

KEFEA

CODE OF CONDUCT
ON THE PROMOTION
OF PRESCRIPTION ONLY MEDICINAL PRODUCTS

CODE OF CONDUCT
 January 7, 2016

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Introduction

The Cyprus Association of Research and Development Pharmaceutical Companies' (**KEFEA**) Code of Conduct, hereinafter called "the Code", covers the promotion of prescription only Medicinal Products. "**Promotion**" includes every activity undertaken, organised or carried out by a pharmaceutical company or commissioned thereby, promoting the prescription, supplying, sale, administration or consumption of the Medicinal Product of companies - members of KEFEA. Pharmaceutical companies which are not members of KEFEA but their mother companies or their representatives in Cyprus are members of EFPIA have an obligation to comply with the provisions of this Code. The term "**Medicinal Product**", as used in the Code, bears the meaning determined in Article 1 of Directive 2004/27 on the Community Code relating to medicinal products for human use (Official Journal of the European Communities L 136/30-11-2004) as well as section 3 of the Medicinal Products for Human Use (Control of Quality, Supply and Pricing) Law of 2001 as amended or to be amended (Law).

KEFEA is the representative body of International Pharmaceutical Companies in Cyprus and is a member of EFPIA. It is particularly sensitive towards supplying objectively correct information to the Healthcare Professionals for the proper use of Medicinal Products, as it is mandated by Directive 2001/83/EC and which includes the existence of a system of self-regulation and correction of practices relating to the promotion of Medicinal Products.

With the introduction and setting up of this Code, **KEFEA** wants to ensure that the promotion of Medicinal Products to Healthcare Professionals is done in a transparent and sincere way without malice in accordance with the Law.

KEFEA has transposed EFPIA's 'Disclosure Code', with first disclosures expected by corporate members in 2016 regarding all transfers of value to Healthcare Professionals and Organisations made in 2015.

CODE OF CONDUCT

Substantial regulations

Article 1 – Field of application of the Code – definitions

1.1. The Code of Conduct, hereinafter called the “Code”, refers to the principles and procedures which must be applied for the promotion of prescription only Medicinal Products to Healthcare Professionals (such as physicians, pharmacists, etc.), as well as the information allowed to be addressed to the public on general health issues, and includes the Disclosure Code set out in Article 24.

It does not refer to the promotion procedures of non-prescription Medicinal Products, when the object of the promotion is to encourage the purchase of the Medicinal Products by the public.

It includes:

- The promotion of Medicinal Products to persons qualified to prescribe or supply Medicinal Products.
- The visits carried out by medical sales representatives to persons qualified to prescribe or supply Medicinal Products.
- The supply of samples.
- The sponsorship of meetings for the promotion of Medicinal Products or/and scientific conferences where persons authorised to prescribe or supply Medicinal Products participate, particularly when the travel and hospitality expenses of participants are covered.
- The provision of information to the general public, either directly or indirectly.

It also includes:

- Advertising in journals or by mail.
- The activities of medical sales representatives including any printed material used by them.
- The provision of hospitality at professional or scientific events and meetings for the promotion of Medicinal Products.
- The sponsorship of promotional material addressed to Healthcare Professionals, including disease awareness materials.
- All the remaining activities for the promotion of sales in any form whatsoever, such as the participation in exhibitions, the use of audio-visual material, films, disks, video tapes, electronic media, interactive data systems etc.
- The documentation and disclosure of transfers of value that pharmaceutical companies make directly or indirectly to or for the benefit of Healthcare Professionals.

It does not include:

- The summary of product characteristics (SPC), for which the relevant regulations are applied.
- The labelling and the package leaflet of Medicinal Products, for which the relevant regulations are applicable.
- Mail correspondence that may be accompanied by any other non-advertising or non-promotional material, needed to answer specific questions with respect to a Medicinal Product.
- Accurate and objective announcements and the relevant documents (bibliography) which refer i.e. to changes in the packaging, warnings with respect to adverse reactions, within the framework of pharmacovigilance, as well as the

sales lists and price lists, provided they do not contain any information with respect to the Medicinal Product.

- Replies to individual enquiries from healthcare professionals or the answers to specific questions or comments.
 - Replies to letters published in scientific journals, provided these refer exclusively to the content of the letter or the question, are accurate and not misleading and do not constitute per se, a means of promotion.
 - Commercial measures or practices relating to prices or profit margins and discounts are not affected by Article 17 of the Code.
- **Radio and television are not mentioned since the promotion of prescription only Medicinal Products to the general public is prohibited.**

1.2. Definitions

“Medicinal Product” has the meaning determined in Article 1 of Directive 2004/27 of the Community Code relating to Medicinal Products for human use (Official Journal of the European Communities L 136/30-11-2004) as well as section 3 of the Medicinal Products for Human Use (Control of Quality, Supply and Pricing) Law of 2001, as amended or to be amended (Law), and includes:

- Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or
- 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 for making a medical diagnosis.
- Summary of Product Characteristics (SPC) is the summary approved by the competent authorities which granted the marketing authorisation in accordance with the legislation in force.
- “Package leaflet” is a leaflet containing information for the user which accompanies the Medicinal Products.
- “Labelling”: Information on the immediate or outer packaging.
- “Medical Information” (ME): The provision of scientific information by pharmaceutical companies to Healthcare Professionals (physicians, dentists, veterinaries and pharmacists), with respect to the Medicinal Products marketed under their responsibility, aiming at the proper use thereof, as authorised by the Drugs Council or the European Medicines Agency (EMA), for the protection of public health. Medical Information may be oral, in writing, audio-visual or using other technological means.
- The term “promotion” includes every activity undertaken by a pharmaceutical company or upon instructions thereof, for the promotion of provision, sales or prescription of its Medicinal Products.
- The term “Healthcare Professional” includes the members of the medical, dental, veterinary, pharmaceutical or nursing profession as well as all other persons authorised to prescribe, supply or administer Medicinal Products in the course of their professional activities.
- “Non-prescription Medicinal Products” are Medicinal Products, which may be administered without a prescription.
- “Medical sales representative” or “scientific associate: a health professional, or a scientist from another sector or a person having the required general and specific knowledge for the oral information, in order to communicate concrete, responsible and accurate information with respect to Medicinal Products.
- “Medical press” are scientific and other journals addressed to Healthcare Professionals.

