declare a simultaneous connection/non-connection with any medical activity as, e.g. a doctor, pharmacist, nurse, etc.

SECTION 4 – SPECIFIC REQUIREMENTS RELATED TO PATIENT ORGANISATIONS

21 COOPERATION WITH PATIENT ORGANISATIONS

21.1 Member Companies must comply with the following principles, which have been agreed between the EFPIA and the pan-European patient organisations:

a) The independence of patient organisations in their political judgement, policies and activities must be assured.
b) Cooperation between patient organisations and Member Companies is based on mutual respect, and the views and decisions of each partner are equally valuable.
c) Patient organisations may not promote specific medicinal products and Member Companies may not ask them to do so.
d) The objectives and scope of all cooperation activities between Member Companies and patient organisations must be transparent. Any financial or in kind support must always be clearly acknowledged.
e) Member Companies welcome broad-based funding of patient organisations from different sources.

21.2 The legislation effective in the EU and Estonia prohibits advertising prescription-only medicinal products to the general public.

21.3 If a Member Company grants financial support, indirect support and/or support in kind to a patient organisation, the Member Company must have in place a written contract about this with the patient organisation. The amount and objective of the support (e.g. general support, support for a specific meeting or publication, etc.) must be set out in the contract. It must also include the description of the indirect support (e.g. allowing for use of the services of a public relations company and its role in said cooperation) and support in kind.

21.4 Member Companies may not influence the text of the materials of the patient organisation they sponsor in a manner that promotes their business interests. However, it does not prohibit Member Companies from correcting factual inaccuracies. At the request of a patient organisation, a Member Company may participate in the preparation of texts proceeding from a fair and balanced scientific point of view.

SECTION 5 – DISCLOSURE OF PAYMENTS

22 DISCLOSURE OF PAYMENTS MADE TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS

22.1 Payments made during a calendar year either directly or indirectly to healthcare professionals and healthcare organisations and to third parties in their benefit shall be disclosed on 1 June after the end of the reporting year on the Member Company's website according to the APME Code Appendix C1 Data disclosure form. Payments referred to in the previous sentence (hereinafter referred to as "payments") paid to healthcare professionals and healthcare organisations or to third parties in their benefit (service providers such as accommodation establishments) are:

a) registration fees for events (e.g. conferences);
b) travel and accommodation expenses for events;
c) service or consultancy fees;

d) research and development related fees;
e) and payments paid to healthcare organisations:
f) donations; and
g) grants.

22.2 The disclosure of the data shall be made at the Member Company's website in Estonian and if needed in English no later than on 1 June after the end of the relevant reporting year.
22.3 Contribution to event-related costs such as registration fees, travel and accommodation costs, fees for service and consultancy paid to health care professionals or such payments made on their behalf shall be disclosed on an individual basis aggregating all payments made per each of the aforementioned categories.
22.4 Donations and grants, contribution to event-related costs such as registration fees, travel and accommodation costs, fees for service and consultancy paid to healthcare organisations shall be disclosed on an individual basis aggregating all payments made per each of the aforementioned categories.
22.5 Payments belonging to the aforementioned payment categories, which cannot be disclosed on an individual basis for legal reasons, shall be disclosed on an aggregate basis, identifying the number of recipients, and the number and percentage of the recipients with aggregated amounts out of the total of recipients of the category in question and the total of the aggregated amount.
22.6 In order to avoid duplication of disclosing the data in cases where payments to healthcare professionals are made through a healthcare organisation the data shall be published once and, if at all possible (considering the need to guarantee the accuracy, consistency and compliance of the data), under the name of the healthcare professional (not the healthcare organisation).
22.7 Research and development payments, including costs related to events clearly connected with such activities, shall be disclosed on an aggregate basis. According to the term generally applied, payments related to research and development made to healthcare professionals and healthcare organisations or on their behalf are payments related to the planning or implementation of the following activities: (i) non-clinical trials (according to the definition given in OECD Principles on Good Laboratory Practice); (ii) clinical trials (according to the definition given in EU Regulation 536/2014); and (iii) non-interventional studies that are prospective in nature and during which data about patients are collected from healthcare professional(s) or on his/her/their behalf for the implementation of the study.
22.8 All payments made to healthcare professionals and healthcare organisations shall be disclosed in euros. Payments agreed in multiannual contracts shall be disclosed in the actual payment amount of the reporting year.
22.9 Each Member Company shall publish a note summarising the methodologies used by it in disclosing the payments made to healthcare professionals and healthcare organisations or in their benefit. The note shall describe the recognition methodologies applied and should include the treatment of multi-year contracts, currency aspects and other issues related to the timing and amount of payments for purposes of this Code, as applicable. The methodology note must include – if necessary, separately for each category of payments and expenditure – information on whether and which taxes included (e.g. VAT, income tax) are included in the amounts disclosed.
22.10 The methodology note referred to in the preceding paragraph must include exhaustively the type of payments included in the research and development amount

