ASSOCIATION OF PHARMACEUTICAL RESEARCH AND DEVELOPMENT (APRAD)

CODE OF PHARMACEUTICAL MARKETING PRACTICES

CONSOLIDATED VERSION 2014
(including a DISCLOSURE Article)

Approved by the Board of Directors of July 4th

PREAMBLE

(i) The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and marketing new medicines. Ethical promotion helps to ensure that healthcare professionals have access to information they need, that patients have access to the medicines they need and that medicines are prescribed and used in a manner that provides the maximum healthcare benefit to patients.

(ii) APRAD and its members are committed to following the highest ethical standards of educational and promotional efforts that benefit patients and promotional programs and collaborations that enhance the practice of medicine. APRAD also seeks to preserve the independence of the decisions taken by healthcare professionals in prescribing medicines to patients. The pharmaceutical industry has an obligation and responsibility to provide accurate information and education about its products to healthcare professionals in order to establish a clear understanding of the appropriate use of prescription medicines. In this regards, each pharmaceutical company should visually identify materials of promotional or non-promotional nature that may be provided to healthcare professionals as those which belong to non-prescription medicines. Industry relationships with healthcare professionals must support, and be consistent with, the professional responsibilities healthcare professionals have towards their patients. Pharmaceutical companies must maintain high ethical standards when conducting promotional activities and comply with applicable legal, regulatory and professional requirements. Through the promotion of this Code, APRAD seeks to ensure that ethical promotional practices are established throughout Ukraine.

(iii) The APRAD Code of Pharmaceutical Marketing Practices (the "APRAD Code") sets forth standards for the ethical promotion of pharmaceutical products to healthcare professionals, and for member companies' interactions with them. **This Code becomes effective January 1st, 2014**.

(iv) APRAD acknowledges the role of relevant codes of ethics developed by IFPMA, EFPIA, PhRMA. APRAD also recognizes the role of the Ethical Criteria for Medicinal Drug Promotion provided by the World Health Organization in 1988.

(v) The APRAD Code contains provisions relating to Scope, Applicability and Guiding principles (Articles 1-2), Standards of promotional information (Articles 3-7); Interactions with Healthcare professionals and Patients associations, Samples and Donations (Articles 8-12); Disclosure of Transfers of Value to Healthcare Professionals and Healthcare Organizations (Article 14); Company Procedures and Responsibilities (Article 14-15); Infringement and Complaints (Article 16); Abuse of the Code (Article 17); Procedures for amending (Article 18). It also includes details the operating procedures for Code complaints (Appendix 1) and Statutes of Ethical Committee (Appendix 2).

(vi) The APRAD Code complies with requirements of local laws and regulations and based on international association codes, such as IFPMA, EFPIA, PhRMA.

(vii) The APRAD Code sets out the minimum standards which APRAD considers must apply. APRAD member companies must comply, and must ensure that their respective subsidiaries comply, with the APRAD Code and any laws and regulations to which they are subject. It is a requirement of APRAD membership that company members accept the conditions of the APRAD Code. Companies not in membership with APRAD may elect to be subject to the APRAD Ethical Code and its complaints handling processes.

(viii) APRAD is open to receive genuine complaints from any source on any aspect of the APRAD Code, in accordance with its operating procedures. Where it is determined that there has been a breach of the APRAD Code, the objective is to correct the matter as rapidly as possible.

(ix) APRAD is a non-profit, non-governmental organization representing pharmaceutical or biotechnology companies, active in the research and development of new medicines, with a presence in Ukraine. The APRAD members develop and market new medicines to enable patients to live longer and healthier life. The APRAD mission is to become a recognized voice of the research-based pharmaceutical industry operating in Ukraine, to promote value of innovations, to conduct effective advocacy for public policies that improve access to quality medicines in Ukraine, and to be effective strategic partner to the Government of Ukraine. Companies are committed to the ethical standards set out in this Code.

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

THE APRAD ETHICS and DISCLOSURE CODE

1. Objective and Scope.

1.1. Objective: The APRAD Code sets out standards for the ethical promotion of pharmaceutical products to healthcare professionals to ensure that member companies' interactions with healthcare professionals are appropriate and perceived as such.

1.2. Scope: For the purposes of the APRAD Code:

"healthcare professional (HCP)" means any member of the regulatory authorities, medical, dental, pharmacy or nursing professions or any other person who in the course of his or her professional activities may prescribe, recommend, purchase, supply, or administer a pharmaceutical product.