Article 2 – Discredit to and reduction of confidence in the pharmaceutical industry (the Industry)

Activities or materials related to the promotion must under no circumstances cause discredit upon or reduction of confidence in the Industry, in general or to a specific pharmaceutical company.

Article 3 – Granting of a marketing authorisation

It is prohibited to promote the sale or supply of any Medicinal Product for which a marketing authorisation has not been granted unless the Drugs Council temporarily permits said marketing under section 9A of the Law.

All data of the medical information with respect to a Medicinal Product must comply with the information included in the summary of product characteristics.

The medical information with respect to a Medicinal Product:

- Must promote the rational use of the Medicinal Product, presenting it in an objective way, without exaggerations concerning the properties thereof.
- Must not be misleading.

Unauthorised indications

It is prohibited to promote indications which are not covered by the marketing authorisation or have not yet been approved.

Article 4 – Promotional material addressed to Healthcare Professionals

4.1. Content of the promotional material

Each promotional material with respect to a Medicinal Product, addressed to persons authorised to prescribe or supply Medicinal Products, must include:

- The substantial information compatible with the summary of product characteristics.
- The classification of the Medicinal Product as far as the administration conditions are concerned (i.e. subject or not to medical prescription).

In the context of promotional material, the retail price of the different packages as well as the reimbursement rate by social security funds must also be included.

The promotional material with respect to a Medicinal Product to persons authorised to prescribe or supply Medicinal Products may include only the name of the Medicinal Product, when the sole purpose thereof is to remind of the name of the Medicinal Product.

All promotional material with respect to a Medicinal Product, which is sent or given in the context of the promotion to persons authorised to prescribe or supply Medicinal Products, must include at least the information under section 4.2 of the Code and state the date on which it was drawn up or last revised.

Promotion must be accurate, balanced, fair, objective and complete in order to enable the recipient to form an opinion with respect to the therapeutic value of the specific Medicinal Product. It must be based on the up-to-date assessment of all relevant findings and clearly reflect it. It must not mislead by distortion, exaggeration, unjustified emphasis, omission or by any other means. Promotional material must be documented, and be given rapidly in reply to

reasonable requests from Healthcare Professionals. In particular, promotional claims with respect to adverse reactions must reflect the authorised indications or must be documented with clinical experience. However, no documentation is required with respect to the information included in the marketing authorisation.

Promotion must encourage the rational use of Medicinal Products, presenting them objectively and without exaggerating their properties. Claims must not imply that a Medicinal Product or an active ingredient has special value, quality or virtue, unless this can be documented.

References to information contained in tables and representations from publications in medical journals or scientific works used in the informative document must be faithfully reproduced and the source thereof accurately indicated.

4.2. Prescribing information and other compulsory information

4.2.1. Prescribing information on a Medicinal Product must be provided in a clear and easy to read manner in all promotional material with the exception of reminder advertisements (see section 4.1) and promotional aids fulfilling the terms and conditions of section 17.4.

Prescribing information must constitute an integral part of the promotional material.

4.2.2. Prescribing information consists of the following:

- The name and the common name of the Medicinal Product.
- The qualitative and quantitative composition thereof in active ingredient(s).
- The name and the legal seat of the pharmaceutical company responsible for marketing the Medicinal Product.
- The authorised indications.
- The adverse reactions, warnings and counter-indications relevant to the indications promoted.
- Any warnings approved or additionally imposed by the authority, which granted the marketing authorisation.
- The classification of the Medicinal Product (e.g. for hospital use, under medical prescription only, etc.)
- The number of the marketing authorisation and the holder of the marketing authorisation.
- A declaration that further information is available and shall be provided upon request by the holder of the marketing authorisation or is included in the summary of the product characteristics, the package's leaflet and the monograph of the Medicinal Product.
- The selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.

Information with respect to the dosage, the method of administration, the adverse reactions, warnings and counter-indications as well as any precaution which must be included in promotional documents or in entries shall be presented in such a way as to enable the readers to assess the connection thereof with the claims and indications of the product.

4.2.3. In case of audio-visual material, such as films, tapes, video tapes, etc., and in case of interactive data systems, the prescribing information may be given:

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- By means of a document distributed to all the persons to whom the material is displayed or sent, or
- By introducing them in the audio-visual material or the interactive data system.

If the prescribing information is included in an interactive data system, clear instructions must appear for access to it.

- 4.2.4.** In case of audio material, i.e. material which consists of sound only, the prescribing information must be provided by means of a document distributed to all the persons to whom the material is displayed or sent.
- 4.2.5.** In case of an insertion in a medical journal where the prescribing information appears on a subsequent page, a reference to where it can be found must appear on the external margin of the first page of the insertion.
- 4.2.6.** In case of printed promotional material, consisting of more than four pages, a clear reference must be given to where the prescribing information is located.
- 4.2.7.** All promotional material must bear at the lower part of the last page, a code with the initials of the Medicinal Product and/or therapeutic area, a reference to the series, the month and the printing time of the journal, and should be certified in accordance with the principles mentioned in Article 14 of the Code. Companies have the obligation to keep in their archives all the printed promotional material for three years.

Article 5 – Promotion in the medical press

Where two pages of an advertisement are not facing each other, none of the two can be misleading or false when read alone.

Article 6 – Information, claims and comparisons

- 6.1.** Companies must provide to Healthcare Professionals and the competent administrative executives, upon request, accurate information with respect to the Medicinal Product distributed by each company.
- 6.2.** Information, **claims and comparisons** must be correct, accurate, objective and clear and must be based on relevant and comparable aspects of the Medicinal Products as well as on an updated assessment of all data, reflecting clearly the facts. They must not be misleading, either explicitly or implicitly, and they must not distort the scientific facts.

