KEFEA CODE OF PRACTICE

Adopted by the KEFEA Board of Directors on 15 December 2022

The KEFEA Code constitutes the collection of ethical rules agreed by KEFEA members for the Promotion of Medicinal Products to Healthcare Professionals (HCPs) and the interactions with HCPs, Healthcare Organisations (HCOs) and Patient Organisations (POs), with the intent of guaranteeing that these activities are conducted while respecting the most stringent ethical principles of professionalism and responsibility.

This Code applies to all types of communication and interaction (traditional and digital).

This Code, as adopted by the KEFEA Board of Directors on 15 December 2022, repeals and replaces any and all previous versions of the KEFEA Code of Conduct, the KEFEA Disclosure Code and the KEFEA Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations.

There will be a grace period of three months after the Code's adoption by the KEFEA Board of Directors for KEFEA members to update their processes from the previous version of the KEFEA Code of Conduct to this one.

The KEFEA Code has been translated into Greek for its members' ease of reference. In the event of any discrepancy between the Greek and the English versions of the Code, the English version shall prevail.

TABLE OF CONTENTS

- **ANNEXES**

Annex A (binding)	KEFEA standardised disclosure template
Annex B (binding)	KEFEA Guidance on Disclosure of Non-Interventional Studies
Annex C (binding)	KEFEA standard operating procedure related to processing of complaints and questions submitted to KEFEA or forwarded from EFPIA
Annex D (binding)	KEFEA Process for Requesting an Exception to Hold an Event at a 5* or more Location

Non-binding annexes:

Annex E	PO Disclosure template (optional but recommended)
Annex F	KEFEA Guideline on a Quality Framework Principles in Lifelong Learning in Healthcare

DEFINITIONS

Definitions of capitalised terms are included to ensure their consistent understanding.

Appeals Board: the five-person disciplinary committee which will be in charge of upholding the Code. It consists of a lawyer or former judge, a health care professional and three members of KEFEA (who are not members of the Disciplinary Committee). The members of the Appeals Board are published on KEFEA's website.

Applicable Codes:

(a) (i) in the case of Promotion or interaction that is undertaken, sponsored or organised by or on behalf of, or with, a Member Company located within Europe, the Member Association National Code of the country in which such Member Company is located; or (ii) in the case of Promotion or interaction that is undertaken, sponsored or organised by or on behalf of, or with, a Member Company located outside of Europe, the EFPIA Code; and

(b) the Member Association's National Code of the country in which the Promotion or the interaction takes place.

In case of an international Event for which a KEFEA member sponsors the attendance of an HCP, if any funding is provided to such HCP in accordance with the provisions of Article 13, such funding is subject to the rules of the National Code where such HCP carries out his/her profession, as opposed to those in which the international Event takes place.

In the event of a conflict between the provisions of the Applicable Codes set forth above, the more restrictive of the conflicting provisions must apply, except for the application of Article 10.05, where the monetary threshold set in the country where the event takes place (i.e. the "host country") must prevail.

Contribution to Costs related to Events: is a support providing or covering the costs of meals, travel, accommodation and/or registration fees to support

the attendance of an individual HCP or PO Representative to an Event organised or created by a KEFEA member and/or a Third Party.

DLC: means a doctors' limited company, pursuant to section 8(5) of the Medical Registration Law (Cap. 250) (as amended).

DELC: means a dentists' limited company, pursuant to section 10A(5) of the Dentists' Registration Law (Cap. 249) (as amended).

Donations and Grants: collectively mean providing funds, 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.

Disciplinary Committee: the three-person disciplinary committee which will be in charge of upholding the Code. It consists of three members of KEFEA. The members of the Disciplinary Committee are published on KEFEA's website.

European Federation of Pharmaceutical Industries and Associations (EFPIA): is the representative body of the pharmaceutical industry in Europe.

EFPIA Code: the EFPIA Code of Practice, including those Annexes which are expressly mentioned as binding and which form part of the same Code.

Europe: includes those countries in which the EFPIA Member Associations' National Codes apply.[1]

Events: All professional, promotional, scientific, educational meetings, congresses, conferences, symposia (including Satellite Symposia), and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) organised or sponsored by or on behalf of a KEFEA member.

GeSY: the national healthcare system established by virtue of the General Healthcare System Law of 2001 (L.89(I)/2001) (as amended).

Government Official: means a person holding any of the below offices or exercising the duties relevant to such office, either directly or as a substitute or otherwise, that is:

i. any public office as well as any public position, if the authority to appoint or dismiss the said person in this position lies with the President of the Republic or the Council of Ministers or any public commission or council; or

[1] As of June 2019, these countries include: Austria, Belgium, Bosnia Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Malta, the Netherlands, North Macedonia, Norway, Poland, Portugal, Romania, Russia, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United Kingdom.

ii. any position, to which a person is appointed by law or is elected; or
iii. any public position, if the authority to appoint or dismiss lies with a person or persons holding public office or a public position; or
iv. any position of an arbitrator or a referee in an arbitration being carried out in accordance with a Court order or Court approval, or within the framework of the application of any law; or
v. the members of any commission of inquiry, appointed by virtue of any law; or
vi. any persons dealing with the execution of warrants and orders of the Court; or
vii. any persons belonging to the National Guard or any Police service of the Republic of Cyprus; or
viii. any persons serving in any government department; or
ix. any persons in the service of any public authority; or
x. the muhtar or any member of the village council.

Healthcare Organisation (HCO): any legal person/entity (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for POs within the scope of Article 21) whose business address, place of incorporation or primary place of operation is in Cyprus or (ii) through which one or more HCPs provide services.

Healthcare Professional (HCP): any natural person that is a 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 primary practice, principal professional address or place of incorporation is in Cyprus. For the purpose of this Code, the definition of HCPs includes: (i) any official or employee of a government, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer Medicinal Products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of Medicinal Products.

Host Country Principle: refers to the primacy of the monetary threshold for a meal (food and beverages) set by the relevant Member Association in its National Code.

The monetary threshold set in the country where the Event takes place must prevail.

Informational or Educational Material: constitutes inexpensive material directly relevant to the practice of medicine or pharmacy and directly beneficial to the care of patients.

Item of Medical Utility: constitutes an inexpensive item aimed directly at the education of HCPs enhancing the provision of medical services and patient care and that do not offset routine business practices of the HCPs. They generally include items that are beneficial to enhancing the provision of medical services and patient care, and have no personal benefit to the HCP.

KEFEA Code: The present document, including those Annexes which are expressly mentioned as binding and which form part of the same Code.

Location: refers to the geographic place where the Event is organised (e.g. the city, town).

Lifelong learning in healthcare (LLH): constitutes non-promotional education related to human health and diseases. It can be provided orally, in writing, remotely or using other technological means.

Medical Sales Representative: personnel, including personnel retained by way of contract with third parties, and any other company representatives who call on healthcare professionals, pharmacies, hospitals or other healthcare facilities in connection with the promotion of medicine.

Medical Sample: sample of Medicinal Product 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.

Medicinal Product: has the meaning set forth in Article 1 of the Directive 2001/83/EC and section 2 of the Medicines for Human Use (Quality Control, Supply and Pricing) Law of 2001 (L. 70(I)/2001) (as amended), namely: (a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Medicines Law: is the Medicines for Human Use (Quality Control, Supply and Pricing) Law of 2001 (L. 70(I)/2001) (as amended).

Member Association: as defined in the EFPIA Statutes, means an organisation representing pharmaceutical manufacturers at national level whose members include, among others, research-based companies. Collectively, the national Member Associations or their constituent members, as the context may require, are bound by the EFPIA Code.

Member Company: means companies that are members of EFPIA.

KEFEA Member Staff: personnel employed by a KEFEA member or retained by way of contract with Third Parties, who are concerned with any matter covered by this Code.

National Code: The code of practice of a Member Association.

Non-Interventional Study (NIS): is a study where the Medicinal Product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current 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 must be applied to the patients and epidemiological methods must be used for the analysis of collected data.

Patient Organisation (PO): non-for-profit legal person/entity (including the umbrella organisation to which it belongs), mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and which business address, place of incorporation or primary place of operation is in Cyprus.

Patient Organisation Representative: is a person who is mandated to represent and express the collective views of a PO on a specific issue or disease area.

Personal Health Data: is 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.

Prescription-Only Medicines (POM): is a Medicinal Product that requires a medical prescription issued by a professional person qualified to prescribe.

Promotion: includes any activity undertaken, organised or sponsored by a KEFEA member, or with its authority, which promotes the prescription, supply, sale, administration, recommendation or consumption of its Medicinal Product(s).

Recipient: any HCP or HCO or PO as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Cyprus.

Reporting Period: refers to the annual disclosure cycle and covers a full calendar year.

Research and Development Transfers of Value: Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Regulation 536/2014); or (iii) NIS that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study.

Satellite Symposia: symposia of a promotional or non-promotional nature, organised by KEFEA Member Companies in the context of third-party scientific/educational events (e.g. congresses organised by HCOs).

Sponsorship: is a support provided by or on behalf of a KEFEA member, when permitted by law, as a contribution to support an activity (including an Event) performed, organised or created by a HCO, a PO or a Third Party.

Third Party: is a legal person/entity or individual that represents a KEFEA member or interacts with other Third Parties on behalf of a KEFEA member or relating to the KEFEA member's Medicinal Product, such as distributors, wholesalers, consultants, contract research organisations, professional congress organisers, contracted sales forces, market research companies,

advertising agencies, providers of services related to Events, public relations services, non-clinical, non-interventional studies management services.

Transfers of Value (ToV): Direct and indirect ToV, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of POM exclusively for human use. Direct ToVs are those made directly by a KEFEA member for the benefit of a Recipient. Indirect ToVs are those made on behalf of a KEFEA member for the benefit of a Recipient, or those made through a Third Party and where the KEFEA member knows or can identify the Recipient that will benefit from the Transfer of Value.

Venue: refers to the logistic place where the Event is organised (i.e. the hotel, the congress centre).

PREAMBLE

This document replaces previous codes issued by KEFEA, namely:

- KEFEA Code of Conduct (dated 7 January 2016);
- KEFEA Code of Practice on Relationships Between the Pharmaceutical Industry and Patient Organisations; and
- KEFEA Disclosure Code.

ETHICAL PRINCIPLES

As pharmaceutical companies, we work in collaboration with various stakeholders including HCPs, HCOs, POs and their representatives, regulatory authorities, governments and the public to improve health and quality of life.

We continuously invest in research and development to deliver new treatments for medical needs and improving the quality of treatment.

As commercial organisations, we encourage competition and economic development to sustain investment and foster innovation.

We believe in what we do and know that there is somewhere a patient whose health and wellbeing is, directly or indirectly, dependent on our work.

We aim at creating an environment where our stakeholders and the general public, consider pharmaceutical companies as trusted partners.

In addition to complying with extensive legal requirements (i.e. laws and regulations applicable to our industry such as pharmaceutical, competition, intellectual property and data protection laws as well as anti-bribery and anti-corruption legislation), the pharmaceutical industry has agreed to comply with additional standards in its self-regulatory codes and joint positions.

For KEFEA, self-regulation means being fully committed to define, implement, comply with and enforce the highest ethical standards through EFPIA and, inter alia, this Code, where breaches are not tolerated.

Self-regulation includes the concept of continuous challenge for us to exceed society's expectations and openness regarding suggestions from others on how we might further strengthen confidence in our industry and our behaviour.

Stakeholders who share the values and principles enshrined in this self-regulation are invited to adhere to these rules and guidance[2].

This demonstrates our commitment to the following ethical principles:

First and foremost, the **PATIENTS ARE AT THE HEART OF WHAT WE DO.** We aspire to ensure that everything we do will ultimately benefit patients. Our

[2] EFPIA Leadership statement on ethical practices – June 2010

primary contribution to society is to make high-quality Medicinal Products and to encourage their appropriate and rational use in the care pathway.

We act with **INTEGRITY**, interact in a responsible manner and aim to ensure that our communications with stakeholders are accurate, legitimate and balanced. We are accountable for our decisions, actions and interactions and we encourage others to follow the same high ethical standards.