"member company" means any company that is a member of APRAD. "Company" can refer to representative office of the worldwide parent researched-based company and/or national researched-based company.

"patient" means any person who may purchase, consume or receive a prescription for a product.

"pharmaceutical product" means all pharmaceutical or biological products (irrespective of patent status and/or whether they are branded or not) which are intended to be used on the prescription of, or under the supervision of, a healthcare professional, and which are intended for use in the diagnosis, treatment or prevention of disease in humans, or to affect the structure or any function of the human body.

"promotion" means any activity undertaken, organized or sponsored by a member company which is directed at healthcare professionals to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all media, including the internet.

"research and development transfers of value" (for the purposes of Article 14 of this Code) menas transfers of value to healthcare professionals or healthcare organizations related to the planning or conduct of (i) pre-clinical studies; (ii) clinical trials; or (iii) post-registration observation (non-interventional) studies that are prospective in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study.

"transfers of value" (for the purposes of Article 14 of this Code) means 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 prescription-only pharmaceutical products exclusively for human use. Direct transfers of value are those made directly by a pharmaceutical company for the benefit of a recipient. Indirect transfers of value are those made on behalf of a pharmaceutical company for the benefit of a recipient, or transfers of value made through an intermediate and where the pharmaceutical company knows or can identify the healthcare professional/healthcare organization that will benefit from the transfer of value.

The APRAD 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, internet and other electronic communications, the use of audio-visual systems such as films, video recordings, data storage services and the like, and the provision of samples, gifts and hospitality.

1.3. Exclusions: This Code does not seek to regulate the following activities:

- The labeling of medicinal products and accompanying package leaflets.
- Correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product.
- Pricing or other trade terms for the supply of pharmaceutical products.

- The engagement of a healthcare professional to provide genuine consultancy or other genuine services to a member company.
- The conduct of clinical trials.
- The provision of non-promotional information by member companies (i.e. general information about companies (such as information directed to investors or to current/prospective employees), including financial data, descriptions of research and development programs, and discussion of regulatory developments affecting the company and its products; ii. information relating to human health or diseases; iii. correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product; iv. 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.)

2. General Principles.

2.1. Basis of Interaction: Member companies' relationships with healthcare professionals are intended to enhance patients care and/or the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information and supporting medical research and education.

2.2. Independence of Healthcare Professionals: No financial benefit or benefit-in-kind (including grants, scholarships, subsidies, support, consulting contracts or educational or practice related items) may be provided or offered to a healthcare professional in exchange for prescribing, recommending, purchasing, supplying or administering products or for a commitment to continue to do so. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a healthcare professional's prescribing practices.

2.3. Appropriate Use: Promotion should encourage the appropriate use of pharmaceutical products by presenting them objectively and without exaggerating their properties.

2.4. Local Regulations: In all cases, all relevant laws and local regulations must be observed and companies have a responsibility to check local requirements, in advance of preparing promotional material or events in Ukraine.

2.5. Transparency of Promotion: Promotion should not be disguised. Clinical assessments, post-marketing surveillance and experience programs and post-authorization studies must not be disguised promotion. Such assessments, programs and studies must be conducted with a primarily scientific or educational purpose. Material relating to pharmaceutical products and their uses, whether promotional in nature or not, which is sponsored by a company should clearly indicate by whom it has been sponsored.

3. Pre-Approval Communications and Off-label Use: No pharmaceutical product shall be promoted in Ukraine until all necessary approvals have been received from local regulatory authorities. If the medical and scientific information about product or new indication is not yet approved, then care must be taken to ensure full transparency and such information shall comply with all pre-approval restrictions on promotion or communication.

4. General Public Interaction: Prescription based medicines should never be promoted to general public.

5. Standards of Promotional Information.

5.1. Consistency of Product Information: It is understood that national laws and regulations dictate the format and content of the product information communicated on labeling, packaging, leaflets, data sheets and in all promotional material. Promotion should be consistent with latest approved leaflets or the instruction for medical use.

Promotion must be consistent with the particulars listed in the leaflets or the instruction for medical use of the relevant pharmaceutical product.

Healthcare professionals in Ukraine should have access to similar data to those being communicated in developed countries.