The direct or indirect promotion of misleading indications of the Medicinal Product, reference to older scientific data (if there is newer different information available), the promotion of inaccurate or undocumented claims, the misleading comparison with other Medicinal Products and the generalisation of isolated observations are prohibited.

- 6.3.** Any information, claims or comparisons must be scientifically documented.
- 6.4.** The documentation of any information, claims or comparisons must be provided without delay upon request of a Healthcare Professional or a competent administrative executive of the health system. However, no documentation is necessary with respect to indications approved in the marketing authorisation.
- 6.5.** In cases where the promotional material refers to published studies, clear bibliographical references must be provided.

In the event that promotional material refers to data included in the file, the corresponding section referring to the said data must be provided, upon request, without delay to Healthcare Professionals or to the administrative personnel.

Wherever there is a claim based on in vitro studies or studies on experimental animals, it must be clearly indicated in the promotional material that these are experimental data.

- 6.6. The overall creative part, including images, graphs and tables, must comply with the letter and spirit of the Code. Graphs and tables must be presented in such a way as to provide a clear, fair and balanced view of the data presented. These must be included only if they are relevant to the claims or comparisons made. Medical information leaflets cannot bear representations irrelevant with the content thereof, misleading or implying any vague indications for the Medicinal Product.
- 6.7. Information and claims with respect to adverse reactions must reflect the data available or must be verifiable with clinical experience. It must not be declared that a product does not have adverse reactions, interactions with other Medicinal Products or a risk of toxicity. The term "safe" must not be used without detailed justification.
- 6.8. No exaggerated or **generalised claims** must be made and superlative must not be used, except in restricted cases where there is a reference to clear facts for specific Medicinal Products. Claims must not imply that a Medicinal Product or active ingredient has a specific advantage, quality or property except in cases where this can be verified.
- 6.9. The words "innovative" or "new" must not be used for the description of a product or package and form which are already marketed, or for a therapeutic indication which has been promoted for more than 12 months.
- 6.10. Trade names of other companies must not be used without the prior authorisation of the holder of the marketing authorisation of the other Medicinal Product.

Article 7 – Discrediting reports

- 7.1. Medicinal Products and activities of other companies must not be mentioned in a discrediting manner.
- 7.2. The healthcare professions, the clinical practice and the scientific opinions of them must not be discredited.

Article 8 – Form of the promotional material and protection of Healthcare Professionals from possible offence

- 8.1. The overall material and the promotional activities must acknowledge the special nature of Medicinal Products and the professional position of the scientists it is addressed to, who must be respected and protected from any offence. A high standard of ethics must always be ensured.
- 8.2. The name or the photo of a Healthcare Professional must not be used in any way whatsoever contrary to his profession's ethics.
- 8.3. The promotional material must not imitate the methods, the prints, the slogans (sayings) or the general layout adopted by another company in a way which may create deception or confusion.

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- 8.4. The promotional material may include references to the Drugs Council, the European Medicines Agency (EMA) or other bodies on condition that for further information the references are mentioned.
- 8.5. Reproductions of official documents may be used in the context of medical information, under the condition that they are presented intact, without any abbreviations or distortions.
- 8.6. Exaggerations must be avoided with respect to the shape, size and cost of the promotional material.
- 8.7. Correspondence **cards**, the uncovered part of mailed materials, envelopes or packaging must not include a text which could be considered by the general population as promotional, and is contrary to Article 19.
- 8.8. Telephone communications, telephone messages, electronic mail and telefax must not be used for promotional purposes without the recipient's prior consent.
- 8.9. All the material related to Medicinal Products and their use, which is distributed by a specific pharmaceutical company, must clearly indicate that it was provided by the said company.

Article 9 – Disguised promotion

- 9.1. Promotional material and activities must not be disguised.
- 9.2. Clinical assessments, post-marketing surveillance, experience programs and post-authorisation studies must not constitute a disguised promotion. Such assessments, programs and studies must be performed mainly for a scientific or educational purpose.
- 9.3. When a pharmaceutical company sponsors or secures in any other way or regulates the publication of promotional material in a scientific journal, the said promotional material must not be presented as an independent article.
- 9.4. The material sponsored by a pharmaceutical company, which refers to Medicinal Products and the use thereof, and refers to the promotion or not of these Medicinal Products, must necessarily not include any deceptive or inaccurate references and indicate clearly that the pharmaceutical company is the one sponsoring the material.

Article 10 – Distribution of reprints

- 10.1. Reprints from medical and scientific bibliography or personal communications must accurately reflect the meaning of the author.
- 10.2. Quotations relating to Medicinal Products which are taken from public communications, e.g. radio, TV or medical congresses or symposia, must not be used without the official permission of the speaker.
- 10.3. 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 11 – Distribution of promotional material

- 11.1. Promotional material must only be sent or distributed to the categories of Healthcare Professionals who need it or who it concerns (or to whom it is destined).

- 11.2.** Pharmaceutical companies must regulate the frequency of distribution and the volume of promotional material in such a way so as to respond to the needs of substantial information.
- 11.3.** Recipients' lists must be updated and be in accordance with the legislative regulations concerning sensitive personal data. Requests from Healthcare Professionals to be removed from a recipient's list must be immediately obeyed, while no name may be restored unless upon request or consent of the recipient.

Article 12 – Scientific service responsible for information

Pharmaceutical companies are obliged to have a scientific service responsible for providing information (usually within the context of the medical department) on the Medicinal Products they market, which shall reply to all questions whether these are received from medical sales representatives, patients or any other sources. The questions may be recorded and archived.

Article 13 – Certification of promotional material

- 13.1.** Before printing, promotional material must be certified in accordance with the provisions of the legislation in force.

The scientific service in Article 12 ensures the proper internal procedures for certification of the promotional material in order to secure implementation of the legislation in force and the Code.

Company material generally related to Medicinal Products, without aiming at providing medical information on particular Medicinal Products, as, for instance, company classified advertisements, press releases, market research material, financial information to shareholders, the value of shares, educational/information material for patients, etc., must be certified in order to ensure compliance with the Code and the legislation in force.