disclosed by the Member Companies – to make it clear whether the amount disclosed includes, for example (but not limited to) expenses of meetings of investigators and Steering Committees and/or research and development-related events, consultancy fees, transport and accommodation costs, etc.
22.11 Disclosed payments shall be kept available at the Member Companies' website for a minimum of three years after the time such information is first disclosed. Member Companies shall maintain the relevant records of the disclosures made for a minimum of five years after the end of the relevant reporting year according to the archiving rules established within the Member Companies.
22.12 The Member Companies shall also proceed from the provisions of the EFPIA Code and its annexes and any other explanations given by the EFPIA in any other format (e.g. guidelines, frequently asked questions) upon the performance of the disclosure obligation arising from this article.
22.13 Payments made to healthcare professionals and/or healthcare organisations with establishments in Estonia are disclosed on the basis of the APME Code. Payments made by Member Companies to healthcare professionals and/or healthcare organisations with establishments in foreign countries are disclosed pursuant to the national code of the respective foreign country.
22.14 Violations of the obligation to disclose payments made to health care professionals and healthcare organisations or in their benefit shall be handled by the APME Ethics Committee according to the procedures and sanctions stipulated in Article 24 of this code.

23 DISCLOSURE OF SUPPORT AND SERVICES PROVIDED TO PATIENT ORGANISATIONS

23.1 Each Member Company must disclose the list of patient organisations to which it grants financial support and/or significant support that is indirect/in kind or from which it receives contractual services.
23.2 The data to be disclosed must include a brief description of the type of the provided support or service that is detailed enough to enable the average reader to understand the nature of the support or agreement without the need to disclose confidential information.
23.3 In addition to the name of the patient organisation, the disclosed data must include:

a) in the case of support:
   (i) monetary value of the support and invoiced costs;
   (ii) benefit in kind, which the patient organisation will obtain if no monetary value can be attributed to the support in kind;
b) in the case of contractual services: the total amount paid to the patient organisation during the reporting period.

23.4 The above data shall be annually disclosed at the Member Companies' website either at the local or European level and each reporting period covers the entire calendar year. Data shall be disclosed by 1 June of the year following the reporting year and kept available for a minimum of three years after the time such information is first disclosed.
23.5 Each Member Company shall disclose the methodologies used by it in disclosing data and identifying the relevant support and services.

SECTION 6 – RULES OF PROCEDURE

24 IMPLEMENTATION OF THE CODE AND RULES OF PROCEDURE

24.1 Notifications of breaches of the APME Code can be filed by the Member Companies or by the representatives of the public.
24.2 Breach notifications shall be handled by the Ethics Committee of the Association of Pharmaceutical Manufacturers in Estonia (Ethics Committee) established under the APME.
24.3 The Ethics Committee shall handle all cases that have occurred on the Estonian pharmaceutical market and been committed both by companies belonging and companies not belonging in the APME. If the case concerns a company not belonging in the APME either via its local office or its parent company, the Committee shall handle the case analogously to cases concerning Member Companies.
24.4 Breach notifications must be filed in the written form with the signature of the official representative and include the following information:

1) name of the person filing the breach notification;
   Personal data of the submitter of the breach notification, his/her exact postal address, e-mail address, and if necessary, fax number.
2) name of the enterprise in alleged violation of the Code:
   In every case referred to in the notification, the name of the company in alleged violation of the Code and the name of the relevant product or products.
3) reference material
   In every case, evidence on the promotion or another activity that the notification is based on shall be presented in print or in another form.
4) date
   The date of the alleged breach of the Code.
5) Content of the notification
   For every case, a short description of the breach with a reference to the Section or Clause of the Code, whose violation the notification addresses, must be given.

24.5 All notifications shall be addressed to:

Association of Pharmaceutical Manufacturers in Estonia
Hobujaama 4
10151 Tallinn
ESTONIA

info@rtl.ee

24.6 One notification may include several cases, i.e. a notification may refer to promotion by various companies and/or concerning various products. The Ethics Committee shall handle each case separately.
24.7 If a notification, which is in compliance with the requirements described in clause 24.04 and refers to an alleged breach of the Code, reaches the coordinator of the Ethics Committee, he/she will register the notification and send it to all members of the Ethics Committee as soon as possible (in electronic format).

24.8 In each case, first the company referred to in the notification is determined, then its location in Estonia (if the company has an office in Estonia), and its headquarters or parent company and address.
24.9 A summary of the case presented in the notification and possible evidence is sent to the Estonian address of the company that has breached the APME Code (if the company has no Estonian address, to the address of its headquarters or the parent company).
24.10 When a notification reaches the Ethics Committee on the matter of an alleged breach of the APME Code, it should first be determined whether:

a) the notification is true and made in good faith;
b) the information presented is adequate enough to handle the notification.