5.2. Accurate and Not Misleading: Promotional information should be clear, legible, accurate, balanced, fair, objective and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the pharmaceutical product concerned. Promotional information should be based on an up-to-date evaluation of all relevant evidence and reflect that evidence clearly. It should not mislead by distortion, exaggeration, undue emphasis, omission or in any other way. Every effort should be made to avoid ambiguity. Absolute or all-embracing claims should be used with caution and only with adequate qualification and substantiation. Any comparison made between different medicinal products must be based on relevant and comparable aspects of the products. Comparison of products should be factual, fair and capable of substantiation. Comparative advertising must not be misleading or disparaging. Descriptions such as 'safe', 'no side effects', 'toxic hazards', and 'risks of addiction or dependency' should generally be avoided and should always be adequately qualified.

5.3. Substantiation: Promotion should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such evidence should be made available on request to healthcare professionals. Companies should deal objectively with requests for information made in good faith and should provide data which are appropriate to the source of the inquiry.

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

5.5. Acceptability of Promotion. Companies must maintain high ethical standards at all times. Promotion must: (a) never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry; (b) be of a nature which recognizes the special nature of medicines and the professional standing of the recipient(s); and (c) not be likely to cause offence.

5.6. Distribution of Promotion. Promotion should only be directed at those who needs for, or interest in, the particular information can reasonably be assumed. Mailing lists must be kept up-to-date. Requests by healthcare professionals to be removed from promotional mailing lists must be complied with. Subject to applicable national laws and regulations, the use of faxes, e-mails, automated calling systems, text messages and other electronic data communications for promotion is prohibited except with the prior permission, or upon the request, of the recipient.

5.7. No Advice on Personal Medical Matters. In the case of requests from individual members of the general public for advice on personal medical matters, the enquirer should be advised to consult a healthcare professional.

6. Printed Promotional Materials.

If national regulations are in force which define requirements, those take precedence.

6.1. All Printed Promotional Material, including Advertisements:

All printed promotional materials other than those covered in 5.2 below must be legible and include:

- the name of the product (normally the brand name);
- the international non-proprietary name;
- the name and address of the pharmaceutical company or its agent responsible for marketing the product;
- "abbreviated prescribing information" which should include an approved indication or indications for use together with the dosage and method of use; and a succinct statement of the contraindications precautions and side effects;
- reference number to allow identifying the date of approval.

6.2. Reminder Advertisements: A "*reminder*" advertisement is defined as a short advertisement that can contain the brand name and established (generic) name, dosage type and strength (e.g., 25mg tablets). For "reminder" advertisements, "abbreviated prescribing information" referred to in 5.1 above may be omitted.

6.3. Artwork: All artwork, including graphs, illustrations and tables taken from published studies included in promotional material should:

- clearly indicate the precise source(s) of the artwork;
- 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 medicine (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).

6.4. The word "**safe**" must never be used to describe a medicinal product without proper qualification.

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

6.6. It must not be stated that a product has no side effects, toxic hazards or risks of addition or dependency.

7. Electronic Materials, including Audiovisuals.

The same requirements shall apply to electronic promotional materials as apply to printed materials. Specifically, in the case of pharmaceutical product related websites:

- the identity of the pharmaceutical company and of the intended audience should be readily apparent;
- the content should be appropriate for the intended audience;
- the presentation (content, links, etc.) should be appropriate and apparent to the intended audience; and
- Ukraine-specific information should comply with national laws and regulations.

8. Interactions with Health Care Professionals (HCPs).

8.1. Promotional Calls.

Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide valuable scientific and educational benefits. Information presented should contain only on-label information and should conform to standards of promo materials.

Medical representatives during promotional calls to HCPs should present information, based on proved scientific data. No meal, entertainment or other benefits, except scientific and educational are allowed during promotion calls.

Group presentations and seminars (round tables or scientific discussions) with more than two healthcare professionals, must have previously approved scientific program. In connection with such presentations occasional reasonable meals is acceptable in the frame of event duration.

8.2. Events.

8.2.1. Scientific and Educational Objectives: The purpose and focus of all symposia, congresses, seminars, conferences and other promotional, scientific or professional meetings (an "**Event**") for HCPs organized or sponsored by a company should be to inform health care professionals about products and/or to provide scientific or educational information.

8.2.2. Promotional Information at Events: Promotional information, which appears on exhibition stands or is distributed to participants at local events, should refer to pharmaceutical products which are registered in Ukraine. Registration of HCPs at the booth is required to provide them with promotional information during events involving general public.