The fact that a non-promotional text/material may be used for promotional purposes and subsequently fall under the provisions of the Code, must be taken into account.

The company personnel and anyone connected with the company in any way and engaged in the creation or approval of the promotional material or activities must be fully familiar with the requirements of the Code (s) in force and the relevant laws and regulations.

- 13.2.** Companies communicate to the committee for the implementation of the Code the name and position of the person responsible for the certification of the promotional material, which the committee may contact on issues concerning implementation of the Code regulations. Any modification of this information must be immediately communicated to the committee.
- 13.3.** 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.

- 13.4.** Companies must keep all certified material, along with the accompanying material in the form it was certified, information indicating the classification of the individuals to which the material was addressed and the method of dissemination, for at least 3 years after their use, in order to submit them and to have access thereto if needed.

It is particularly important that an archive be kept for the audio-visual material as well.

Article 14 – Medical sales representatives

- 14.1.** Medical sales representatives must be sufficiently trained by the employing company in accordance with the Medicinal Sales Representative Law 74(I)/2002, as has or will be amended, and must have satisfactory scientific knowledge in order to provide accurate and, as much as possible, complete information with respect to the Medicinal Products they present.
- 14.2.** Medical sales representatives must comply with all the relevant requirements of the Code and all the legislative regulations in force. Pharmaceutical companies shall ensure the compliance of medical sales representatives with the aforementioned regulations. Medical sales representatives must carry out their duties with responsibility and respect for Ethics.
- 14.3.** During each visit, medical sales representatives must remit to the visited person, or keep at their disposal for each Medicinal Product they present, the summary of product characteristics, duly completed with the information indicated in Article 4 of the Code with respect to price and reimbursement by social security funds when applicable.
- 14.4.** Medical sales representatives must report to the scientific service of their company (which is provided for in Article 12 of the Code) all the information with respect to the use of the Medicinal Products they promote, in particular with respect to reactions communicated by the persons they have visited. These must be immediately communicated to the person responsible for pharmacovigilance in order to start the legal procedures, if needed.
- 14.5.** Medical sales representatives must at all times have a high standard of ethical conduct while carrying out their duties and must comply with all the requirements of the Code and the legislation in force.
- 14.6.** Medical sales representatives must ensure that the frequency, timing and duration of the visits to Healthcare Professionals or hospitals, health authorities' administrative executives and related persons, do not hinder the exercise of medical practice of health professionals. The wishes of the persons who the representatives request to visit as well as the regulations in force in each hospital must be respected.
- 14.7.** During a visit, or when asking for a visit, medical sales representatives must be careful not to create any deception with respect to their identity or the company they represent.
- 14.8.** Companies are responsible for the activities of their representatives, when these activities are performed in the framework of the purpose for which they are employed.
- 14.9.** Medical sales representatives must not use any incentive or pretext in order to pay a visit. During a meeting or when a meeting is pursued, medical sales representatives must, in principle, proceed in rational steps, in order to ensure that they are not misleading with respect to their identity or the identity of the company they represent.

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14.10. Medical sales representatives must, under the responsibility of the company they work for, be taught the Code during their training period and periodically undergo systematic training with respect to the overall work of the company.

Article 15 – Training

All the related personnel, including the members of personnel involved in any way whatsoever with the preparation or the approval of the promotional material, the information to be given to Healthcare Professionals and competent administrative executives or information to be given to the general population, must fully comply with the requirements of the Code.

Article 16 – Medical samples

- 16.1** The production, importation and free distribution of medical samples to persons authorised to provide medicinal products or to supply the relevant prescriptions are permitted only pursuant to section 69 of the Law.
- 16.2** Without prejudice to the aforesaid, for prescription only medicinal products supplied to the local market after **1 January 2012**, a number of medical samples may be supplied on an exceptional basis and for a limited period. For the purposes of this section, the word (a) "limited" shall be interpreted as meaning that each Healthcare Professional 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 date that the first pack is placed on the local market and (b), "products" shall be interpreted as meaning a Medicinal Product for which a new marketing authorisation (MA) has been granted, either following an initial MA application or following an extension application for new strengths / dosage forms that include a new indication. Extensions of the MA to additional strengths / dosage forms for existing indications or pack sizes (number of units in the pack) cannot be considered as new Medicinal Products.
- 16.3** 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 Healthcare Professionals qualified to prescribe that particular medicine. Written requests must be signed and dated by the recipient.
- 16.4** For Medicinal Products launched before 1 January 2012, a transition period until 31 December 2013 should apply. During this transition period, the local regulation of a maximum of 6 samples of a particular Medicinal Product per year per prescriber will still hold.
- 16.5** Companies must have adequate systems of control and accountability for samples which they distribute and for all Medicinal Products handled by their representatives. This system shall also clearly establish, for each Healthcare Professional, the number of samples supplied in application of the provision in section 16.2 above.
- 16.6** Each sample shall be no larger than the smallest presentation on the market.
- 16.7** Each 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 17 - Informational or educational materials and items of medical utility – Grants and sponsoring

17.1. The transmission of informational or educational material is permitted provided it is:

- (i) "of negligible value"; (ii) directly relevant to the practice of medicine or pharmacy; and (iii) directly beneficial to the care of patients. The transmission of such materials or items shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a Medicinal Product.

Items of medical utility aimed at the education of Healthcare Professionals and patient care can be provided if they are of negligible value and do not offset routine business practices of the recipient.

Negligible value is if their value does not exceed **30 Euros** per item.

Items such as gloves, tissues, blood pressure cuffs, pens and pads of paper are considered gifts and are therefore banned.

Companies can provide pens or paper pads exclusively during company-organised meetings, as long as they are non-product branded and inexpensive. Companies are not allowed to distribute pens or paper pads at exhibition stands. Pens or paper pads included in conference bags should not bear company or product logos.

Examples of the above which are permissible include:

- Use of company logo on medical utility items.
- Use of company logo on writing pads and pens during company / internal organised meetings.