We interact with all our stakeholders with **RESPECT**. We commit to approaching our stakeholders in an open manner, with a responsive, constructive and learning attitude and mutual respect. We value the importance of independent decision-making by stakeholders, based on evidence and including patient interest. With respect to society, we listen to what is expected from us and adapt our way of working accordingly. We follow applicable laws and make ethical judgements when processing Personal Health Data.

We are committed to ensuring that **TRANSPARENCY** is respected. We are open about our activities and interactions and encourage stakeholders to act with the same openness.

INTRODUCTION

KEFEA's membership[3] is composed of full and affiliate members, which are either research-based pharmaceutical companies or members of EFPIA.

Separate entities belonging to the same multinational company – which could be the parent company (e.g. the headquarters, principal office, or controlling company of a commercial enterprise), subsidiary company or any other form of enterprise or organisation – are deemed to constitute a single company, and are as such committed to comply with the KEFEA Code.

KEFEA and its members[4] are conscious of the importance of (i) providing accurate, fair and objective information about Medicinal Products so that rational decisions can be made as to their use, (ii) ensuring that interactions with HCPs, HCOs and POs, which are key to sharing knowledge aiming to improve the quality of patient care, take place in an ethical manner and (iii) introducing greater transparency around the pharmaceutical industry's interactions with HCPs, HCOs and POs.

Chapters 1, 2 and 3 reflect the requirements of Council Directive 2001/83/EC (transposed into Cypriot law by the Medicines Law, as amended), relating to Medicinal Products, and fit 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.

[3] Article 3 of KEFEA Articles of Association

[4] The updated list of KEFEA membership can be found on http://kefea.org.cy/members/.

KEFEA encourages competition among pharmaceutical companies. The KEFEA Code is not intended to restrain the Promotion of Medicinal Products to HCPs, or limit interactions with HCPs, HCOs, and POs in a manner that is detrimental to fair competition. Instead, it seeks to ensure that pharmaceutical companies conduct such Promotion and interactions in a truthful manner, avoiding deceptive practices and potential conflicts of interest with stakeholders, and in compliance with applicable laws and regulations.

The KEFEA Code thereby aims to foster an environment where the Cypriot general public can be confident that the choices regarding their Medicinal Products are being made on the basis of the merits of each product and the healthcare needs of patients.

HCPs and HCOs provide the pharmaceutical industry with valuable, independent and expert knowledge derived from their clinical and scientific experience. This expertise makes an important contribution to the industry's efforts to improve the quality of patient care, with benefits for individuals and society at large. HCPs and HCOs should be fairly remunerated for the legitimate expertise and services they provide to the industry.

EFPIA and KEFEA believes that interactions between their members and HCPs have a profound and positive influence on the quality of patient treatment and the value of future research. At the same time, the integrity of the decision of an HCP to prescribe a Medicinal Product is one of the pillars of the healthcare system. EFPIA and, inter alia, KEFEA recognise that interactions between the industry and HCPs/HCOs can create the potential for conflicts of interest. Consequently, professional and industry associations, including EFPIA and, inter alia, KEFEA, have adopted codes and guidelines to ensure that these interactions meet the high standards of integrity that patients, governments and other stakeholders expect.

In order, to continue to be successful, self-regulation needs to respond to the evolving demands of society. In particular, EFPIA and, inter alia, KEFEA recognise the growing expectation that interactions with society are not only conducted with integrity but are also transparent.

In the same way, the pharmaceutical industry works with POs to learn from their knowledge and experience of patient's condition that is able to provide a true picture of what it is like to live with a specific condition, how care is delivered, how that impacts on them, their careers and families and how medicines and other treatments can change their quality of life and meet their needs.

POs have a key role in helping to shape, develop and define the outcomes that make the most difference to patients. KEFEA members disclose the amounts provided to POs in the framework of these interactions.

EFPIA and KEFEA strongly support public scrutiny and the understanding of these relationships and disclosure contributes to the confidence of stakeholders in the pharmaceutical industry.

In relation to working with HCPs and HCOs, since the introduction of the KEFEA Disclosure Code, KEFEA has worked hard to encourage its members to always

look to disclose and to encourage HCPs (and HCOs where relevant) to agree to individual disclosure. Members will not be criticised for over-disclosure.

SCOPE OF THE KEFEA CODE

The KEFEA Code covers:

- Promotion of POMs to HCPs;
- interactions between KEFEA members and HCPs, HCOs and POs;
- disclosure of ToVs from KEFEA members to HCPs, HCOs and POs; and
- procedural requirements of the KEFEA Code.

Members of KEFEA are responsible for the obligations imposed under this Code even if they commission a Third Party to design, implement or engage in activities covered by the Code on their behalf. In addition, members of KEFEA must take reasonable steps to ensure that any other parties that they commission to design, implement or engage in activities covered by the Code but that do not act on behalf of the member (e.g. joint ventures, licensees) comply with the Code.

The KEFEA Code covers all methods of Promotion including, but not limited to, oral and written promotional activities and communications, journal and direct mail advertising, the activities of Medical Sales Representatives, the use of digital communications and channels, such as websites and social media, the use of audio-visual systems such as films, video recordings, data storage services and the like. It also covers the provision of Informational or Educational Materials, Items of Medical Utility, hospitality in relation to Events and Medical Samples.

The KEFEA Code also covers interactions between its members and HCPs and HCOs including, but not limited to, those in the context of research or contractual arrangements (including certain aspects of clinical trials, non-interventional studies as well as consultancy and advisory board). It also covers the interactions between its members and POs.

The KEFEA Code is not intended to restrain or regulate activities directed towards the general public which relate solely to non-prescription Medicinal Products.

The KEFEA 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 2001/83/EC;
- correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular Medicinal Product;
- factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general precautions, trade catalogues and price lists, provided they include no product claims;
- activities which relate solely to non-prescription Medicinal Products; or

- non-promotional, general information about KEFEA members (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programmes, and regulatory developments affecting a KEFEA member and its Medicinal Products.

The following documents are attached to the KEFEA Code and are binding for KEFEA members:

- Annex A (binding) KEFEA standardised disclosure template
- Annex B (binding) KEFEA Guidance on Disclosure of Non-Interventional Studies
- Annex C (binding) KEFEA standard operating procedure related to processing of complaints and questions submitted to KEFEA or forwarded from EFPIA
- Annex D (binding) KEFEA Process for Requesting an Exception to Hold an Event at a 5* or more Location

Additional documents are developed to illustrate the provisions of the KEFEA Code and provide explanations for a consistent implementation, such as the following:

- Annex E PO Disclosure template (optional but recommended)
- Annex F KEFEA Guideline on a Quality Framework Principles in Lifelong Learning in Healthcare

APPLICABILITY OF THE KEFEA CODE

The KEFEA Code sets out the minimum standards which KEFEA considers must apply.

Promotion and interactions which take place within Europe must comply with applicable laws and regulations. In addition, Promotion and interactions which take place within Europe must also comply with Applicable Codes.

KEFEA members must comply with any Applicable Codes and any laws and regulations to which they are subject.

Non-member associations and companies that decide to voluntarily implement the KEFEA Code must require that each of their respective members, affiliates and subsidiaries, as applicable, comply with all provisions of the KEFEA Code.

The spirit, as well as the provisions of the KEFEA Code must be complied with. KEFEA also encourages compliance with the letter and spirit of the provisions of the International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA") Code of Practice, where applicable.

CHAPTER 1. PROMOTION OF POM TO HCPs

ARTICLE 1. MARKETING AUTHORISATION

Section 1.01. A Medicinal Product must not be promoted prior to the grant of the marketing authorisation allowing its sale or supply or outside of its approved indications.

Section 1.02. Promotion must be consistent with the particulars listed in the summary of product characteristics of the relevant Medicinal Product.

ARTICLE 2. INFORMATION TO BE MADE AVAILABLE

Section 2.01. All promotional material must include the following information clearly and legibly:

a. essential information consistent with the summary of product characteristics, specifying the date on which such essential information was generated or last revised;
b. the supply classification of the Medicinal Product; and
c. when appropriate, the selling price or indicative price of the various presentations and the conditions for reimbursement by GeSY.

Section 2.02. Subject to applicable national laws and regulations, where an advertisement is intended only as a reminder, the requirements of Section 2.01 above need not be complied with.

It is clarified that a "reminder" advertisement means that the advertisement includes no more than the name of the Medicinal Product or its international non-proprietary name, where this exists, or the trademark.

ARTICLE 3. PROMOTION AND ITS SUBSTANTIATION

Section 3.01. Promotion must be accurate, balanced, fair, objective and sufficiently complete to enable the HCP to form his/her own opinion of the therapeutic value of the Medicinal Product concerned. It must 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.

Section 3.02. Promotion must be capable of substantiation which must be promptly provided in response to reasonable requests from HCPs. 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.

Section 3.03. 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.

Section 3.04. When Promotion refers to published studies, clear references must be given.

Section 3.05. Any comparison made between different Medicinal Products must be based on relevant and comparable aspects of the Medicinal Products. Comparative advertising must not be misleading or disparaging.

Section 3.06. All artwork, including graphs, illustrations, photographs and tables taken from published studies included in promotional material must: (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 Promotion does not mislead about the nature of a Medicinal Product (for example, whether it is appropriate for use in children) or mislead about a claim or comparison (for example, by using incomplete or statistically irrelevant information or unusual scales).

Section 3.07. The word "**safe**" must never be used to describe a Medicinal Product without proper qualification.

Section 3.08. The word "**new**" must not be used to describe any Medicinal Product or presentation which has been generally available or any therapeutic indication which has been generally promoted, for more than one year.

Section 3.09. It must not be stated that a Medicinal Product has no side-effects, toxic hazards or risks of addiction or dependency.

Section 3.10. The use of unpublished data regarding efficacy and safety of products (data on file) for promotional purposes is prohibited. Such data may constitute the subject-matter of discussions between HCPs and the scientific service of the pharmaceutical company, but cannot be included in promotional material. Only general data are acceptable, such as the total number of patients in clinical programmes where the medicinal product has been studied, the total duration of the clinical programme and financial data, i.e. data that only the company possesses and can provide upon request to HCPs or the authorities.

Section 3.11. Where a claim is based on in vitro studies or tests in animals, the experimental nature of the data must be clearly stated.

Section 3.12. Data derived from studies in animals, in healthy volunteers or in vitro studies and pharmacologic remarks of questionable clinical significance must not be
presented as evidence of clinical value or, if it is decided that such data must be presented, the type of the relevant data must always be stated (e.g. in vitro trial, data from a study in healthy volunteers, etc.).

Section 3.13. Press releases are discouraged due to the strict interpretation by the Drugs Council of the prohibition against advertising of medicines.

ARTICLE 4. USE OF QUOTATIONS IN PROMOTION

Section 4.01. 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.

Section 4.02. Quotations relating to Medicinal Products which are taken from public communications, e.g. radio, TV or medical congresses or symposia, cannot be used.

Section 4.03. Maximum attention must be paid in order to avoid the attribution of allegations or opinions to authors, when these do not reflect the current views of the said authors.

ARTICLE 5. ACCEPTABILITY OF PROMOTION

KEFEA members 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 Medicinal Products and the professional standing of the intended audience; and (c) not be likely to cause offence.

ARTICLE 6. DISTRIBUTION OF PROMOTION

Section 6.01. Promotion must only be directed at those HCPs whose need for, or interest in, the particular information can reasonably be assumed.

Section 6.02. Mailing lists must be kept up-to-date. Requests to be removed from mailing lists must be complied with.

Section 6.03. Subject to applicable national laws and regulations, the use of faxes, e-mails, automated calling systems, text messages and other digital communications for Promotion is prohibited except with the prior permission, or upon the request, of those who receive it.

ARTICLE 7. TRANSPARENCY OF PROMOTION

Section 7.01. Promotion must not be disguised.

Section 7.02. 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.

Section 7.03. Where a KEFEA member pays for or otherwise secures or arranges the publication of promotional material in journals, such promotional material must not resemble independent editorial matter.

Section 7.04. Material relating to Medicinal Products and their uses, whether promotional in nature or not, which is sponsored by a KEFEA member must clearly indicate that it has been sponsored by that KEFEA member.