8.3. Events Involving Foreign Travel.

No company may organize or sponsor an event for healthcare professionals (including sponsorship of individuals to attend such event as described in Article 8.4) that take place outside of Ukraine unless it is justified to do so from the logistic or security or scientific point of view. International scientific events that derive participants from many countries are therefore justified and permitted.

8.4. Sponsorship of Health Care Professionals (HCPs).

Member companies may sponsor HCPs to attend events if such sponsorship (financial support) is provided in accordance with the following requirements and a respective national legislation:

- The event complies with the hospitality requirements in this Code as described in 8.6;
- Health care professionals are qualified as participants in their own right;
- Sponsorship to HCPs is limited to the payment of travel, meals, accommodation and registration fees;
- No payments are made to compensate health care professionals for time spent in attending the event; and
- Any sponsorship provided to individual health care professionals must not be offered to influence or reward the recipients for present, past or future use or support of pharmaceutical product, to gain access to a customer's management, or formulary decision makers, or to influence the outcome of clinical trials.

8.5. Guests: Companies should not pay any costs associated with individuals accompanying invited healthcare professionals.

8.6. Hospitality.

8.6.1. Appropriate Venue: All events should be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies **should avoid using extravagant venues**.

"***Extravagant***" venues are like: luxury hotels, resorts, spa-centers, leisure or entertaiment facilities.

8.6.2 Limits of Hospitality: Hospitality should be limited to **refreshments and/or meals** incidental to the main purpose of the Event and should only be provided:

- to participants of the Event and not their guests; and
- if it is moderate and reasonable as judged by local standards.

As a general rule, the hospitality provided should not exceed what healthcare professional recipients would normally be prepared to pay for themselves. APRAD establishes the following thresholds for meals and refreshments:

- **300 UAH** per meal per a health care professional and the overall hospitality expenses per day should not exceed **570 UAH** (for non-personalized meals during conferences, seminars, etc.);
- **Up to 800 UAH per meal** for an individual interaction when a contract between a company and HCP is concluded or in line with the current Ukrainian legislation.

The monetary threshold set in the country where the event takes place (i.e. the "***host country***") shall prevail.

8.6.3. Entertainment: No stand-alone entertainment or other leisure or social activities should be provided or paid for by member companies.

8.7. Scholarships and Educational Funds.

An unrestricted educational grant is a financial support provided to a permitted recipient to carry out a specific independent medical educational program or activity developed for healthcare professionals.

A grant is always unrestricted which means it shall be made without any tangible benefit for pharmaceutical company.

If company receives any compensation or is involved in any way in the conception of the program or selection of participants, the financial support will not be considered as an unrestricted educational grant.

8.7.1. Permitted Unrestricted Grants may be provided only to support independent educational programs relating to pharmaceutical therapies, disease states or other public health concerns.

8.7.2. Prohibited Unrestricted Grants:

- constitute an inducement to prescribe, purchase, supply, sell or recommend of any pharmaceutical company product or service;
- promoting a pharmaceutical company product or service;
- providing a direct or indirect discount on product purchase.

8.7.3. Permitted Unrestricted Grant Recipient:

- non-for-profit associations, foundations and professional societies whose mission includes research and development of the knowledge in a specific therapeutic area and/or public health education;
- providers of medical and scientific education that are not customers of pharmaceutical company;
- hospitals and institutions whose mission includes research and development of the knowledge in a specific therapeutic area and/or public health education;

Recipient is capable by reason of training, expertise, experience, and organizational capability to provide the proposed educational program.

8.7.4. Prohibited Unrestricted Grant Recipients.

Unrestricted educational grants **may never be provided**:

- to any individuals;
- on behalf of any customer, patient, or any individuals; and
- to political bodies.

8.8. Informational or educational materials and items of medical utility.

No gifts, pecuniary advantage or benefit in kind may be supplied, offered or promised to HCP as an inducement to recommend, prescribe, purchase, supply, sell or administer a medicinal product.

Providing HCPs with informational or educational materials and items of medical utility is allowed as long as they are non-product branded.

8.8.1. Informational and educational materials.

Informational or educational materials generally include items that advance disease or treatment education, are designed for the education of patients or HCPs, and have no personal benefit to the HCP. The transmission of such materials or items shall not constitute an inducement to recommend, prescribe, purchase, supply, sell or administer a medicinal product.