The above amendments shall enter into force as of 1 July 2014.

17.2. Prescribing information for a Medicinal Product as required under section 4.2 does not have to be included in the informational or educational material if the informational or educational material includes no more than the following:

- The name of the Medicinal Product
- An indication that the name of the Medicinal Product is a trade mark.

17.3. Donations, grants and benefits in kind to institutions, organisations or associations that are comprised of Healthcare Professionals and/or that provide healthcare or conduct research are only allowed if:

- i. they are made for the purpose of supporting healthcare or research;
- ii. they are documented and kept on record by the donor/grantor; and
- iii. they do not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer specific Medicinal Products.

Donations and Grants to individual healthcare professionals are not permitted.

17.4. Persons authorised to prescribe or supply Medicinal Products may not seek or accept any gifts for personal benefit (e.g. tickets for entertainment purposes).

17.5. It is permitted to offer medical and educational goods and services which improve patients' healthcare and which are to the patients' benefit or to the benefit of the National Health System, to private hospital institutions, healthcare centres and to general hospital institutions of the public sector, monitored by the Ministry of Health, which are directly associated with the provision of healthcare services.

The various medical or diagnostic equipment, scientific publications, electronic aids (electronic connections with data bases, electronically supported programs etc.), are classified in this category.

It is also permitted to sponsor independent scientific and research programs of hospital institutions.

The donation of items under the present paragraph as well as these services must not be effected in a way which constitutes an inducement to prescribe or purchase the Medicinal Product. It is allowed to indicate the name of the company on the objects donated to hospital institutions but not the name of a Medicinal Product.

Application of the present paragraph requires compliance with the procedures foreseen for each kind of grant (donation, sponsoring, etc.), in a regime of complete transparency, publicity, and with compulsory application of the relevant regulations, as well as the related regulations of the provisions of Cypriot tax legislation.

- 17.6** With the exception of the abovementioned paragraphs of this Article, provision, offer or promise of any consideration, monetary gift or benefit to persons who are not authorised to prescribe or supply Medicinal Products is strictly prohibited in any form whatsoever.

Article 18 – Safeguarding of personal data

- 18.1. The processing of personal data of healthcare professionals must be done in accordance with the Processing of Personal Data (Protection of Individuals) Law 138 (I)/2001, as has or will be amended.**
- 18.2.** Mailing lists must always be updated. The request of Healthcare Professionals to be removed from the lists must be satisfied.
- 18.3.** With the reservation of the application of national laws and regulations, the utilisation of fax, emails, automatic phone dial-systems, text messages and other communications with electronic data are prohibited except with the prior consent or upon request of the recipient.

Article 19 Sponsoring of scientific congresses / Events – hospitality

19.1. Organisation of and participation in Events by pharmaceutical companies

- a.** Congresses of scientific content. The term “scientific content” refers to congresses, seminars and similar Events, which are organised by governmental institutions, including universities, as well as public hospitals, associations of Healthcare Professionals, scientific associations of every legal form, taking place in Cyprus or abroad and with an exclusively scientific content. Such Events can also be sponsored by pharmaceutical companies.
- b.** Events aimed at providing medical information. Congresses, seminars and similar Events aiming to provide medical information are all those organised by pharmaceutical companies in collaboration with the local associations of Healthcare Professionals, the scientific councils of hospitals and scientific companies, in order to ensure the possibility of participation in them by every interested scientist. The Events in question take place in Cyprus or abroad and their entire program is of scientific content.
- c.** Events for the promotion of sales. Congresses, seminars and similar Events aiming at the promotion of sales of Medicinal Products are all those Events organised by pharmaceutical companies, taking place in Cyprus and having as a main purpose the promotion of Medicinal Products.

- 19.2.** A pharmaceutical company is not allowed, directly or indirectly (through its parent company or any other third company to which it is permanently or temporarily

connected by any legal bond whatsoever), to organise or to be the sponsor of an Event which is taking place outside the country where it is established (“international Event”), unless:

- a) the majority of the invited people come from countries other than the country of establishment of the pharmaceutical company and, given the country of origin of most of the people invited, it is more reasonable to carry out the Event in another country, or
- b) given the position of the related resources or the experience on the subject or topic of the Event, it is more reasonable to carry out the Event in another country. Should the above exceptions concur, the procedure of section 19.3 of the present shall be strictly observed.

19.3. Terms and conditions for carrying out the various Events

- a. With respect to congresses of scientific content and Events for the provision of medical information and activities for the promotion of sales, when organised in Cyprus and are sponsored by pharmaceutical companies or the parent companies thereof or through any promotional or other service company established in Cyprus or abroad and physicians established in Cyprus participate therein, before carrying out the Event, a notification with a detailed program shall be submitted each time to the Cyprus Medical Association.
- b. The notification under the above paragraph shall be submitted, as the case may be, by the relevant organisation organising the Event or the pharmaceutical or commercial or promotional company or any other company, sponsoring or participating in the Event.

19.4. Conditions for sponsoring different Events

- a. Sponsoring of congresses of scientific content under section 19.1 by pharmaceutical and other companies as mentioned above, established in Cyprus, shall be effected providing a cheque or wire transfer or deposit in the name of the association to the organising party/committee for covering all expenses for the organisation of the congress and in accordance with the written instructions of the appropriate authority. The account shall be opened, as the case may be, by the organising committee of the congress or the Board of Directors of the association, the institution, or the scientific company, according to their statutes. In case the organisation and collection of funds was assigned in writing to a company organising congresses, then the deposit of funds may be made to the account of the company undertaking the organisation.
- b. Recipients of funds, according to the above paragraph, are jointly obliged to include in their annual accounts the relevant receipts and payments for the scientific Event in accordance with the applicable law, along with the notification referred to in section 19.3 par. (a), a budget of the revenues and expenses of the event, and within a month of the completion of the Event, an account of revenues and expenses thereof.