ARTICLE 8. PROMOTIONAL INFORMATION PROVIDED DURING INTERNATIONAL EVENTS

Promotional information which appears on exhibition stands or is communicated to participants at international Events may, unless prohibited or otherwise regulated by local laws and regulations, refer to Medicinal Products (or uses) which are not registered in the country where the Event takes place, or which are registered under different conditions, as long as: (i) any such promotional material is accompanied by a suitable statement indicating the countries in which the Medicinal Product is registered and makes clear that the Medicinal Product or indication is not registered locally, and (ii) any such promotional material which refers to the prescribing information (indications, warnings etc.) authorised in a country or countries where the Medicinal Product is registered must be accompanied by an explanatory statement indicating that registration conditions differ internationally.

It is clarified that promotional information which appears on exhibition stands or is communicated to participants at international Events taking place in Cyprus may not refer to Medicinal Products (or uses) which are not registered in Cyprus.

ARTICLE 9. PERSONAL MEDICAL MATTERS

In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer must be advised to consult an HCP.

CHAPTER 2. INTERACTIONS WITH HCPs, HCOs AND POs

ARTICLE 10. EVENTS AND HOSPITALITY

Section 10.01. All Events must be held in "appropriate" Locations and Venues that are conducive to the main purpose of the Event, avoiding those that are "renowned" for their entertainment facilities or are "extravagant".

A 4* hotel is taken to be included in the definition of a "appropriate" establishment, whereas hotels with 5* or more are prima facie excluded from such definition and are considered to be "renowned" or "extravagant". The process for requesting an exception in order to hold an event in a 5* or more location is set out in Annex D to this Code.

For Events held outside Cyprus, accommodation can only be organised in a 4* hotel unless it is otherwise specified by the hosting country's National Code.

Section 10.02. No KEFEA member may organise or sponsor an Event that takes place outside its home country unless:

- 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
- 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.

Section 10.03. KEFEA members may only offer hospitality when such hospitality is "appropriate" and otherwise complies with the provisions of any Applicable Code(s).

A €75 threshold per person per meal (excluding taxes and tips), and an accommodation threshold for local hospitality up to €250 per night applies for Events held in Cyprus.

Section 10.04. Hospitality extended in connection with Events must be limited to travel, meals, accommodation and genuine registration fees.

Section 10.05. KEFEA members must not provide or offer any meal (food and beverages) to HCPs, HCOs' members or POs' Representatives, unless, in each case, the value of such meal does not exceed the monetary threshold set by the relevant Member Association in its National Code (following the "Host Country Principle").

For Events held outside Cyprus, and if no reference in the National Code of the hosting country, a €90 threshold applies per person per meal (excluding taxes and tips), and an accommodation threshold of up to €400 per night.

Section 10.06. Hospitality may only be extended to persons who qualify as participants in their own right. In exceptional cases of established health needs (e.g. disability or injury), the travel, meals, accommodation and genuine registration fee costs of an accompanying person can be reimbursed within the same parameters.

Section 10.07. All forms of hospitality offered to HCPs, HCOs' members or POs' Representatives must be "reasonable" in level and strictly limited to the main purpose of the Event. As a general rule, "reasonable" is taken to mean that the hospitality provided must not exceed what those individuals would normally be prepared to pay for themselves.

Section 10.08. Hospitality must not include sponsoring or organising entertainment events (e.g., sporting or leisure).

ARTICLE 11. PROHIBITION OF GIFTS

Section 11.01. Gifts for the personal benefit (such as sporting or entertainment tickets, social courtesy gifts) of HCPs, HCOs' members or POs' Representatives (either directly or indirectly) are prohibited.
Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the profession and that confer a personal benefit to the Recipient.

Section 11.02. A promotional aid (e.g. pens, notepads, mousepads, USB sticks, etc.) is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in Chapter 1). Providing or offering them to HCPs, HCOs'members or POs' Representatives in relation to the promotion of POM is prohibited.

ARTICLE 12. DONATIONS AND GRANTS TO HCOs AND POs

Section 12.01. Donations and Grants (in cash or in kind or otherwise) to HCOs and/or POs are only allowed if: (i) they are made for the purpose of supporting healthcare, research or education; (ii) they are documented and kept on record by the donor/grantor; and (iii) they do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

Section 12.02. Donations and Grants to individuals are not permitted. The Contribution to Costs related to Events for HCPs to attend international Events is covered by Article 13.

ARTICLE 13. CONTRIBUTION TO COSTS RELATED TO EVENTS AND SPONSORSHIP

Section 13.01. KEFEA members must comply with criteria governing the selection and support of HCPs or POs' Representatives to attend Events as provided in, or in connection with, any Applicable Code(s). No payment must be offered to compensate merely for the time spent by the HCP or PO's Representative in attending Events.

Section 13.02. The public use of an HCO or PO´s logo and/or proprietary material by a KEFEA member requires written permission from that organisation. In seeking such permission, the specific purpose and the way the logo and/or proprietary material will be used must be clearly stated.

Section 13.03. KEFEA members must ensure that their Sponsorship to HCOs and POs is always clearly acknowledged and apparent from the outset.

ARTICLE 14. KEFEA MEMBER FUNDING

No KEFEA member may require that it be the sole funder or sponsor of a PO or HCO or any of its programmes.

KEFEA members welcome broad funding and sponsorship of POs and HCOs from multiple sources.

ARTICLE 15. CONTRACTED SERVICES

Section 15.01. Contracts between KEFEA members and HCPs, HCOs, POs or POs' Representatives under which those provide any type of services to KEFEA members (not otherwise covered by the Code) are only allowed if such services : (i) are provided for the purpose of supporting healthcare, research or education; and (ii) do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific Medicinal Products.

Section 15.02. It is permitted to contract HCPs or POs' Representatives as consultants, whether in groups or individually, for services such as speaking at and/or chairing 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 genuine consultancy or other services must, to the extent relevant to the particular arrangement, fulfil all the following criteria:

a. a written contract is agreed in advance of the commencement of the services which specifies the nature of the services to be provided and, subject to clause (g) below, the basis for payment of those services;
b. a legitimate need for the services has been clearly identified and documented in advance of requesting the services and entering into arrangements;
c. the criteria for selecting consultants are directly related to the identified need, which may include clinical experience in the treatment, product, and/or in the relevant scientific issue, the prospective consultant's scientific reputation, his/her academic work and/or his/her publications;
d. the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular consultant meets those criteria;
e. the number of consultants retained and the extent of the service are not greater than reasonably necessary to achieve the identified need;
f. the contracting KEFEA member maintains records concerning, and makes appropriate use of, the services provided by consultants;
g. the engagement of the consultant to provide the relevant service is not an inducement to recommend and/or prescribe, purchase, supply, sell or administer a particular Medicinal Product;
h. the remuneration 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 compensating the HCPs or PO Representatives;
i. Compensation for HCPs based in Cyprus must be calculated with a threshold of not more than €170 per hour and for HCPs based outside Cyprus must be calculated with the threshold in the country of practice of the HCP;
j. Compensation for POs based in Cyprus must be calculated with a threshold of not more than €100 per hour and for POs based outside Cyprus must be calculated with the threshold in the country of practice of the PO. Contractual arrangements need to be made with the PO itself, and payment effected only to POs – not to individuals.

In the event that such an HCP or PO's representative is a Cyprus Government Official, such interactions fall under private employment and require prior approval by the Minister of Labour. Care must be taken by KEFEA members to ensure that these approvals have been procured.

Section 15.03. In their written contracts with consultants, KEFEA members must include provisions regarding the obligation of the consultants to declare that they are consultants to the KEFEA member whenever they write or speak in public about a matter that is the subject of the agreement or any other matter relating to that KEFEA member.
Similarly, KEFEA members that employ, on a part-time basis, HCPs that are still practising their profession are strongly encouraged to ensure that such

persons have an obligation to declare their employment arrangements with the KEFEA member whenever they write or speak in public about a matter that is the subject of the employment or any other matter relating to that KEFEA member. The provisions of this Section 15.03 apply even though the Code does not otherwise cover non-promotional, general information about KEFEA members (as discussed in the "Scope of the KEFEA Code" section).[5]

Section 15.04. Limited market research, such as one-off phone interviews or mail/e-mail/internet questionnaires are excluded from the scope of this Article 15, provided that the HCP, HCO's member or PO's Representative is not consulted 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.

"Minimal" remuneration means that there is an absolute cap of 3 hours' remuneration.

Section 15.05. If an HCP or a PO's Representative attends an Event (an international Event or otherwise) in a consultant capacity the relevant provisions of Article 10 must apply.

CHAPTER 3. SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH HCPs AND HCOs

ARTICLE 16. LIFELONG LEARNING IN HEALTHCARE

Lifelong learning in healthcare (LLH) is aimed at increasing the scientific knowledge and competence of HCPs to enhance medical practice and improve patient outcome.

KEFEA members can be engaged in or support different types of educational programmes but such activities must not constitute Promotion. These activities can be one of three types: 1) independent medical education i.e. conducted by an independent organisation and funded by the industry; 2) programs that are developed in collaboration with another stakeholder; or 3) pharmaceutical industry led LLH activities.

When funding independent medical education or organising LLH activities directly or in collaboration with Third Parties, KEFEA members must ensure that their participation and role is clearly acknowledged and apparent from the outset.
LLH activities must have content that is fair, balanced and objective, designed to allow the expression of diverse evidence-based science and fulfil unmet educational needs in healthcare.

This Article is complemented by a Guideline on a Quality Framework for LLH (Annex F).

[5] Companies are strongly encouraged to include such provisions in any contracts covered by this Section 15.03.

ARTICLE 17. INFORMATIONAL OR EDUCATIONAL MATERIALS AND ITEMS OF MEDICAL UTILITY

Section 17.01. The provision of Informational or Educational Materials is permitted provided it is: (i) "inexpensive" (i.e. no more than EUR 30 per item); (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly beneficial to the care of patients.

Section 17.02. Items of Medical Utility aimed directly at the education of HCPs and patient care can be provided if they are "inexpensive" (i.e. no more than EUR 30 per item) and do not offset routine business practices of those who receive them.

Section 17.03. The nature of Informational or Educational Materials and Items of Medical Utility considered may not constitute a circumvention of the prohibition on gifts defined under Article 11 of this Code. The transmission of such materials or items must not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

Section 17.04. Informational or Educational Materials and Items of Medical Utility can include the KEFEA member name, but must not be product-branded, unless the Medicinal Product's name is essential for the correct use of the material or item by the patient.

ARTICLE 18. NON-INTERVENTIONAL STUDIES

Section 18.01. Non-Interventional Studies must be conducted with a primarily scientific purpose and must not be disguised Promotion.

Section 18.02. 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, HCPs specifically for the study must comply with all of the following criteria:

a. There is a written study plan (observational plan/protocol);
b. In countries where ethics committees are prepared to review such studies, the study plan must be submitted to the ethics committee for review;
c. The study plan must be approved by the KEFEA member's scientific service and the conduct of the study must be supervised by the KEFEA member's scientific service as described in Section 20.01.a;
d. The study results must be analysed by or on behalf of the contracting KEFEA member and summaries thereof must be made available within a reasonable period of time to the KEFEA member's scientific service (as described in Section 20.01.a), which service must maintain records of such reports for a reasonable period of time. The KEFEA member must send the summary report to all HCPs that participated in the study and must make the summary report available to industry self-regulatory bodies and/or committees that are in charge of supervising or enforcing Applicable Codes upon their request. If the study shows results that are

important for the assessment of benefit-risk, the summary report must be immediately forwarded to the relevant competent authority;[6] and

e. Medical Sales Representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the KEFEA member's scientific service that will also ensure that the Medical Sales Representatives are adequately trained. Such involvement must not be linked to the Promotion of any Medicinal Product.

Section 18.03. To the extent applicable, KEFEA member are encouraged to comply with Section 18.02 for all other types of NIS, including epidemiological studies and registries and other studies that are retrospective in nature. In any case, such studies are subject to Article 15.01.