Possible informational and educational materials are like: anatomical models, educational brochures on diseases, patient self-assessment and tracking tools, and brochures that inform patients about adherence to medicine regimens, healthy lifestyle choices or the availability of patient assistant programs.

8.8.2. Items of Medical Utility

Items of medical utility generally include items that are beneficial to enhancing the provision of medical services and patient care, and have no personal benefit to the HCP. Items of medical utility may be provided to healthcare professionals free of charge, if such items are designated primarily to:

- educate HCPs; or
- help HCPs to educate patients about disease management in relevant disease;
- improve medical services and/or patient care.

Items of medical utility must only be provided directly to HCPs and only in conjunction with a product or informational discussion.

Possible items of medical utility are like: anatomical models for examination rooms, inhalation devices (with no active ingredient), devices intended to assist patients to learn how to self-inject and other items related to practice of a respective health care professional.

8.8.3. Guidance on Values: This Code provides guidance using the Ukrainian currency on the precise value for the following:

- value for items described in 8.8.1 and 8.8.2. above should be reasonable in price and **should not exceed 450 UAH per item**.

8.8.4. Promotional Aids and/or Reminder Items are prohibited.

Under promotional aids and/or reminder items are supposed souvenirs, stationary and accesorises.

Promotional literature (such as detailed aid, leave-behind pieces, booklets, etc.) **is not considered to be promotional aids** (see 8.8.1. and 8.8.2.).

8.8.5. Cultural Courtesy Gifts are prohibited.

9. Interaction with Patient Associations.

The pharmaceutical industry recognizes that it has many common interests with patient organizations, which represent and/or support the needs of patients and/or caregivers. In order to ensure that the relationships between the pharmaceutical industry and patient organizations take place in an ethical and transparent manner, APRAD has adopted this Code on interacting with patients associations.

This Code covers relationships between the member-companies and patient associations which operate in Ukraine. Patient associations are defined as not-for-profit organizations (including the

umbrella organizations to which they belong), mainly composed of patients and/or caregivers which represent and/or support the needs of patients and/or caregivers.

9.1. Relationships between the pharmaceutical industry and patient associations are built upon the following principles:

- the independence of patient associations with respect to their policies and activities (including political decisions) shall be assured;
- collaborations between patient associations and the member-companies must be based on mutual respect and trust;
- the member-companies shall not ask or encourage any patient association to promote any of its products;
- objectives and scope of any partnership shall be transparent;
- the member-companies welcome broad funding of patient associations from multiple sources.

9.2. Written Documentation.

Member-companies that provide financial support or in-kind contribution to patient organizations must have in place written documentation setting out the nature of support, including the purpose of any activity and its funding.

9.3. Editorial Control.

The member-companies must not seek to influence on texts of a patient organization's materials they sponsor in a manner, which is favorable to their own commercial interests.

9.4. Events and Hospitality.

Rules of hospitality towards HCPs during sponsored scientific events should apply to all events, which are sponsored or organized by (or on-behalf of) a member-company and are associated with patient organizations.

10. Fees for Services.

Health care professionals may be engaged as consultants and advisers for services such as speaking at and/or chairing meetings and events, 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. The arrangement which cover these genuine consultancies or other services must, to the extent relevant to the particular arrangement, fulfill all the following criteria:

- a written contract or agreement must be agreed in advance of the commencement of the services which specifies the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services must be clearly identified and documented in advance;
- the criteria for selecting consultants must be related to the identified need and the consultants must have the expertise necessary to provide the services;
- the number of consultants retained must not be greater than the number reasonably necessary to achieve the identified need;
- the hiring of the consultant to provide the relevant service must not be an inducement to prescribe, recommend, purchase, supply, and/or administer any medicine;
- honoraria (fee) for the services must be reasonable and reflect the **fair market value** of the services provided.

10.1. Payments for Speakers and Presenters.

Payments of reasonable fees and reimbursement of travel, accommodation, meal may be provided to health care professionals who are providing genuine services as speakers or presenters on the basis of a written contract with the company at the event. Member-companies are responsible for information provided by a speaker from/on behalf of the company.

11. Samples.

Samples are NOT permitted according to the Ukrainian legislation.

12. Donation.

As a demonstration of good corporate citizenship, member-companies recognize their responsibility to support worthwhile activities both within and outside their communities.