24.11 If the initial information provided in the notification is insufficient to handle the case, the coordinator of the Ethics Committee will contact the person who filed the complaint as soon as possible to obtain additional information.
24.12 If a notification does not constitute grounds to initiate proceedings or is clearly guided by the submitter's commercial interests, the Ethics Committee shall have the right to reject the notification.
24.13 Should the submitter of the notification wish, he/she can withdraw the notification before the first meeting of the Ethics Committee regarding the specific notification. The withdrawal must be justified to the Ethics Committee in writing. The Ethics Committee will decide whether or not to satisfy the withdrawal application on the meeting following the receipt of the application.
24.14 Within five working days since registering the initial notification (during the holiday period, as soon as possible), the coordinator of the Ethics Committee shall send the notification to the head of the pharmaceutical company referred to as the alleged Code violator in the notification, who has the right to submit his/her explanations to the Ethics Committee within 10 working days.
24.15 A case shall be included in the agenda of the next planned Ethics Committee meeting, if 15 working days remain between forwarding the notification to the alleged Code violator and the date of the planned meeting. Otherwise, discussions on the case shall be postponed.
24.16 Information concerning the content of notifications, relevant materials and submitters shall only remain known to the Ethics Committee, the coordinator of the Ethics Committee and the effective manager of the APME, and shall not be disclosed to third parties without the corresponding decision of the Ethics Committee.
24.17 If the Ethics Committee is unable to make a relevant decision on the basis of the information provided in the notification and by the alleged violator, the Ethics Committee may request additional information from the parties and postpone the decision being made until the next Ethics Committee meeting.
24.18 If necessary, the Ethics Committee may involve experts in handling the case or ask the opinion of an expert.
24.19 If a notification is aimed against an enterprise belonging in the Ethics Committee, then the representative of the enterprise shall remove himself/herself from making decisions on the case.
24.20 The representatives of both the submitter of the notification as well as the company that is the subject of the notification may participate in the meeting and give explanations about the case concerning them, should they so wish.

24.21 In case of a repeat breach of the Code damaging the reputation and credibility of the Ethics Committee, the Ethics Committee may request that the APME Board remove the representative of the company belonging in the Committee from the work of the Committee, if the representative has not resigned himself/herself.
24.22 Upon a first-time breach, the Ethics Committee shall have the right to issue a warning to the enterprise that violated the provisions of the Code, along with the order to terminate the breach immediately. In the case of a serious first-time breach, the Ethics Committee shall have the right to make a financial claim of up to 1300 euros, which shall be transferred to the bank account of the APME within 10 working days as of receipt the claim.
24.23 Serious first-time breaches are considered to be cases of obvious malicious activity, which ignore ethical standards on purpose.
24.24 In the case of a repetitive and malicious breach of the APME Code, the Ethics Committee shall have the right to present the violator of the Code's provisions with a financial claim of up to 6400 euros, and demand that the violator terminate the breach immediately and compensate for any damage.
24.25 The Ethics Committee's decision shall be disclosed on the APME website. The decisions shall be published in summary and do not contain data on individuals. If necessary, the parent company of the enterprise in violation of the provisions of the Code, the State Agency of Medicines, and the EFPIA can be notified of the breach, and the case can also be publicised in the media.
24.26 The Ethics Committee shall include five members of which three members are not associated with pharmaceutical companies. The Ethics Committee shall be elected for three years on the proposal of the APME members and on the approval of the APME Supervisory Board.
24.27 The three members of the Ethics Committee that are not associated with pharmaceutical companies ("external members") receive a fee for their work in the Ethics Committee in an amount that is agreed with the APME Board. The Chairman of the Ethics Committee shall be elected from the external members; the external members take part in the election.
24.28 The work formats of the Ethics Committee are meetings, phone meetings and virtual communication. The meetings of the Ethics Committee take place according to the number of the notifications submitted and the questions arisen, but no less frequently than three times a year.
24.29 The coordinator of the work of the Ethics Committee, who is an employee of the Association of Pharmaceutical Manufacturers in Estonia, will also take part in the Ethics Committee's meetings as (he/she will take minutes of the meeting, concord the minutes/decision after the meeting with the members of the Ethics Committee, inform the members of the APME about the decisions of the Ethics Committee, and perform other relevant information exchange, meeting planning and document management of the Ethics Committee).
24.30 The Ethics Committee has a quorum, if all three external members with voting rights take part in the meeting. The Ethics Committee decisions shall be made in an open vote by a simple majority.
24.31 The pharmaceutical company which the Ethics Committee has decided against has the right to appeal the decision by submitting a relevant application to the APME Board within 10 calendar days from the announcement of the decision. Within 30 calendar days of receiving the appeal referred to in the previous sentence the APME

Board convenes on an ad hoc basis an Appeals Committee which includes 3 members not related to pharma-ceutical manufacturers. The Appeal Committee's review of the Ethics Committee decision is carried out following the same procedures that are applied to the Ethics Committee in this chapter.

24.32 The Ethics Committee is authorised to give advice and recommendations on implementing and interpreting the requirements of the APME code.

25 ENTRY INTO FORCE OF APME CODE

25.1 This version of the APME Code adopted on 8-th of June 2023 enters into force on the date of its adoption.