ARTICLE 19. MEDICAL SAMPLES

Section 19.01. In principle, no Medical Samples should be given, except on an exceptional basis.
Medical Samples must not be given as an inducement to recommend, prescribe, purchase, supply, sell or administer specific Medicinal Products, and must not be given for the sole purpose of treating patients.
Medical Samples are provided to HCPs so that they may familiarise themselves with the Medicinal Product and acquire experience in dealing with them.
A limited number of Medical Samples may be supplied on an exceptional basis and for a limited period. KEFEA's interpretation of this provision is that each HCP should receive, per year, not more than 4 Medical Samples of a particular Medicinal Product he/she is qualified to prescribe for 2 years after the launch of each particular Medicinal Product (i.e. the "4x2" standard).
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.
Without prejudice to the ban on medical sampling of Medicinal Products containing psychotropic and narcotic substances, Medical Samples can only be given in response to a written request from HCPs qualified to prescribe that particular Medicinal Product.
Written requests must be signed and dated by those who ask for the Medical Samples.

Section 19.02. KEFEA members must have adequate systems of control and accountability for Medical Samples which they distribute and for all Medicinal Products handled by theirs Medical Sales Representatives. This system must also clearly establish, for each HCP, the number of Medical Samples supplied in application of the provisions in Section 19.01.

Section 19.03. Each Medical Sample must be no larger than the smallest presentation of that particular Medicinal Product in the relevant country.

---

[6] KEFEA members are encouraged to publicly disclose the summary details and results of NIS in a manner that is consistent with the parallel obligations with respect to clinical trials.

Each Medical Sample must be marked "free medical sample – not for sale" or words to that effect and must be accompanied by a copy of the summary of product characteristics.

ARTICLE 20. KEFEA MEMBER STAFF

Section 20.01. All KEFEA member staff must be fully conversant with the relevant requirements of the KEFEA Code and local laws and regulations.

a. Each KEFEA member must establish a scientific service in charge of information about its Medicinal Products and the approval and supervision of NIS. KEFEA members are free to decide how best to establish such service(s) in accordance with this Section 20.01 (i.e. whether there is one service in charge of both duties or separate services with clearly delineated duties), taking into account their own resources and organisation. The scientific service must include a suitably trained person with a healthcare scientific background who will be responsible for approving any promotional material before release. Such suitable training must be documented and kept up to date by the KEFEA member.
b. Such person must certify that he or she has examined the final form of the promotional material and that in his or her belief it is in accordance with the requirements of the KEFEA Code and any relevant laws and regulations, is consistent with the summary of product characteristics and is a fair and truthful presentation of the facts about the Medicinal Product.
c. Certification means that the signatories examined the final form of the material and that in their opinion, it is compliant with the requirements of the legislation and the relevant regulations of the Code, the material is in compliance with the marketing authorisation and the summary of product characteristics or the package leaflet, and constitutes a fair and correct presentation of the facts with respect to the Medicinal Product it refers to. Material should be recertified in a timely manner as per the content, in order to ensure continuous compliance with the legislative regulations in force and the Code.
d. Special attention is required in cases of revision of the summary of product characteristics (SPC). When changes to the SPC affect the content of a promotional material, then the latter should be revoked and amended:
    (I) Immediately, in cases of urgent safety-related updates;
    (II) As soon as possible (and no later than 4 months), in cases of other safety-related updates; and
    (III) Within 6 months, in cases of any other amendment.
e. In addition, the scientific service must include a medical doctor or, where appropriate, a pharmacist, who will be responsible for the oversight of any NIS (including the review of any responsibilities relating to such studies, particularly with respect to any responsibilities assumed by Medical Sales Representatives). Such person must certify that he or she has examined the protocol relating to the NIS and that in his or her belief it is in accordance with the requirements of the KEFEA Code and any relevant laws and regulations.
f. Each KEFEA member must appoint at least one senior employee who must be responsible for supervising the KEFEA member and its subsidiaries to ensure that the standards of the KEFEA Code are met.

Section 20.02. Each KEFEA member must ensure that its Medical Sales Representatives are familiar with the relevant requirements of the KEFEA Code, 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 the KEFEA Code, and all applicable laws and regulations, and KEFEA members are responsible for ensuring their compliance.
b. Medical Sales Representatives must approach 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 present.
d. Medical Sales Representatives must transmit to the scientific service of their companies forthwith any information they receive in relation to the use of their company's Medicinal Products, particularly reports of side effects.
e. Medical Sales Representatives must ensure that the frequency, timing and duration of visits to HCPs, pharmacies, hospitals or other healthcare facilities, together with the manner in which they are made, do not cause inconvenience.
f. Medical Sales Representatives must not use any inducement or subterfuge to gain an interview. In an interview, or when seeking an appointment for an interview, Medical Sales Representatives must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the KEFEA member they represent.

CHAPTER 4. SPECIFIC REQUIREMENTS FOR INTERACTIONS WITH POs

ARTICLE 21. INTERACTIONS WITH POs

Section 21.01. KEFEA members must comply with the following principles that EFPIA, together with pan-European POs, have subscribed to:

1. The independence of POs, in terms of their political judgement, policies and activities, must be assured.
2. All interactions between POs and KEFEA members must be based on mutual respect, with the views and decisions of each partner having equal value.
3. KEFEA members must not request, nor shall POs undertake, the Promotion of a particular POM.
4. The objectives and scope of any collaboration must be transparent. Financial and non-financial support provided by KEFEA members must always be clearly acknowledged.

Section 21.02. EU and Cyprus laws and regulations prohibit the advertising of POM to the general public.

Section 21.03. When KEFEA members provide support (whether financial or non-financial) to POs, they must have in place a written agreement. This must state the amount of funding and also the purpose (e.g. unrestricted grant, specific meeting or publication, etc). It must also include a description of significant indirect support (e.g. the donation of public relations agency´s time and the nature of its involvement) and significant non-financial support.

Section 21.04. KEFEA members must not influence the text of PO's material they sponsor in a manner favourable to their own commercial interests. This does not preclude KEFEA members from correcting factual inaccuracies. In addition, at the request of POs, KEFEA members may contribute to the drafting of the text from a fair and balanced scientific perspective.

Section 21.05. As a general principle, patient programmes have specific requirements and characteristics and should not be disguised under the umbrella of corporate social responsibility programmes.

a. A patient education and support programme aims to support the patient, under the directions of the treating physician. These programs aim at enhancing information, at education and the compliance of a patient with his/her prescribed therapy, having as a final objective the reduction of difficulties related to the implementation procedure of the treatment.
b. Patient education and support programmes are not clinical trials; they have a purely educational and supportive role and no patients' personal data is collected, further to the necessary information for the compliance with the legislative framework on pharmacovigilance.
c. Such programmes are implemented by companies providing health services contracted by the sponsoring pharmaceutical company of the program and fulfil the procedures provided by relevant legislation in order to ensure independent and correct provision of support and/or education services.
d. No direct or indirect communication between a patient (or his family) and the pharmaceutical company dealing with the trade/ allocation/ promotion of a drug is permitted within the framework of these education programmes, apart from cases of reporting side effects in line with the relevant legislative provisions.
e. The pharmaceutical company and their employees should not have access to personal data and files which may lead to the reveal of the identity of specific patients or be associated with specific patients, apart from the case of reporting side effects.
f. The treating physicians who may recommend the participation of the patient in such a program should not receive any fee or any other indirect grant.
g. Before the introduction of such programmes, the company must keep a file containing the following documents:
   • In-depth description of the program with the relevant scientific documentation and rationale;
   • Contract with the company providing the programme services including pharmacovigilance provisions (where applicable) and timelines;
   • Compliance with the legislation about protection of personal data of those participating in the programme; and
   • All the supportive documents that will be used during the application of the program

CHAPTER 5. DISCLOSURE OF ToVs FROM KEFEA MEMBERS

ARTICLE 22. DISCLOSURE OF ToVs TO HCPs, HCOs, AND POs

Section 22.01. Time of Disclosure
Disclosures must be made by each KEFEA member within 6 months after the end of the relevant Reporting Period and the information disclosed must be required to remain in the public domain for 3 years after the time such information is first disclosed unlessthe relevant data protection legal basis (e.g. the legitimate interest grounds, a legal duty or the Recipient's consent relating to a specific disclosure) is no longer applicable.
The reporting period for publication of ToVs to Recipients is set during the time interval from 20th to 30th June each year at the latest.

ARTICLE 23. DISCLOSURE OF ToVs TO HCPs AND HCOs

Section 23.01. Rationale
The following article provides for disclosures of ToVs to HCPs and HCOs, whether directly or indirectly. When deciding how a ToV must be disclosed, KEFEA members should, wherever possible, identify and publish at the individual HCP (rather than HCO) level, as long as this can be achieved with accuracy, consistency and in compliance with applicable laws and regulations.

Section 23.02. Disclosure Obligation
General Obligation. Subject to the terms of this article, each KEFEA member must document and disclose ToVs it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in Article 23.04.

Excluded Disclosures. Without limitation, ToVs that (i) are solely related to over-the-counter medicines; (ii) are not listed in Section 23.04 of this Article, such as Items of Medical Utility (governed by Article 17), meals (governed by Article 10, especially Section 10.05), Medical Samples (governed by Article 19); or (iii) are part of ordinary course purchases and sales of Medicinal Products by and between a KEFEA member and a HCP (such as a pharmacist) or a HCO do not fall within the scope of the disclosure obligation described above in *"General Obligation"*.

Section 23.03. Form of Disclosure
Annual Disclosure Cycle. Disclosures must be made on an annual basis and each Reporting Period must cover a full calendar year.

Template. Subject to "Platform of Disclosure", for consistency purposes, disclosures pursuant to this article will be made using a structure set forth in Annex A for reference, reflecting the requirements of this article. Deviations from this template are only acceptable where legal requirements justify that this article is not transposed in full – therefore, within a given country, only one template must apply.

Platform of Disclosure. Disclosures must be made on the relevant section of the KEFEA website, with a relevant link being sent in advance by each KEFEA member to KEFEA's Compliance Committee.

Language of Disclosure. Disclosures must be made in Greek or English. If in Greek, KEFEA members are encouraged to make disclosures additionally in English.

Documentation and Retention of Records. Each KEFEA member must document all ToVs required to be disclosed pursuant to Section 23.02 and maintain the relevant records of the disclosures made under this article for a minimum of 5 years after the end of the relevant Reporting Period, unless a shorter period is required under applicable national laws or regulations.

Section 23.04. Individual and Aggregate Disclosure
Individual Disclosure. Except as expressly provided by this article, ToVs must be disclosed on an individual basis. Each KEFEA member must disclose, on an individual basis for each clearly identifiable Recipient, the amounts attributable to ToVs to such Recipient in each Reporting Period which can be reasonably allocated to one of the categories set out below. Such ToVs may be aggregated on a category-by-category basis, provided that itemised disclosure must be made available upon request to (i) the relevant Recipient, and/or (ii) the relevant authorities.

1. For ToVs to a HCO, an amount related to any of the categories set forth below:

   a. Donations and Grants. Donations and Grants to HCOs that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare (governed by Article 12).
   b. Contribution to costs related to Events. Contribution to costs related to Events, through HCOs or Third Parties[7], including support to HCPs to attend Events, such as:
   i. Registration fees;
   ii. Sponsorship agreements with HCOs or with Third Parties appointed by an HCO to manage an Event; and
   iii. Travel and accommodation (to the extent governed by Article 10).

   c. Fees for Service and Consultancy. ToVs resulting from or related to contracts between KEFEA members and HCOs under which such HCOs provide any type of services to a KEFEA member or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

2. For ToVs to an HCP, DLC or DELC:

[7] cf. Guidance of indirect ToVs through Third Parties – Support to/Sponsorship to Events through Professional Conference Organisers in Annex B

a. Contribution to costs related to Events. Contribution to costs related to Events, such as:
i. Registration fees; and
ii. Travel and accommodation (to the extent governed by Article 10).

b. Fees for Service and Consultancy. ToVs resulting from or related to contracts between KEFEA members and HCPs under which such HCPs provide any type of services to a KEFEA member or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand ToVs relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

It is clarified that where the contract for the ToV has been concluded with a DLC or a DELC, the terms and conditions of the afore-mentioned contract will, where possible, contain a lawful basis for the disclosure of the names of the individual HCPs involved in the ToV.