Donations, including donations in kind, may be provided to organizations involved in promoting artistic, charitable, cultural, community, educational, humanitarian, health, philanthropic and sporting activities. Member-companies must ensure that such support is not undertaken for product promotional reasons, and is not directed to product promotion purposes. Acknowledgement by the recipient organization of such support must be restricted to an appropriate statement of support, and the corporate name and logo of the donating member.

Member-companies may provide with product donation to hospitals. Such donations should be reasonable, modest and in proportion to the scale and scope of the recipient institution.

Any kind of donation should be in a regime of complete transparency, publicity and with compulsory application of the relevant Ukrainian regulations.

Donations, grants and benefits in kind to institutions, organizations or associations that are comprised of health care 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.

Companies are encouraged to make available publicly information about donations, grants or benefits in kind made by them.

Donations and grants to individual HCPs are not permitted.

13. Pharmaceutical Company Staff.

13.1. Medical Representatives have an important role in the promotion of medicinal products. Therefore, certain obligations should be imposed upon them:

- Medical representatives must be adequately trained and have sufficient scientific knowledge to be able to provide precise and complete information about the medicinal products they promote.
- Medical representatives must approach their duties responsibly and ethically.

Medical representatives must not use any inducement or subterfuge to gain an interview. They must, from the outset, take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.

13.2. Medical Representatives and Non-Interventional Studies of Marketed Medicines.

A non-interventional study of a marketed medicine is defined as a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization. The assignment of the patient to the particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.

Non-interventional studies that are prospective in nature can involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study.

Medical representative must not have access to the personal patient data at any stage of the non-interventional studies.

Medical representatives may only be involved in an administrative capacity and such involvement must be under the supervision of the company's scientific service that will also ensure that the representatives are adequately trained. Such involvement must not be linked to the promotion of any medicinal product.

14. Disclosure of Transfers of Value to Healthcare Professionals and Healthcare Organizations.

14.1. Disclosure Obligations.

14.1.1. Each pharmaceutical company shall document and disclose transfers of value it makes, directly or indirectly, to or for the benefit of any healthcare professional or healthcare organization being a recipient, as described in more detail in clause 14.3.

14.1.2. Without limitation, transfers of value that (i) are solely related to over-the-counter pharmaceutical products; (ii) are not listed in clause 14.3 of this Code, such as items of medical utility, meals and drinks, samples to the extent they are not restricted by applicable legislation and this Code; or (iii) are part of ordinary course purchases and sales of pharmaceutical products by and between a pharmaceutical company and an healthcare professional or a healthcare organization, as relevant, do not fall within the scope of the disclosure obligation described in sub-clause 14.1.1.

14.1.3. For the avoidance of doubt, in the setting of a group of companies, the primary responsibility to make a disclosure is borne by a legal entity and/or other form of legal representation of a member-company in Ukraine, which enters into a contract with the healthcare professional or healthcare organization under which the transfer of value is performed.

14.2. Form of Diclosure.

14.2.1. Disclosures shall be made on an annual basis and each reporting period shall cover a full calendar year. Pharmaceutical companies, which became subject to the provisions of this Code in the course of the reporting period, should make disclosures after the end of the relevant reporting period as set forth in sub-clause 14.2.2 below and should cover only the relevant part of the calendar year.

14.2.2. Disclosures shall be made by each pharmaceutical company 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 sub-clause 14.2.4, unless, in each case, (i) a shorter period is required under applicable national data privacy or other laws or regulations, or (ii) the recipient's consent relating to a specific disclosure has been revoked.

14.2.3. Subject to second item of sub-clause 14.2.4, for consistency purposes, disclosures pursuant to this Code will be made using a structure, reflecting the requirements of this Code.

14.2.4. Disclosures can be made in either of the following ways, provided that they are unrestricted and publicly available:

- on the relevant pharmaceutical company's website in accordance with sub- clause 14.2.5 while posting corresponding hyperlink on a central platform of APRAD; or
- on a central platform of APRAD.

14.2.5. Disclosures shall be made pursuant to the code governing disclosure of the transfers of value to the recipients enacted in the country where the recipient has its physical address, e.g., as it is set forth in the contract, covering transfer of value. If a pharmaceutical company is not resident or does not have a subsidiary, an affiliate or any other presence in a county, defined in accordance with the above rule, this pharmaceutical company shall disclose such transfer of value in a manner consistent with the code governing disclosure of the transfers of value to the recipients enacted in the country of registration of a legal entity, which enters into a contract with the healthcare professional or healthcare organization under which the transfer of value is performed, or, if no such code is enacted in that county, any other similar code applicable to a pharmaceutical company should govern.