19.5. Control of the sponsoring by companies of the participation of physicians in congresses

- a. Events and meetings offered to Healthcare Professionals
Pharmaceutical and other companies mentioned above are allowed to cover the expenses of physicians participating in congresses. Expenses include exclusively expenses for the registration in the corresponding Event, food and accommodation of the physician during the Event and transportation from the seat of the physician’s professional practice to the location of the Event, and it must be reasonable with respect to the main scientific purpose of the Event.

b. Legality of participation of Healthcare Professionals

- 19.6.** When pharmaceutical companies are the sponsors of meetings or satellite conferences, this must be mentioned in the related prints and published minutes. The procedure of section 19.3 of the present is followed.
- 19.7.** The provisions of sections 18.1 to 18.3 are also applied when any services are provided by the pharmaceutical company through third parties and by virtue of any legal relation.
- 19.8.** Events and meetings may be extended only to persons classified as participants according to their profession.

All forms of Events and meetings offered to Healthcare Professionals must be reasonable as to the level and the cost and strictly restricted to the main purpose of the Event. As a general rule, expenses granted must not exceed the level which Healthcare Professionals would be ready to pay, should they be bearing the cost themselves.

Events and meetings must not include Events organised by the sponsor or entertainment programs (e.g.: involvement in a sport or leisure time). Companies must avoid using establishments known for their venue facilities.

Companies must comply with the criteria governing the selection and provision of sponsorship to Healthcare Professionals in order to attend Events organised in accordance with the relevant regulations provided for in any applicable code(s). Sponsoring must not be offered merely as a compensation for the time spent by Healthcare Professionals for attending the Events.

- 19.9.** All promotional, scientific or professional meetings, conferences, congresses, symposia and other similar Events, or each particular Event organised or carried out with the sponsorship of a company, must take place in a proper establishment, which contributes to the main purpose of the Event and offers hospitality, only in accordance with the regulations of any applicable code(s). For the purposes of this section the words "proper establishment" shall not include extravagant establishments, namely: with a reputation for being the best venue or hotel in the country or town, but shall include reasonable establishments, namely: those which Healthcare Professionals would be willing to pay for personal purposes or appropriate establishments, namely those: with standard hotel meeting rooms, conference centres, hospital or clinic premises; and in any case, a €70 threshold per person per meal applies for Events and congresses held locally (excluding taxes and tips). Accommodation threshold for local hospitality is €250 per night. For Events and congresses held internationally, the list of daily thresholds applicable per city/country should be followed according to the country's local industry association and if no reference is made therein, a €90 threshold applies per person per meal.

A four star hotel is taken to be included in the definition of a "proper establishment", whereas hotels with five stars or more are prima facie excluded from such definition. In the event that a Member exceptionally considers either the holding of an Event or is contemplating his participation in any way in an Event in a hotel with five stars or more, then prior approval should be sought from the board of directors of KEFEA in this respect. Such an approval should be sought following a written substantiated application, based on the criteria found in the Regulations governing the operations of the Compliance Committee, addressed to the board of directors of KEFEA in the format which can be found on KEFEA website, at least three (3) months prior to the date of

the Event, stating the reasons why a hotel with five stars or more will be chosen and producing evidence in this respect. The Board of Directors has the discretion after assessing the above mentioned application to approve or decline the granting of such approval and its decision, which has to be communicated within 45 days to the Member, should be considered final.

Health Care Professionals (HCO) and congress organizers (CO) wishing to hold events in hotels with five stars or more may apply to the Board of Directors of KEFEA for a ruling for approval. The Board of Directors would examine such an application, based on the criteria mentioned above and will provide its ruling. A ruling for non approval of an application by an HCO or a CO is effective only towards the Member and not towards the HCO or the CO who can still proceed with the holding of the event without the participation of the Member.

Article 20 – Promotion addressed to the public

- 20.1.** It is prohibited to address a promotion whether directly or indirectly to the public for Medicinal Products administered only upon medical prescription. This prohibition does not apply to information campaigns approved by the competent authorities.
- 20.2.** In case isolated parts of the public request counselling on personal medical matters, they must be told to consult a Healthcare Professional.

Article 21 – Provision of counselling services or similar collaborations by Healthcare Professionals to the Industry

- 21.1.** Pharmaceutical companies can ask physicians to provide counselling or expert services or other similar services related to their specialty.
- 21.2.** Provision of such services must not jeopardise the counsellor's or the collaborating physician's clinical autonomy, who must at all times be bound to the ethical obligation to take independent medical decisions and exercise the medical profession to the patients' best interest.
- 21.3.** The provided collaboration / service shall be performed on the grounds of a special agreement signed between the company and the collaborating Healthcare Professional. Remuneration shall be set in accordance with the related legislation and in any case with the compulsory compliance with the relevant tax provisions.
- 21.4.** Whenever physicians/counsellors present opinions or results to third parties, concerning the medical/pharmacological part of their counselling services, a declaration of interest must be presented in order to ensure transparency towards all parties.

Article 22 – Clinical trials

- 22.1.** Collaboration between the Industry and physicians in carrying out clinical trials, pharmaco – epidemiological and pharmaco – genetic trials are of crucial importance for the development of Medicinal Products, for thorough knowledge of their properties and for their best use to the interest of the patients.
- 22.2.** In all clinical trials, the following principles must be applied:
- a) All persons participating in a clinical trial must respect the ethical and professional principles and guidelines, such as the Helsinki Declaration and the ICH guidelines for Good Clinical Practice.