Aggregate Disclosure. For ToVs where certain information, which can be otherwise reasonably allocated to one of the categories set forth in Section 23.04, cannot be disclosed on an individual basis for legal reasons, a KEFEA member must disclose the amounts attributable to such ToVs in each Reporting Period on an aggregate basis. Such aggregate disclosure must identify, for each category, (i) the number of Recipients covered by such disclosure, on an absolute basis and as a percentage of all Recipients, and (ii) the aggregate amount attributable to ToVs to such Recipients.

Legal reasons may include instances where a KEFEA member is relying on "consent" as a lawful basis for the disclosure of the Recipient's name, and such consent is not provided. KEFEA members are strongly encouraged to review the lawful bases for disclosure with their legal counsel on a regular basis.

Non duplication. Where a ToV required to be disclosed pursuant to Section 23.04 is made to an individual HCP indirectly via an HCO, such ToV must only be required to be disclosed once. To the extent possible, such disclosure must be made on an individual HCP named basis pursuant to Section 23.04.

Research and Development ToV. Research and Development ToVs in each Reporting Period must be disclosed by each KEFEA member on an aggregate basis. Costs related to Events that are clearly related to activities covered in this section can be included in the aggregate amount under the "Research and Development Transfers of Value" category.

Methodology. Each KEFEA member must publish a note summarising the methodologies used by it in preparing the disclosures and identifying ToVs for each category described in Section 23.04. The note, including a general summary and/or country specific considerations, must describe the recognition methodologies applied, and should include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amounts of ToVs for purposes of this article, as applicable.

ARTICLE 24. DISCLOSURE OF SUPPORT AND SERVICES PROVIDED TO POs

Each KEFEA member must disclose a list of POs to which it provides support (whether financial or non-financial) or with whom it has engaged to provide contracted services for that KEFEA member.

This disclosure must be listed separately from the disclosure in accordance with Article 23.

This disclosure must include a description of the nature of the support or services provided that is sufficiently complete to enable the average reader to form an understanding of the nature of the support or the arrangement without the necessity to divulge confidential information.
In addition to the name of the PO, the following elements must be included:

a. For support:
   i. the monetary value of financial support and of invoiced costs.
   ii. the non-monetary benefit that the PO receives when the non-financial support cannot be assigned to a meaningful monetary value.

b. For contracted services: the total amount paid per PO over the Reporting Period.

This information must be disclosed on the KEFEA member's website either on a national or European level on an annual basis and each Reporting Period shall cover a full calendar year.

Methodology. Each KEFEA member must publish the methodologies used by it in preparing the disclosures and identifying supports and services provided.

CHAPTER 6. PROCEDURAL REQUIREMENTS

ARTICLE 25. ENFORCEMENT

Section 25.01. Enforcement through Member Associations
In the event that a breach is established pursuant to the procedures of this Code, KEFEA shall require from the offending company an immediate cessation of the offending activity and a signed undertaking by the company to prevent recurrence.

KEFEA has adopted Implementation and Procedure Rules (as set forth in more detail in Article 28), which are binding upon its members, and set forth the framework for the implementation of this Code, the processing of complaints and the enforcement of sanctions in a manner consistent with applicable data protection, competition and other laws and regulations.

ARTICLE 26. AMENDMENTS TO, AND GUIDANCE REGARDING COMPLIANCE WITH, THE KEFEA CODE

Section 26.01. Code Compliance
The KEFEA Compliance Committee shall assist KEFEA members to comply with their obligations under this Code. The key tasks of the Committee are set forth in Article 28.

Section 26.02. Amendments to the KEFEA Code
The KEFEA Compliance Committee shall regularly review this Code and any guidance issued regarding compliance with this Code.
Any proposed amendments to the KEFEA Code will be submitted to the KEFEA Board of Directors for a decision and to the KEFEA annual general meeting for ratification.

ARTICLE 27. AWARENESS AND EDUCATION

KEFEA aims to facilitate its members' awareness of and education about the KEFEA Code, including by providing guidance to members in order to prevent breaches of the Code. Members are encouraged to share their respective interpretations of the KEFEA Code through the regular meetings organised by Compliance Committee.

ARTICLE 28. IMPLEMENTATION AND PROCEDURE RULES

The Implementation and Procedure Rules set forth herein establish the framework for the implementation of the KEFEA Code, the processing of complaints and the initiation or administration of sanctions by KEFEA.

Section 28.01. KEFEA Implementation

a. KEFEA has established national procedures and structures (set out in Annex B) to receive and process complaints, to determine sanctions and to publish appropriate details regarding the same;
b. KEFEA's Code, together with its administrative procedures and other relevant information, are easily accessible through its website; and
c. KEFEA is obliged to provide to the EFPIA Codes Committee (defined below), an annual report summarising the work undertaken by its Compliance Committee in connection with the implementation, development and enforcement of the KEFEA Code during the year.

Section 28.02. Reception of Complaints
Complaints may be lodged either with KEFEA or with EFPIA, which undertakes to forward it to KEFEA. Adjudication of complaints is a matter solely for KEFEA.

Section 28.04. Processing of Complaints and Sanctions by KEFEA

a. KEFEA commits to ensuring that all complaints, whether originating from within the industry or not, are processed in the same manner, without regard to the origin of the complaint.
b. Complaints are processed at national level through the procedures and structures established by KEFEA pursuant to Section 28.01 and set out in Annex C. The Compliance Committee must take decisions and pronounce any sanctions on the basis of the KEFEA Code.
c. Each Member Association should establish effective procedures for appeals against the initial decisions made by its national body. Such procedures and appeals should also take place at national level.

The process used by KEFEA is set out in a standard operating procedure (Annex C).

ANNEX A (binding)
Standardised disclosure template

ANNEX A - STANDARDISED DISCLOSURE TEMPLATE Date of publication:													
	Full Name	**HCPs:** City of Principal Practice HCO**s:** city where registered	Country of Principal Practice	Principal Practice Address	Unique country identifier *OPTIONAL*	Donations and Grants to HCOs	Contribution to costs of Events			Fee for service and consultancy			**TOTAL** *OPTIONAL*
							Sponsorship agreements with HCOs / third parties appointed by HCOs to manage an Event	Registration Fees	Travel & Accommodation	Fees	Related expenses agreed in the fee for service or consultancy contract, including travel & accommodation relevant to the contract		
HCPs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCP*** *(i.e. all transfers of value during a year for an individual HCP will be summed up: itemisation should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
	Dr A					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		
	Dr B					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		
	etc.					N/A	N/A	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to transfers of value to such Recipients					N/A	N/A	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*	*Aggregate HCPs*		*Optional*
	Number of Recipients in aggregate disclosure					N/A	N/A	*number*	*number*	*number*	*number*		*Optional*

	% of the number of Recipients included in the aggregate disclosure in the total number, by category, of Recipients disclosed					N/A	N/A	%	%	%	%		N/A
HCOs	***INDIVIDUAL NAMED DISCLOSURE - one line per HCO*** *(i.e. all transfers of value during a year for an individual HCO will be summed up: itemisation should be available for the individual Recipient or public authorities' consultation only, as appropriate)*												
	HCO 1					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	HCO 2					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	etc.					*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*	*Yearly amount*		*Optional*
	OTHER, NOT INCLUDED ABOVE - where information cannot be disclosed on an individual basis for legal reasons												
	Aggregate amount attributable to transfers of value to such Recipients					*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*	*Aggregate HCOs*		*Optional*
	Number of Recipients in aggregate disclosure					*number*	*number*	*number*	*number*	*number*	*number*		*Optional*
	% of the number of Recipients included in the aggreate disclosure in the total number, by category, of Recipients disclosed					%	%	%	%	%	%		N/A

R&D	***AGGREGATE DISCLOSURE***		
	Transfers of Value re Research & Development as defined in the EFPIA Code of Practice	*TOTAL AMOUNT*	*OPTIONAL*

This can also be accessed on KEFEA's website at: …

ANNEX B (binding)
KEFEA guidance

GUIDANCE ON DISCLOSURE OF NON-INTERVENTIONAL STUDIES

Background

In application of the KEFEA Code to exemption on individual reporting of ToVs relating to non-interventional studies (NIS) is limited to **NIS that are prospective in nature**. The Code prescribes that **retrospective NIS** must be reported on an individual names basis, in line with applicable codes.

KEFEA understands that it is not always possible to distinguish ToVs relating to prospective (included in the aggregated reporting of R&D ToVs) and retrospective (to be reported on an individual basis) NIS.

The EFPIA Ethics & Compliance Committee (E&CC) had considered that definitions in the new EU Clinical Trials Regulation 536/2014[8] could be used for reference when implementing the Disclosure requirements, thus anticipating and align with the regulatory change that will eventually take place. KEFEA adopts this consideration in turn.

This Guidance relates to the disclosure of all NIS on an individual basis in case ToVs relating prospective and retrospective non-interventional studies cannot be distinguished.

This Guidance provides a basis for distinguishing between prospective versus retrospective NIS and aims at ensuring consistency in reporting of ToVs relating to NIS.

Relevant KEFEA Code provision

Schedule 1: Definition of Terms
Research and Development Transfers of Value – Transfers of Value to HCPs or HCOs related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice); (ii) clinical trials (as defined in Regulation N° 536/2014); or (iii) **NIS that are prospective in nature** and that involve the collection of patient data from or on behalf of individual, or groups of, HCPs specifically for the study (Section 15.01 of the Code).

[8] Application date of the new Clinical Trials Regulation 536/2014 is dependent on the development of the IT system "EU Clinical Trial Portal and Database". At the moment, the "go-live date" is expected in second half of 2019. The effective implementation date of the Regulation will not change definitions, these definitions are considered as an appropriate reference for consistent implementation of provisions relating to the disclosure of ToVs relating to NIS.

Guidance

Transfers of Value relating to non-interventional studies (NIS) that are not within the definition of R&D ToVs under the KEFEA Code must be reported on an individually named basis. In this regard, prospective versus retrospective NIS will be considered following classification in the table below:

Prospective NIS	Retrospective NIS
Prospective cohort studies in which the prescription of the medicine is independent from the inclusion of the patient in the study **A retrospective study to which a prospective element is subsequently introduced** **Long-term extension studies with patient follow up beyond trial protocol specified time for observation and active collection of additional data**	**Purely observational database review and/or research** **Retrospective review of records where all the events of interest have already happened** - e.g. case-control, cross-sectional, and purely retrospective cohort studies **Studies in which the prescriber later becomes an Investigator, but prescribing has already occurred** - e.g. retrospective data collection from individual medical records at the site of the investigator

For the sake of clarity, activities not falling within the definition of R&D ToVs, including NIS that are not conducted to maintain a marketing authorisation (in application and following definitions of the "Clinical Trials" Regulation 536/2014), will be disclosed under "consultancy/fee-for-services".

KEFEA members are encouraged to include a comment in the Methodological Note, where appropriate.

This Guidance will apply at the latest to 2021 ToVs (reported in 2022).

DISCLOSURE OF INDIRECT TRANSFERS OF VALUES (ToVs) THROUGH THIRD PARTIES

Support to / Sponsorship to Events through Professional Conference Organisers (PCOs)

Background

Third parties[9] provide support to KEFEA members in a variety of capacities, impacting more or less on the conduct of activities regulated by the KEFEA Code. Such activities would be reported as **indirect Transfers of Values** (ToVs) following provisions of the KEFEA Code. When KEFEA members provide support / sponsorship to PCOs involved in the organisation of scientific Events, it is understood that the KEFEA members' intention is to provide support to HCPs/HCOs *at arm's length*.

Indirect ToVs are those made on behalf of a KEFEA member for the benefit of a Recipient, or ToVs through an intermediate and where the KEFEA memberknows or can identify the HCP/HCO that will benefit from the ToV[10].

In consideration of the multiple ways collaboration with third parties can be contracted, it may not be straightforward to report in application of the KEFEA Code *in full*. As this may lead to underreporting of ToVs through third parties, further Guidance aims at providing a consistent approach towards improved reporting wherever possible in compliance with applicable law and regulations.

This Guidance clarifies reporting of Indirect ToVs to HCOs made through Professional Congress Organiser (PCOs[11]).

In consideration of legal issues that may arise in the reporting of ToVs through Distributors on behalf of a KEFEA member, reporting of such ToVs are not within scope of this Guidance.