14.2.6. Disclosures shall be made in Ukrainian and/or in English languages.

14.2.7. Each pharmaceutical company shall document all transfers of value required to be disclosed pursuant to sub-clause 14.1.1 and maintain the relevant records of the disclosures made under this Code for a minimum of 5 years after the end of the relevant reporting period, unless a shorter period is required under applicable Ukrainian laws or regulations.

14.3. Individual and Aggregated Disclosure.

14.3.1. Except as expressly provided by this Code, transfers of value shall be disclosed on an individual basis, provided that applicable personal data protection rules are complied with. Each pharmaceutical company 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 (i) the relevant recipient, and/or (ii) the relevant authorities.

14.3.2. Categories for transfers of value to a healthcare organization include:

- Donations and grants. Donations and grants to healthcare organizations that support healthcare, including donations and grants (either cash or benefits in kind) to institutions, organizations or associations that are comprised of healthcare professionals and/or that provide healthcare.
- Contribution to costs related to events. Contribution to costs related to events, through healthcare organizations or third parties such as:
  - Registration fees;
  - Sponsorship agreements with healthcare organizations or with third parties appointed by a healthcare organization to manage an event; and
  - Travel and accommodation.
- Fees for service and consultancy. Transfers of value resulting from or related to contracts between pharmaceutical companies and healthcare organizations under which such healthcare organizations provide any type of services to a pharmaceutical 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.

14.3.3. Categories for transfers of value to a healthcare professional include:

- Contribution to costs related to events. Contribution to costs related to events when it is not prohibited by the applicable legislation, such as:
    - Registration fees;
    - Travel and accommodation.
- Fees for service and consultancy. Transfers of value resulting from or related to contracts between pharmaceutical companies and healthcare professionals under which such healthcare professionals provide any lawful type of services to a pharmaceutical 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.

14.3.4. For transfers of value where certain information, which can be otherwise reasonably allocated to one of the categories set forth in sub-clauses 14.3.2 and 14.3.3, cannot be disclosed on an individual basis for legal reasons, a pharmaceutical company 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.

14.3.5. Where a transfer of value required to be disclosed pursuant to sub-clauses 14.3.1 - 14.3.4 is made to an individual healthcare professional indirectly via a healthcare organization, such transfer of value shall only be required to be disclosed once. To the extent possible, such disclosure shall be made on an individual healthcare professional named basis pursuant to sub-clause 14.3.3.

14.3.6. Research and development transfers of value in each reporting period shall be disclosed by each pharmaceutical company 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.

14.3.7. Each pharmaceutical company shall publish a note summarizing the methodologies used by it in preparing the disclosures and identifying transfers of value for each category described in sub-clauses 14.3.2 and 14.3.3. The note, including a general summary and/or country specific considerations, shall 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 amount of transfers of value for purposes of this Code, as applicable.

15. Company Procedures and Responsibilities.

Companies should establish and maintain appropriate procedures to ensure full compliance with the Code and applicable laws and to review and monitor all of their activities and materials in that regard.

A designated company employee, with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications.

Each company must appoint at least one senior employee who shall be responsible for supervising the company and its subsidiaries to ensure that the standards of APRAD Code are met.

16. Infringement and Complaints.

Genuine complaints relating to infringements of the APRAD Code are encouraged. Detailed procedures for complaints and the handling of complaints (including the respective roles and jurisdiction of APRAD) are set out in Appendix 1: Operating Procedures of the APRAD Code.

17. Abuse of the Code and Its Procedures.

Abuse of the Code and its Procedures shall in itself be a breach of the Code.

18. Procedures for Amending Provisions of the Code.

It is important that the Code and its associated procedures should accurately reflect the highest standards and for this reason it is kept under constant review and amended from time to time where necessary, to clarify it and bring it up to date.

APRAD Code Project team will be convened as necessary to consider proposals to amend provisions of the Code and make appropriate recommendations. The Ethics Committee, the APRAD members and any other external interested parties may refer items for discussion by the Project Team.

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Ms. Irina Panarina	**Mr. Andrej Skirta**
For and on behalf of	For and on behalf of
AstraZeneca Ukraina LLC	**Bayer Ltd.**
Ms. Edit Pung	**Mr. William H. Wickham**
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