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- b) The purpose of the trial must always be the improvement of therapeutic, diagnostic methods and/or medical knowledge to the best interest of patients.
- c) A trial must not be performed with the view to increasing sales or prescribing.
- d) The purpose of the trial must be declared in advance. The trial protocols must be compiled in such a way as to ensure success of the aim of the trial and that valid conclusions are drawn.
- e) All kinds of clinical trials are carried out only upon approval by the competent authorities (Drugs Council) or / and the BIO Ethics Committee.
- f) The sponsor must be known to patients participating in the trial.
- g) The physician must not receive any remuneration or compensation for the mere inclusion of patients in clinical trials.
- h) The physician may receive remuneration for his/her work in the trial. Remuneration must be given in connection with the work provided and must be declared to the National BIO Ethics Committee, the management of the organisation that he or she belongs to and the Drugs Council, who supervise the trial. Remuneration must not be connected with the expected outcome of the trial.
- i) Remuneration shall be effected in accordance with the applicable law.
- j) All data on safety and efficacy with respect to marketed products must be truthfully published on the internet irrespective of the outcome of the trial, at least in summary, within the year following the grant of the marketing authorisation. Furthermore, other important clinical results must be published in the same way.
- k) In publications, lectures and other presentations, the identity of the sponsor must be known.
- l) The physician may receive remuneration for lectures relating to the clinical trial and the results thereof.
- m) When presenting clinical trials, the physician must make known his or her connections with all the companies of the therapeutic area covered by his or her lecture.

22.3. Indispensable condition for the acknowledgement of any clinical trial or investigation is its documentation each time with the corresponding scientific results or findings.

22.4. With respect to epidemiological trials, the regulations provided for in the relevant national legislation are applied.

Article 23 – Internet

23.1. Access to promotional material available on the Internet and addressed to the public in Cyprus, on prescription only Medicinal Products (or Medicinal Products which even if they are not administered on medical prescription only, may not be promoted to the public), must be restricted to Healthcare Professionals and the suitable administrative personnel.

23.2. Promotional material for Medicinal Products addressed to Healthcare Professionals on the internet must, in principle, all have a technical, scientific or professional content. For the certification of this promotional material, the provisions of sections 13.1, 13.3, and 13.4 of the Code are applied.

23.3. Additionally, measures must be taken to ensure that access to the promotional material is restricted to Healthcare Professionals, who will obtain access by entering a password.

23.4. Promotional material must include a characteristic and legible warning which must state that the information contained on the web page is exclusively addressed to Healthcare Professionals who are authorised to prescribe or supply Medicinal Products and, therefore, specific training is necessary for the correct interpretation thereof.

23.5. Information with respect to Medicinal Products under section 23.1 of the present Article, included on the internet and accessible to the public, must be in compliance with Article 19 of the Code.

24. Article 24 – Disclosure of transfer of value and Disclosure Code

DISCLOSURE OBLIGATION

24.1.01. General Obligation. Subject to the terms of this Disclosure Code, each KEFEA member shall document and disclose any Transfers of Value it makes, directly or indirectly, to or for the benefit of a Recipient, as described in more detail in section 24.3.

24.1.02. Excluded Disclosures. Without limitation, Transfers of Value that (i) are solely related to over-the-counter medicines; (ii) are not listed in Article 3 of this Code, such as items of medical utility, meals and drinks, medical samples; or (iii) are part of ordinary course purchases and sales of medicinal products by and between a Member Company and an HCP (such as a pharmacist) or an HCO do not fall within the scope of the disclosure obligation described in section 24.1.01.

24.1.03. Schedules. Each of the attached Schedules forms part of this Disclosure Code. Definitions of capitalised terms are included in Schedule 1 to ensure consistent understanding of such terms and in the event of conflict with definitions in the remainder of the Code, the latter prevail.

FORM OF DISCLOSURE

24.2.01. Annual Disclosure Cycle. Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year (the “**Reporting Period**”). The first Reporting Period shall be the calendar year 2015.

24.2.02. Time of Disclosure. Disclosures shall be made by each KEFEA member within 6 months after the end of the relevant Reporting Period and the information disclosed shall be required to remain in the public domain for a minimum of 3 years after the time such information is first disclosed in accordance with section 24.2.04, unless, the Recipient’s consent relating to a specific disclosure, which is required by Cyprus law, has been revoked.

24.2.03. Template. Subject to section 24.2.02, disclosures shall be made using the standardised template set forth in Schedule 2.

24.2.04. Platform of Disclosure. Disclosures must be made in the following way:

On KEFEA’s website through a link that directs to each KEFEA Member Company’s mother company website, using the template set forth in Schedule 2.

24.2.05. Applicable National Code. Disclosures shall be made pursuant to the national code of the country where the Recipient has its physical address. If a KEFEA member is not resident or does not have a subsidiary or an affiliate in the country where the Recipient has its physical address, the KEFEA member shall disclose such Transfer of Value in a manner consistent with the national code to which it is subject.

24.2.06. Language of Disclosure. Disclosures shall be made in Greek or English.

24.2.07. Documentation and retention of records. Each KEFEA Member Company shall document all Transfers of Value required to be disclosed pursuant to section 24.1.01 and maintain the relevant records of the disclosures made under this Disclosure Code for a minimum of 5 years after the end of the relevant Reporting Period.

INDIVIDUAL AND AGGREGATE DISCLOSURE

24.3.01. Individual Disclosure. Except as expressly provided by this Disclosure Code, Transfers of Value shall be disclosed on an individual basis. Each KEFEA member shall disclose, on an individual basis for each clearly identifiable Recipient, the amounts attributable to Transfers of Value to such Recipient in each Reporting Period, which can be reasonably allocated to one of the categories set out below. Such Transfers of Value may be aggregated on a category-by-category basis, provided that itemised disclosure shall be made available upon request to the relevant Recipient.

1. For Transfers of Value to an 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, grants and benefits in kind to institutions, organisations or associations that are comprised of HCPs and/or that provide healthcare

b. **Contribution to costs related to Events.** Contribution to costs related to Events, including sponsorship of HCPs directly or through HCOs 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 19.).

c. **Fees for service and consultancy.** Transfers of Value resulting from or related to contracts between a KEFEA member and institutions, organisations or associations of HCPs under which such institutions, organisations or associations 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 Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

2. For Transfers of Value to an HCP:

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 19).

b. Fees for service and consultancy. Transfers of Value resulting from or related to contracts between Member Companies and HCPs under which such HCPs provide any type of services to a Member Company or any other type of funding not covered in the previous categories. Fees, on the one hand, and on the other hand Transfers of Value relating to expenses agreed in the written agreement covering the activity will be disclosed as two separate amounts.

c. In the instances where Member Companies contract a HCP for service and consultancy, fees must be calculated with a threshold of €170 per hour (for both local and international HCPs).