Relevant KEFEA Code provision

Section 3.01.1.b

Contribution to costs related to Events, through HCOs or third parties, including sponsorship to HCPs to attend Events, must be disclosed individually under the name of the Recipient; such costs may relate to:

i. Registration fees;
ii. Sponsorship agreements with HCOs or with third parties appointed by an HCO to manage an Event; and

---

9 Third parties are entities or individuals that represent a company in the market place or interact with other third parties on behalf of a company or relating to the company's product. Among others, these thirds parties can be distributors, travel agents, consultants, contract research organisations. **This Guidance applies to PCOs as third parties involved in Events involving HCOs**.

10 Definition of an indirect ToV in Schedule 1 of this Code

11 A PCO is a company/individual specialised in the organisation and management of congresses, conferences, seminars and similar events (all "Events"). For the application of this Guidance, commercial companies involved in organisation of travel (travel agencies) or accommodation (hotels, banqueting functions in hotels, etc.) are not considered PCOs.

iii. Travel and accommodation (to the extent governed by Article 10 of the Code).

Schedule 1: Definitions

Indirect transfers of value are those made on behalf of a KEFEA memberfor the benefit of a Recipient, or transfers of value made through an intermediate and where the KEFEA memberknows or can identify the HCP/HCO that will benefit from the Transfer of Value.

Guidance

Contributions provided to Events through PCOs – that would therefore be the Recipient of the ToVs – must be considered as indirect ToVs.

When a KEFEA member contributes to the costs related to Events through PCOs, the following reporting approaches are considered compliant with EFPIA and KEFEA reporting requirements:

- All ToVs to an HCO (either as Recipient or as Beneficiary) are reported in the relevant category under the name of the HCO
- ToVs through PCOs are reported:
  - either in the name of benefitting HCO (through *include the name of Recipient PCO*), if not included in direct ToVs to the HCO;
  - or in the name of Recipient PCO (to the benefit of *include the name of benefitting HCO*)

This Guidance applies whether PCOs organise Events on their own initiative, or at the request of an HCO.

For further clarification, the attached table reviews scenarios of support / sponsorship to Events through PCOs that may help in preparation of reporting according to this Guidance.

For good order, it is reminded that contribution to costs related to Events paid through third parties to the benefit of individual HCPs that the KEFEA member knows, must be reported on an individually named basis, as Indirect ToVs to HCPs.

KEFEA members must confirm support / sponsorship to Events through PCOs in written agreements, and include provisions relating to information that the PCOs must communicate to the KEFEA members to allow appropriate reporting of ToVs in accordance with this Code.

Further recommendation

KEFEA members are encouraged to describe the process followed to collect the information in their Methodological Note, where it must also be stated that the full value ToVs to the PCO will not constitute a benefit (in cash or in kind) to the HCO as the PCO may retain a "service fee".

This Guidance will apply at the latest to 2021 ToVs (reported in 2022).

Additional Guidance on ToVs through PCOs
SUPPORT TO / SPONSORSHIP TO EVENTS THROUGH PROFESSIONAL CONFERENCE ORGANISERS (PCOs)

For further clarification, the table below reviews scenarios of support / sponsorship to Events through PCOs, which may help in preparation of reporting according to this KEFEA Guidance.

Examples of possible scenarios in support of Events

These examples are offered to help KEFEA members when preparing their disclosure reports in the perspective of optimal reporting of Events which they sponsor / support

Recipient PCO receiving the ToVs	Beneficiary HCP/HCO benefitting	Disclosure
PCO on behalf of / in collaboration with an HCO	**where the KEFEA member knows the HCP/HCO benefitting**	**Individual disclosure following guidance**
PCO on behalf of / in collaboration with HCO	where the KEFEA member does not know the HCP/HCO benefitting	Whilst disclosure on an individual HCP/HCO named basis is preferred, the KEFEA member may consider disclosing under the PCOs name with indication of the specialty area
PCO with HCO Scientific Committee	**HCO(s) is (are) known to the KEFEA member**	**Individual disclosure following guidance**
PCO with HCP Scientific Committee	**HCP(s) is (are) known to the KEFEA member**	**Individual disclosure following relevant KEFEA Code provisions**
PCO developing / organising an Event at its own initiative (independent event)	**where the KEFEA member knows the HCP/HCO participating in the Event**	**Individual disclosure following guidance**
PCO developing / organising an Event at its own initiative (independent event)	where the KEFEA member does not know the HCP/HCO participating in the Event	Whilst disclosure on an individual HCP/HCO named basis is preferred, the KEFEA member may consider disclosing under the PCOs name with indication of the specialty area

Disclosures on an individual names basis are subject to appropriate consent; where such consent cannot be secured, related ToVs will be disclosure in aggregate.

ANNEX C (binding)
KEFEA standard operating procedure related to processing of complaints and questions submitted to KEFEA or forwarded from EFPIA

IMPLEMENTATION & ENFORCEMENT OF CODES
Processing of Complaints & Questions submitted to KEFEA or forwarded from EFPIA

1. INTRODUCTION

1.1. The KEFEA Code of Practice is a self-regulatory Code. All members of KEFEA, as a condition of their membership of the Association, are signatories to the Code.

1.2. Non-KEFEA member companies may also choose to become signatories to the Code.

1.3. Where a person or body is concerned that the promotional activities of any signatory to the Code may be in breach of the Code, a complaint may be submitted to KEFEA for consideration. Documents may be submitted to KEFEA in either soft or hardcopy. The Code of Practice is administered by the Disciplinary Committee and the Appeals Board (see Schedule 1 - Definitions) and complaints are heard in the first instance by the Disciplinary Committee.

1.4. Decisions of the Disciplinary Committee cannot be appealed.

1.5. Alleged breaches of the Code by a Code signatory which come to KEFEA's attention other than by way of a formal written complaint are defined as "referrals" and are dealt with in accordance with the procedure set out in Section 7 of this Annex.

2. INTER-COMPANY RESOLUTION

2.1. For inter-company complaints, it is recommended that every reasonable effort should be made to resolve differences between companies directly. Only after such efforts have been exhausted, should the matter be referred to the Disciplinary Committee for resolution.

2.2. Where a KEFEA member expresses concerns regarding the Code compliance of specific claims included in electronic promotional material belonging to another company it is highly recommended (in order to facilitate inter-company resolution) that a hard copy of the relevant part of the electronic material is shared by the other company with the company that has the concern.

3. DISCIPLINARY COMMITTEE AND APPEALS BOARD

3.1. Composition of the Disciplinary Committee

3.1.1. The Disciplinary Committee comprises three members of KEFEA, the names of whom are published on the KEFEA website.

3.1.2. The Appeals Board comprises a lawyer or former judge, a health care professional and three members of KEFEA (who are not members of the Disciplinary Committee, the names of whom are published on the KEFEA website.

3.1.3. All three members of the Disciplinary Committee must sit in order for there to be a quorum to hear complaints or referrals.

3.1.4. All five members of the Appeals Board must sit in order for there to be a quorum to hear appeals.

3.2. Selection of the Disciplinary Committee and the Appeals Board

3.2.1. Nomination papers are sent by the KEFEA Board of Directors to all KEFEA members when a position on the Disciplinary Committee becomes available.

3.2.2. The nominations are considered by the KEFEA Board of Directors, who will vote to decide the three KEFEA members on the Disciplinary Committee and the three KEFEA members of the Appeals Board.

3.2.3. If insufficient nominations are received, the Board of Directors may fill any remaining vacancies as it deems appropriate.

3.2.4. The selection of the lawyer/judge and the healthcare professional of the Appeals Board is made by the KEFEA Board of Directors.

3.3. Composition of the Disciplinary Committee and the Appeals Board

3.3.1. Most areas of management in the industry (e.g. general, regulatory, marketing, medical, sales, management) are considered to provide appropriate or relevant skills/expertise with regard to membership of the Disciplinary Committee and the Appeals Board.

3.3.2. A mix of skills and expertise across the Disciplinary Committee and the Appeals Board is desirable and should be taken into account by the Board of Directors in the selection process.

3.4. Term of Office

3.4.1. Selection to the Disciplinary Committee and the Appeals Board will be for a three-year term. All members are eligible for re-selection.

3.5. Consultation

3.5.1. The Disciplinary Committee and the Appeals Board shall have the right to consult external experts and/or obtain any assistance in any field.

3.5.2. Individual members of the Disciplinary Committee and the Appeals Board are encouraged to inform themselves by researching or consulting externally on issues in a general sense, whilst maintaining confidentiality.

3.6. Conflict of Interest

3.6.1. If a Disciplinary Committee and/or Appeals Board member is employed by a company directly involved in a complaint or referral, either as Complainant/Appellant or Respondent, such member cannot participate in the Disciplinary Committee and/or Appeals Board established to consider that complaint, referral or appeal, and a temporary substitute will need to be appointed by the Board of Directors.

3.6.2. It is recognised that, on occasion, members of the Disciplinary Committee and/or Appeals Board while not employed directly by a company involved in a complaint, referral or appeal, may have some degree of conflict of interest (e.g. direct competitor, same therapeutic area etc.). However, it may not be feasible or practicable to require such a member to stand down for consideration of a given complaint or referral. A member of the Disciplinary Committee and/or Appeals Board should declare his or her interest to the non-KEFEA members of the Disciplinary Committee and/or Appeals Board to make an appropriate decision. Confidentiality must be maintained.

3.7. Substitution

3.7.1. No substitution or replacement is allowed on the Disciplinary Committee and/or Appeals Board during the hearing of a particular complaint, referral or appeal (as the case may be).

3.8. Autonomy

3.8.1. Disciplinary Committee and/or Appeals Board members must have autonomy vis-à-vis their company/employer in the context of their participation in the Disciplinary Committee and/or Appeals Board.

3.9. Confidentiality

3.9.1. Absolute confidentiality must be maintained by the Disciplinary Committee and Appeals Board members.

3.9.2. As a rule, parties to proceedings before the Disciplinary Committee and Appeals Board shall maintain confidentiality concerning any dealings with the Disciplinary Committee and Appeals Board until such time as the Disciplinary Committee and/or Appeals Board reaches a final decision.

3.9.3. Parties in exceptional circumstances may discuss issues before the Disciplinary Committee and/or Appeals Board with third parties but only to the extent that they can show to the satisfaction of the

Disciplinary Committee and/or Appeals Board that this was absolutely necessary because of the intimate involvement of the third party with the matter to be considered by the Disciplinary Committee and/or the Appeals Board and only to the extent that such discussion was factual, fair and balanced.

3.10. Time frames

3.10.1. The time frames for complaints, referrals and/or appeals can be shortened or lengthened at the discretion of the Disciplinary Committee and/or Appeals Board (as the case may be) depending on the complexity of the issues presented and having regard to the availability of the members of the Disciplinary Committee and/or Appeals Board.

4. CODE COMPLAINTS PROCEDURE TO THE DISCIPLINARY COMMITTEE

4.1. Who can make a complaint?

4.1.1. Complaints may be made by a company, healthcare professional or any other body or person.

4.2. What constitutes a valid complaint?

4.2.1. **Complaint made by a Code signatory**: the following requirements must be satisfied for a complaint to be considered valid:

(i) The complaint must be in writing, fully cross referenced, of good quality and with relevant passages highlighted etc;
(ii) It must specify those clauses of the Code which are alleged to have been breached;
(iii) An electronic complaint is preferred; however, if submitted in hardcopy, five bound copies of the complaint must be supplied.

The Complainant must also provide in writing:

• an unqualified undertaking that the company will comply with every reasonable request of the Disciplinary Committee;
• confirmation that the company will accept the final decision of the Disciplinary Committee (although it may reserve the right to appeal and/or have recourse to law, should it consider that route necessary)

Failure by the Complainant to provide the required written undertaking of compliance and confirmation of acceptance of the Decision of the Disciplinary Committee will result in the Complaint not being processed further.

4.2.2. **Other Complainants** (e.g. members of the public, healthcare professionals (other than those working directly for or on behalf of a company), etc): the complaint must be submitted in writing. Anonymous complaints will not be accepted. The Complainant's identity will be disclosed to the Respondent, only in exceptional circumstances, where it may be necessary for the Respondent to know the identity of the Complainant so that the matter can be fully

investigated, and only with permission from the Complainant.The Disciplinary Committee will examine the complaint in detail and determine which clauses of the Code have been breached.

4.3 Disciplinary Committee Procedure and Timelines

4.3.1 The deliberation of the Disciplinary Committee is performed on a case-by-case basis taking overall context, intent and the contents of the activity into account, and does not follow the principle of precedence.

4.4 The Disciplinary Committee will endeavour to consider and deal with complaints in accordance with the following procedure and timelines:

4.4.1 The formal timeline starts when a valid complaint is received at the KEFEA offices.

4.4.2 A copy of the complaint is sent to the company alleged to have breached the Code (i.e. the Respondent) who is requested to:

- Provide a written response within 10 working days;
- Provide an unqualified undertaking that the company will comply with every reasonable request of the Disciplinary Committee;
- Confirm that the company will accept the final decision of the Disciplinary Committee (although it may reserve the right to appeal and/or have recourse to law should it consider that route necessary).
- An electronic response is preferred, however, if responding in hardcopy, supply five bound copies of the response;

4.4.3 Failure by the Respondent to provide the required written undertaking of compliance and confirmation of acceptance of the Decision of the Disciplinary Committee, will result in the matter being referred to the KEFEA Board of Directors.

4.4.4 The clock will stop until the Board has considered the matter and advised how the complaint is to be dealt with.

4.4.5 A meeting of the Disciplinary Committee will be arranged within 30 working days of the date of receipt of the complaint (i.e. whether or not the Respondent has replied). It is desirable, but not always possible, to reach a decision at that meeting. From time to time, subsequent meetings may be required.

4.4.6 The Complainant and Respondent shall be kept informed of progress with the complaint.

4.4.7 The Disciplinary Committee will issue a decision within 10 working days of its last meeting and provide it to the Complainant and the Respondent.

4.4.8 Except in exceptional circumstances, that must be notified in advance to the Disciplinary Committee, the respondent must execute the Disciplinary Committee requirements in full within 20 working days

of the issuing of the decision. Also within those 20 working days the respondent must provide written details of the precise actions that it took to the Disciplinary Committee.

4.5 Withdrawal of complaints

4.5.1 The Complainant may withdraw the complaint at any time up until the response has been forwarded to the Respondent. If a complaint is withdrawn before it has been sent to the Respondent, the Respondent will not be informed about the complaint.

4.5.2 Where the Disciplinary Committee is of the view that the alleged breach is serious, it may choose to continue the investigation of the matter in the manner outlined under the referral system (see Section 7 of this Annex) regardless of the withdrawal of the complaint.

5. REQUIREMENT FOR COMPLAINTS TO HAVE SUBSTANCE

All complaints submitted for consideration must have substance. In the event of doubt about whether a complaint has substance, the non-KEFEA members of the Disciplinary Committee will be asked to adjudicate.

5.1 Complaints concerning promotional activities other than printed matter

5.1.1 The difficulty in particular of establishing evidence for the Disciplinary to consider in relation to complaints concerning promotional activities such as meetings, hospitality, samples etc. is recognised. The following requirements will therefore apply to such complaints:

(i) Any complaint in relation to such activity must have substance;
(ii) The complaint must be in writing and should contain enough detail about the activity alleged to be in breach of the Code, as to justify the Disciplinary Committee's consideration;
(iii) Any available material evidence must be included e.g. invitation or correspondence from the Respondent's company. The absence of such material evidence will not preclude the Disciplinary Committee's consideration of the complaint. If the Disciplinary Committee considers that such a complaint justifies investigation, it will have the right to ask the Respondent's company to demonstrate that it was in compliance with the Code.

5.2 Where a complaint fails to establish a prima facie case for a violation of the KEFEA Code, such complaint shall be dismissed with respect to the KEFEA Code.

5.3 Any complaint which pursues an entirely or predominantly commercial interest shall be dismissed.

6. REFERRALS (I.E. ALLEGED BREACHES OF CODE WHERE THERE IS NO FORMAL WRITTEN COMPLAINT)

6.1 Alleged breaches of the Code by a Code signatory which come to KEFEA's attention other than by way of a formal written complaint are defined as

"referrals". Such referrals are to be kept as confidential as possible and forwarded to the Disciplinary Committee for consideration.

6.2 Referrals are dealt with in accordance with the following procedure:

6.2.1 Establishing if referral is appropriate and has substance

6.2.1.1 Where the Disciplinary Committee receives information, from whatever source, from which it appears that a Code signatory may have contravened the Code, the Code signatory concerned shall be requested to comment on the matter(s) of complaint.

6.2.1.2 The Disciplinary Committee shall decide, having taken into consideration any information received, if the referral has substance and in particular if there is enough detail about the alleged activity as to justify its investigation. If the Disciplinary Committee decides that the matter does not warrant investigation, that decision will be final and the complainant shall be so advised.

6.3 Use of the referral mechanism by a Code signatory

6.3.1 Code signatories shall normally use the complaints mechanism to seek redress for alleged breaches of the Code. Where they use the referral mechanism they must provide the Disciplinary Committee with a satisfactory explanation as to why it was not possible to utilise the normal complaints mechanism.

6.3.2 The Disciplinary Committee shall then decide whether it is appropriate for the matter to be dealt with in this way or whether the Code signatory, should it wish to progress the matter further, should be required to use the complaints procedure outlined in Section 4 of this Annex. Where the Disciplinary Committee decides it is appropriate for the matter to be dealt with by way of the referral mechanism, it shall proceed accordingly.

6.4 Role of Disciplinary Committee

6.4.1 The Disciplinary Committee will be responsible for investigating the alleged breach and, in particular, for identifying any clauses of the Code which may have been breached. The referral will be handled using the standard procedures and timelines that apply to Code complaints. The Disciplinary Committee will have the same powers to apply sanctions as in the case of a complaint.

6.5 Procedure for Consideration of Referrals by the Disciplinary Committee

6.5.1 The following procedure shall apply to the Disciplinary Committee's investigation of a referral:–

(i) In order to expedite matters, the Disciplinary Committee may write to the company that is alleged to have breached the Code before the first meeting of the Disciplinary Committee seeking preliminary information to consider at its first meeting;

(ii) In any case, the company will be required to provide the standard undertakings that apply to complaints, i.e. an unqualified undertaking that it will comply with every reasonable request of the Disciplinary Committee and confirmation that it will accept the decision of the Disciplinary Committee;

(iii) After its first meeting, the Disciplinary Committee will issue a letter to the company setting out the alleged breaches of the Code and it will be required to submit a written response.

(iv) The Disciplinary Committee has the authority to seek any further additional information considered necessary from the company which is alleged to have breached the Code;

All information requested by the Disciplinary Committee must be provided within 10 working days, with extensions only possible at its discretion. If submitted in hardcopy, five bound copies of the information must be supplied. One electronic copy will suffice in lieu of five bound hardcopies.

(v) Thereafter the complaints procedure is applied, mutatis mutandis.

6A. APPEALS

6A.1 The complainant or the respondent company may appeal against a ruling of the Disciplinary Committee to the Appeals Board. Appeals must be accompanied by reasons as to why the Disciplinary Committee's ruling is not accepted. These reasons will be circulated to the Appeals Board. Notice of appeal must be given within five working days of notification of the Disciplinary Committee's ruling and the appeal itself must be lodged within ten days of notification of the Disciplinary Committee's ruling.

6A.2 If the Disciplinary Committee has so required, where the respondent company gives notice of appeal it must, within five working days of notification of the Disciplinary Committee's ruling, suspend the use of the promotional material or activity at issue, pending the final outcome of the case, and must notify the Disciplinary Committee that such action has been taken.

6A.3 If the respondent company accepts one or more of the Disciplinary Committee's rulings of breaches of the Code, but appeals one or more other such rulings, then within five working days of notification of the Disciplinary Committee's rulings it must provide the undertaking required by Paragraph 6.5.1(ii) above in respect of the ruling or rulings which it is not appealing.

6A.4 Where an appeal is lodged by the complainant, the respondent company has five working days to comment on the reasons given by the complainant for the appeal and these comments will be circulated to the Appeals Board.

The complainant has five working days to comment on the respondent company's comments upon the reasons given by the complainant for the appeal and these comments will be circulated to the respondent company and the Appeals Board.

Relevant material previously submitted to the Disciplinary Committee is provided to the Appeals Board. All additional material which the complainant and the respondent company want the Appeals Board to consider must be submitted in writing with the appeal, with the respondent company's comments on the reasons given by the complainant for the appeal or with the complainant's comments on the respondent company's comments on the reasons given by the complainant for the appeal. No new material may be introduced when the appeal is heard by the Appeals Board.

In the event that the respondent company objects to certain of its comments being made available to the complainant on the grounds of confidentiality, then it will be referred to an independent referee identified by the Chair of the Appeals Board, for example a former independent member of the Appeals Board, who will determine whether those particular comments can be included in the evidence which goes before the Appeals Board. The referee's decision is final.

6A.5 Where an appeal is lodged by the respondent company, the complainant has five working days to comment on the reasons given by the respondent company for the appeal and these comments will be circulated to the respondent company and the Appeals Board.

Relevant material previously submitted to the Disciplinary Committee is provided to the Appeals Board. All additional material which the complainant and the respondent company want the Appeals Board to consider must be submitted in writing with the appeal or with the complainant's comments on the reasons given by the respondent company for the appeal. No new material may be introduced when the appeal is heard by the Appeals Board.

In the event that the respondent company objects to certain details of its appeal being made available to the complainant on the grounds of confidentiality, then it will be referred to an independent referee identified by the Chair of the Appeals Board, for example a former independent member of the Appeals Board, who will determine whether those particular details can be included in the evidence which goes before the Appeals Board. The referee's decision is final.

Where an appeal is lodged by the respondent company, the complainant is sent a copy of the *initial* comments and enclosures submitted by the respondent company in relation to the complaint. If the respondent company objects to this because it regards part of the material as being confidential, then it will be referred to an independent referee identified by the Chair of the Appeals Board, for example a former independent member of the Appeals Board, for his/her determination which is final.

6A.6 Where the Appeals Board rules that there is no breach of the Code, the complainant and the respondent company are so advised in writing and are given the reasons for the decision.

7. SANCTIONS

7.1 Where the Disciplinary Committee, having considered a complaint or referral, has found that the Code has been breached it shall, without prejudice to the right of any affected party to have the matter resolved through the judicial process, have the authority to:

(i) Require the company concerned to cease the practice found to be breach of the Code and take all necessary steps to avoid a similar breach in the future;
(ii) Reprimand the company for the breach of the Code;
(iii) Order the recovery of material found to have been in breach of the Code;
(iv) Order the correction of inaccurate information by way of direct contact with relevant healthcare professionals or by publication, in the medical and/or pharmaceutical press, of a corrective notice in terms approved by the Disciplinary Committee;
(v) Impose a fine not exceeding Euro 5.000 for a first violation and a fine not exceeding Euro 10.000 for a second or further violation;
(vi) Order the immediate publication of the decision in whole or in part on KEFEA's website and specify how and to whom the decision is to be sent;
(vii) Recommend to the KEFEA Board of Directors suspension or expulsion from KEFEA of the offending party, which decision is immediately published on the KEFEA website.

This list is not exhaustive and other sanctions may be applied by the Disciplinary Committee as appropriate.

7.2 Where a Disciplinary Committee decision involves an action to be taken by KEFEA, the Disciplinary Committee should inform the Chairman of the Board of Directors of this in writing.

7.3 Where the Appeals Board rules that there is a breach of the Code, the respondent company is so advised in writing and is given the reasons for the decision. The respondent company then has five working days to provide a written undertaking providing relevant information as specified in Paragraph 6.5.1(ii) above.

7.4 Where the Appeals Board rules that there is a breach of the Code, it may require the company to take steps to recover items given in connection with the promotion of a medicine or non-promotional items provided to health professionals and members of the public and the like. Written details of the action taken must be provided to the Appeals Board.

7.5 Where the Appeals Board rules that there is a breach of the Code, it may reprimand the company and publish details of that reprimand.

7.6 Where the Appeals Board rules that there is a breach to the Code, it may require the company to issue a corrective statement. Details of the proposed content and mode and timing of dissemination of the corrective statement must be provided to the Appeals Board for approval prior to use.