24.3.02. *Aggregate Disclosure.* For Transfers of Value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in section 24.3.01 cannot be disclosed on an individual basis for legal reasons, a KEFEA member shall disclose the amounts attributable to such Transfers of Value in each Reporting Period on an aggregate basis. Such aggregate disclosure shall 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 Transfers of Value to such Recipients.

24.3.03. *Non-Duplication.* Where a Transfer of Value required to be disclosed pursuant to section 24.3.01 or 24.3.02 is made to an individual HCP indirectly via an HCO, such Transfer of Value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made pursuant to section 24.3.01(2).

24.3.04. *Research and Development Transfers of Value.* Research and Development Transfers of Value in each Reporting Period shall 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.

24.3.05. *Methodology.* Each KEFEA member shall publish a note summarising the methodologies used by it in preparing the disclosures and identifying Transfers of Value for each category described in section 24.3.01. The note, including a general summary and/or country specific considerations, shall describe the recognition methodologies applied, and may include the treatment of multi-year contracts, VAT and other tax aspects, currency aspects and other issues related to the timing and amount of Transfers of Value for purposes of this Disclosure Code.

24.4.01. *Enforcement through KEFEA.* KEFEA has adopted implementation and procedure rules, which are binding upon its members, and set forth the framework for the implementation of this Disclosure Code, the processing of complaints and the enforcement of sanctions in a manner consistent with applicable data protection, competition and other applicable laws and regulations.

24.4.02 If laws or regulations, a national code or other Industry self-regulation prescribes equivalent or more stringent disclosure requirements, the relevant Member Company shall comply with such equivalent or more stringent requirements in a manner as consistent as possible with the substantive disclosure requirements of this Disclosure Code.

ENFORCEMENT

24.4.03. *Reporting.* The EFPIA Codes Committee shall produce at least annually reports summarising:

- (i) the transposition by Member Associations of this Disclosure Code into their national codes (such report to be produced by 31 March 2014, which date is three months after the deadline for the transposition of this Code by Member Associations and prior to the 2014 General Assembly so as to allow sufficient time to remedy inadequate or incomplete transposition by any Member Association); and

- (ii) once this Code has been transposed into national codes and disclosures are made for the first time in 2016 (no later than 30 June 2016), activities related to this Code (first such report to be produced in September 2016).

Article 25 – Compliance with the principles of the Code

- 25.1.** Pharmaceutical companies, for all their activities falling under the field of application of the Code (and including the Disclosure Code contained herein), are obliged to ensure compliance with the regulations thereof.
- 25.2.** KEFEA has established a five-person disciplinary committee which will be in charge of upholding the Code. It shall consist of a lawyer or former judge, a health care professional and three members of KEFEA. The disciplinary committee shall apply its own rules for submitting and examining complaints and determine by decision the sanctions.
- 25.3** Without prejudice to the above, the disciplinary committee may by decision issue a warning against the offending company, request that it ceases the offending activity within a prescribed time period and in the event of failure to comply or in any other event, 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. It may also expel a company from its membership and is allowed to make its abovementioned decision public by posting it on KEFEA's website.
- 25.4.** The disciplinary committee shall ensure that the Code and relevant procedures as to its functioning are available to all the KEFEA members and other interested parties through a webpage.

Schedule 1

Definition of terms used in the EFPIA HCP/HCO Disclosure Code

Donations and Grants. Collectively, means those donations, grants and benefits in kind within the scope of Article 17.

Events. All promotional, scientific or professional meetings, congresses, conferences, 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) (each, an “**Event**”) organised or sponsored by or on behalf of a company. (Article 19)

HCO. Any legal person (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 patient organisations within the scope of the PO Code) or (ii) through which one or more HCPs provide services.

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 or her professional activities, may prescribe, purchase, supply or administer a medicinal product and whose primary practice, principal professional address or place of incorporation is in Europe. For the avoidance of doubt, the definition of HCP 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 or administer medicinal products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes all other employees of a Member Company and a wholesaler or distributor of medicinal products.

HCP Code. EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals, adopted by the EFPIA Board on 5 July 2007 and ratified by the EFPIA Statutory General Assembly on 19 June 2008 and amended on 14 June 2011, and as may be amended, supplemented or modified from time to time.

Medicinal Products. (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. (Article 1 of Council Directive 2001/83/EC, as amended)

Member Associations. Collectively, the national member associations or their constituent members, as the context may require, that are members of EFPIA and bound by the EFPIA codes of conduct.

Member Companies. The Members of KEFEA and their respective parent companies, if different, and subsidiary companies (a subsidiary is a company or such other form of enterprise or organisation) and any companies affiliated with corporate members or their subsidiaries if such affiliated companies have agreed to be bound by this Disclosure Code.

PO Code. EFPIA Code of Conduct on Relationships between Pharmaceutical Industry and Patient Organisations, adopted in 2007 and as amended by the General Assembly on 14 June 2011, and as may be amended, supplemented or modified from time to time.

Recipient. Any HCP or HCO, as applicable, in each case, whose primary practice, principal professional address or place of incorporation is in Europe.

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 Directive 2001/20/EC); and (iii) 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 (Article 22).

Transfers of Value. Direct and indirect Transfers of Value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development and sale of generic or branded prescription-only Medicinal Products exclusively for human use. Direct Transfers of Value are those made directly by a KEFEA Member Company for the benefit of a Recipient. Indirect transfers of value are those made by a third party (such as contractors, agents, partners or affiliates - including foundations) on behalf of a KEFEA Member Company for the benefit of a Recipient, where the identity of such KEFEA Member Company is known to or can be identified by the Recipient.

Schedule 2

Disclosure Template (see excel sheet in Annex)

The template includes:

Unambiguous identification of each HCP/HCO, as applicable, including:

- Full name;
- City of practice;
- Country of practice;
- Complete address of practice;
- A unique identifier, where applicable.