7.7 Any decision of the Disciplinary Committee and/or Appeals Code taken in an individual case shall be published in **English** its entirety or, where only selected details are published, in a level of detail that reflects the seriousness and/or recurrence of the breach as follows:
(a) in cases of a serious/repeated breach, the company name(s) should be published together with details of the case;
(b) in cases of a minor breach, or where there is no breach, publication of the details of the case may exclude the company name(s).

8. ABUSE OF CODE

Abuse of the Code procedure shall in itself be a breach of the Code.

9. RECOURSE TO LEGAL SYSTEM

9.1 A company's right to have recourse to the legal system is not affected by participation in, and compliance with, the Code of Practice and the Disciplinary Committee and or Appeals Board's decisions.

9.2 However, it is envisaged that the transparency of procedures in this Code will ensure that the necessity for such action will not arise.

9.3 A Complainant/Respondent must advise the Disciplinary Committee and/or Appeals Board in the unlikely event of recourse to the legal system before or during a complaint or appeal. The Disciplinary Committee and/or Appeals Board, as appropriate, will have the right to take whatever action it sees fit under the circumstances.

10. ADMINISTRATION FEES

KEFEA reserves the right to set fees for the operation of the Disciplinary Committee and/or the Appeals Board at any time in the future.

ANNEX D (binding)
KEFEA Process for Requesting an Exception to Hold an Event at a 5* or more Location

PROCESS FOR REQUESTING EXCEPTION TO HOLD AN EVENT AT A 5* OR MORE LOCATION

A 4* hotel is taken to be included in the definition of an "appropriate establishment", whereas hotels with 5* or more are prima facie excluded from such definition, as they are considered to be "renowned" or "extravagant". If a KEFEA member exceptionally is contemplating either the holding of an Event or its participation in any way in an Event in a 5* or more hotel, then prior approval should be sought from the KEFEA Board of Directors in this respect.

Such an approval should be sought through a written substantiated application, addressed to the Board of Directors of KEFEA in the format which can be found on the KEFEA website, at least six (6) months prior to the date of the Event, stating the reasons why the specific location was chosen and producing evidence in this respect.

The Board of Directors has the discretion after assessing the above-mentioned application to approve or decline such an application and its decision, which has to be communicated within 45 days to the KEFEA member, should be considered final.

HCOs wishing to hold events in 5* or more hotels may apply to the Board of Directors of KEFEA for a ruling. The Board of Directors will examine such an application, based on the criteria mentioned above and will provide its ruling. Non-approval of an application by an HCO is applicable only towards the KEFEA member and not towards the HCO, which can still proceed with the holding of the Event without the participation of the KEFEA member.

ANNEX E (optional)
PO Disclosure template (optional but recommended)

Patient Organisation disclosure template						
PO name	**Country**	**Types of the support or services provided**	**Description of the support or services 1**	**Monetary value of financial support and of invoiced costs**	**Non-monetary benefit for PO 2**	**Fees for services paid**
		Financial support		In euros		
		Financial support		In euros		
		Financial support		In euros		
		Financial support		In euros		
		Significant indirect support		In euros		
		Significant indirect support		In euros		
		Significant indirect support		In euros		
		Significant indirect support		In euros		
		Non-financial support			In euros	
		Non-financial support			In euros	
		Non-financial support			In euros	
		Non-financial support			In euros	
		Contracted services				In euros
		Contracted services				In euros
		Contracted services				In euros
		Contracted services				In euros
1: Add a clear description of the purpose of the support or services						
2: For example, employee hours or companies facilities offered to support a Patient Organisation activity						

Preamble

The purpose of this document is to provide a guideline for the implementation of KEFEA Code Article 16. The guideline must be read with the requirements and spirit of the Code in mind and in accordance with applicable laws and regulations, in particular, the EU Directive 2001/83/EC Titles VIII and VIIIa on information and advertising.

The intention of this guideline is to ensure that LLH by the pharmaceutical industry adheres to high ethical standards and robust educational principles with the ultimate common goal to benefit patients.

LLH must not constitute promotion.

High scientific standards and the process of quality assurance for medical learning programmes are required to maximise transparency, ensure quality, fair and balanced content, and mitigate bias. The pharmaceutical industry strives to use educational principles which are based on, learner-centric engagement to advance the value and impact of learning.

The Value of the Pharmaceutical Industry in LLH

The pharmaceutical industry has a legitimate role among other stakeholders in providing evidence to ensure innovations are used safely and in the appropriate patient populations.

To keep up with the speed and breadth of scientific and medical progress, different LLH providers are needed for rapid diffusion of new evidence and innovations in healthcare. Given that the pharmaceutical industry must ensure its medicines are used safely and in the right populations, it provides important high quality and a complementary channel for LLH.

To facilitate a robust and practical learning experience with a fair and balanced presentation of evidence, the pharmaceutical industry often partners with leading and recognised experts.

The pharmaceutical industry is in constant dialogue with healthcare professionals at the global, regional and local levels and may be in a position to identify and address learning needs that may not be covered by other providers of LLH.

With its large geographic footprint, the pharmaceutical industry can provide opportunities for education to HCPs in countries with limited access to LLH offerings.

With innovation in therapeutic areas, the pharmaceutical industry is frequently at the forefront of the provision of LLH to assist and accelerate the translation of clinical research and other advancements into clinical practice.

Introduction

Multiple terms are used to describe learning and Continuous Professional Development (CPD). These vary across regions and countries and may or may not be associated with formal accreditation. In the KEFEA and EFPIA Code Article 16 as well as in this document the term Lifelong Learning in Healthcare (LLH) is used to describe non promotional educational activities led and/or funded by the pharmaceutical industry and that fulfil unmet educational needs in healthcare.

LLH must not be to promote company products, devices or healthcare solutions, but to translate evidence relevant for enhancing patient care into respective learning interventions in disease areas. Company-driven, product only specific educational activities which promote medicinal products are out of scope for this document. Such activities must comply with laws and regulations for the promotion of medicines.

The following types of educational activities are covered by this guideline and have common objectives, but differ as to the level of pharmaceutical industry involvement, ownership and funding:

1. Independent Medical Education (IME), with or without Continuous Medical Education (CME) or Continuous Professional Development (CPD) accreditation. IME is conducted by an independent organisation without industry involvement or influence and can be funded by the pharmaceutical industry.

2. LLH programmes developed through collaboration or partnership of one or more pharmaceutical company(ies) with professional societies, healthcare organisations, education providers, or other key stakeholders. The collaboration/partnership includes a commitment to a definition of mutual relationships and goals; a jointly developed structure and shared responsibility; mutual authority and accountability for success.

3. Pharmaceutical industry led LLH activities, which may address human health, and diseases -specific learning needs. These activities are organised by individual pharmaceutical companies and may involve scientific committees, and/or independent scientific and professional organisations. Ownership, accountability and funding for these programmes remains that of the pharmaceutical company.

Whatever the type of LLH, the pharmaceutical industry is committed to delivering and supporting high-quality learning. The pharmaceutical industry expects other stakeholders, such as IME providers, scientific committees, scientific organisations or professional associations to adhere to the following principles when receiving pharmaceutical industry support/funding for LLH.

Quality Framework

This document describes the following 3 elements:

1. Ethical, transparent and responsible engagement;
2. Quality content: programmes and activities must not be promotional, either in content or intent; and
3. Robust processes: educational needs assessment, learning design and outcomes measurement.

Ethical, transparent and responsible engagement is mandatory for any LLH activity. Quality content and robust processes are strongly recommended to meet the highest quality learning standards and educational impact.

1. Mandatory requirements: Ethical, transparent, and responsible engagement

Ethical, transparent and responsible engagement is the overarching and basic principle of the quality framework and is mandatory. It is supported by robust educational processes and quality content. It is the responsibility of the funding pharmaceutical company to ensure the scientific integrity of LLH activity.

The purpose of ethical, transparent and responsible engagement is to address the following major considerations:

- **Funding**: Transparency regarding the reporting of funding and other value provided to those delivering or receiving the education as per EFPIA Code Chapter 2 and 5
- **Disclosure**: Disclosure of interests and potential conflicts of interest for any activity type of LLH by all party(ies) involved
- **Intent:** Transparency regarding intent, involvement, roles and responsibilities and nature of potential collaboration with external stakeholders (clinicians, medical associations/organisations)
- **Data privacy:** respect regulations (such as per GDPR)
- **Compliance** with pharmaceutical industry codes of practice [such as IFPMA, EFPIA], EU regulations and local applicable laws and regulations

2. Recommended practices

2.1 Quality content

The objective of LLH is to increase the scientific knowledge and competence of HCPs to enhance medical practice and improve the overall patient and healthcare outcomes. Quality content is the foundation of LLH.

To ensure high quality content is provided by pharmaceutical industry led and/or funded LLH activities, the programmes must not be promotional, either in content or intent. They must not include product branding (trade name, logo, brand colours etc.), nor product claims.

It is recommended that a scientific committee formed of experts in the specific disease areas is responsible for developing the agenda/programme, selecting the faculty and guaranteeing the scientific integrity of the programme. With the exception of IME, members of pharmaceutical industry scientific/medical functions and therapeutic area specialists can be members of scientific committees.

Companies should consider the following principles in order to ensure high quality content for LLH programmes:

- Needs-based: needs may be identified through scientific literature review, by a scientific committee and/or a dedicated educational needs assessment - see Section 3.1
- Up to date, factual and of high scientific standard capable of substantiation: use of the most appropriate, current and evidence-based content relevant to current clinical practice and standards
- Balanced and objective: provision of scientifically balanced perspectives on the subject matter with involvement of independent scientific input when appropriate and allowing time for scientific peer to peer exchange
- Incorporates multiple sources of scientific data
- Referenced: all content should be referenced so learners can assess the level of statistical and clinical relevance of the content

Different learning styles, the cultural differences of the audience and modes of delivery should be considered to best meet the learning objectives. All components of the programme, regardless of method, design or channel (digital, visual and practical) must give a clear, fair and balanced view of the information/data they aim to convey and allow the expression of diverse theories and recognised opinions.

2.2 Robust processes

To ensure high educational quality; a robust and standardised process is strongly recommended, including:

- Educational needs assessment
- Learning design
- Outcomes assessment

Each pharmaceutical company will individualise their own educational processes. Examples below are intended to assist companies in the design of their processes

2.2.1. Educational needs assessment

A disciplined and accurate assessment of programme participants´ learning needs is a recommended initial step in planning educational activities and should ensure clarity on the selection criteria. Selection of delegates should be based on educational needs.

Needs can be classified as:

- Perceived needs; expressed and perceived by learners– e.g. a survey among HCPs attending a specific LLH activity
- Expressed needs; expressed in action – e.g. a clinical centre's need to understand new guidelines in clinical practice

- Normative needs; stated by experts
- Comparative needs; expressed in group comparison for instance between clinical institutions and their clinical practice.

An educational needs assessment should include input from multiple stakeholders in healthcare. Methods for assessing learner´s needs can include reviewing literature, qualitative exploratory research, surveys, input from experts and other stakeholders in healthcare, advisory boards and multiple other data collection methods.

2.2.2. Learning design

The current healthcare ecosystem is undergoing a major transformation. This is driven by a more patient centric approach towards healthcare and vast improvements in technology. This transformation requires all stakeholders in the healthcare ecosystem to collaborate for LLH processes to meet high educational standards.

A quality assurance framework may include a standardised process for learning design and should be part of a developed higher-level strategy that aims at increasing the scientific knowledge and competence of HCPs to enhance medical practice and improve patient and healthcare outcomes.

Such processes could include an outcomes-based planning approach and should communicate what LLH should achieve. The following steps may be used in education:

1. Identify the intended outcomes based on educational needs (see needs assessment)
2. Agree on acceptable evidence e.g. discuss programme and faculty with scientific committee based on identified learning outcomes
3. Plan the learning experience

2.2.3. Outcomes measurement

To ensure continuous improvement in LLH, different approaches for measurement should be used and outcomes used to improve future programmes. Measurements may apply to different learning or instructional design and delivery channels. Although objective measures are preferred, subjective measures are used where the opinion of learners is sought, (e.g. ‘satisfaction’ or ‘relevance’).