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In accordance with modern standards and requirements of the pharmaceutical-medical community and international professional associations, In addition to Rulebook on the manner of advertising medicinal products and medical devices (Official Gazette of Bosnia and Herzegovina, No. 40/10) and Rulebook on Clinical Trials of Medicines and Medical Devices ("Official Gazette of Bosnia and Herzegovina", No. 4/10), Association of International Pharmaceutical Manufacturers in Bosnia and Herzegovina (AIPM BH), as a member of IFPMA, adopts the following

Code of Practice

Preamble

I. The ethical promotion of prescription medicines is vital to the pharmaceutical industry's mission of helping patients by discovering, developing and promoting new medicines. Ethical promotion helps to ensure that Healthcare Professionals (HCPs) globally 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. The AIPM BH is a non-profit, non-governmental organization representing industry associations and companies from both developed and developing countries. Member companies of the AIPM BH include global research-based pharmaceutical companies. Companies are committed to the ethical standards set out in this Code.

III. The AIPM BH Code includes standards for the ethical promotion of pharmaceutical products to HCPs and helps ensure that member companies' interactions with HCPs and other stakeholders, such as medical institutions and patient organizations, are appropriate and perceived as such.

IV. It is a requirement of AIPM BH membership that member associations / companies accept the conditions of the AIPM BH Code and, subject to local laws and regulations, adopt codes that meet local requirements but are consistent with, and as comprehensive as, the AIPM BH and IFPMA Code.

V. It is accepted that where there is an established framework of stringent regulatory and/or legal controls which are effectively as comprehensive in their provisions and application as the AIPM BH Code, it may be more appropriate for a national member association not to establish new duplicative provisions and procedures. AIPM BH acknowledges that many AIPM BH member associations have already established their own codes of conduct, which, together with local laws and regulations, fully embody the principles set forth in the AIPM BH and IFPMA Code.

VI. AIPM BH member companies and anyone acting on their behalf must comply directly with applicable national codes of member associations where such codes exist. In all other territories, (i.e. where there are no local codes or appropriate laws and regulations, or where a member company is not a member of local/regional association), the AIPM BH Code acts as a default code for the activities of member companies and the AIPM BH and IFPMA operating procedures apply.

VII. AIPM BH member companies are accountable for addressing and correcting infringements under relevant codes. Companies not in membership with AIPM BH may elect to be subject to the AIPM BH Code and its complaints handling processes.

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

IX. AIPM BH acknowledges the role of relevant codes of ethics developed by the World Medical Association, the International Council of Nurses and the International Federation of Pharmacists. AIPM BH also recognizes the role of Ethical Criteria for Medicinal Drug Promotion provided by the World Health Organization in 1988.

X. Effective 1st January 2019, this AIPM BH Code of Practice replaces all previous regulations of AIPM BH in this area.

1. Scope and Definitions

1.1. Scope

The AIPM BH Code covers interactions with HCPs, medical institutions and patient organizations, and the promotion of pharmaceutical products. Where direct promotion to the public is allowed, this is covered by local laws, regulations and/ or relevant codes of practice. Member companies should, of course, comply with these local laws, regulations and/or codes.

1.2. Definitions

For the purposes of the AIPM BH Code:

- “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 HCP, 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 HCPs to promote the prescription, recommendation, supply, administration or consumption of its pharmaceutical product(s) through all methods of communications, including the internet.
- “Healthcare Professional (HCP)” means any 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, recommend, purchase, supply, sell or administer a pharmaceutical product.
- “Patient organization” means typically a not-for-profit institution that primarily represents the interests and needs of patients, their families and/or caregivers.
- “Medical institution” means typically an organization that is comprised of HCPs and/or that provides healthcare or conducts healthcare research.

- "Member Company" means any company that is a member of AIPM BH (direct member) or a member of any association that is a member of AIPM BH (indirect member). "Company" can refer to national companies and/or the worldwide parent company.
- "Member association" means any association that is a member of AIPM BH.

2. Basis of Interactions

2.1. Basis of Interactions

Member companies' relationships with HCPs and other stakeholders are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing HCPs about medicines, providing scientific and educational information and supporting medical research and education.

2.2. Transparency of Promotion

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. Promotion should not be disguised.

3. Pre-Approval Communications and Off-Label Use

No pharmaceutical product shall be promoted for use in a specific country until the requisite approval for marketing for such use has been given in that country.

This provision is not intended to prevent the right of the scientific community and the public to be fully informed concerning scientific and medical progress. It is not intended to restrict a full and proper exchange of scientific information concerning a pharmaceutical product, including appropriate dissemination of investigational findings in scientific or lay communications media and at scientific conferences. Nor should it restrict public disclosure of information to stockholders and others concerning any pharmaceutical product, as may be required or desirable under law, rule or regulation.

4. Standards of Promotional Information

4.1. Consistency of Product Information

It is understood that national laws and regulations usually dictate the format and content of the product information communicated on labelling, packaging, leaflets, data sheets and in all promotional material. Promotion should not be inconsistent with locally approved product information.

Respecting the requirement that promotion should be consistent with the label and approved uses locally, HCPs in developing countries should have access to similar data to those being communicated in developed countries.

4.2. Accurate and Not Misleading

Promotional information should be clear, legible, accurate, balanced, fair, 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. Descriptions such as “safe” and “no side effects” should generally be avoided and should always be adequately qualified.

4.3. 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 HCPs. 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. Printed Promotional Material

Where local regulations or codes are in force, which define requirements, those take precedence.

5.1. All Printed Promotional Material, including Advertisements

All printed promotional materials, other than those covered in Article 5.2 below, must include:

- the name of the product (normally the brand name);
- the active ingredients, using approved names where they exist;
- the name and address of the pharmaceutical company or its agent responsible for marketing the product;
- date of production of the advertisement;
- “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.

5.2. Reminder Advertisements

A “reminder” advertisement is defined as a short advertisement containing no more than the name of the product and a simple statement of indications to designate the therapeutic category of the product. For “reminder” advertisements, “abbreviated prescribing information” referred to in Article 5.1 above may be omitted.

6. 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
- Country-specific information should comply with local laws and regulations.

7. Interactions with Healthcare Professionals

7.1. Events and Meetings

7.1.1. Scientific and Educational Objectives

The purpose and focus of all symposia, congresses and other promotional, scientific or professional meetings (an "Event") for HCPs organized or sponsored by a company should be to provide scientific or educational information and/or inform HCPs about products.

7.1.2. Events Involving Foreign Travel

No company may organize or sponsor an Event for HCPs (including sponsoring individuals to attend such an Event as described in Article 7.2) that takes place outside of the HCP's country of practice unless it is appropriate and justified to do so from the logistical or security point of view. International scientific congresses and symposia that derive participants from many countries are therefore justified and permitted.

7.1.3. Promotional Information at Events

Promotional information which appears on exhibition stands or is distributed to participants at international scientific congresses and symposia may refer to pharmaceutical products which are not registered in the country where the Event takes place, or which are registered under different conditions, provided that the following conditions are observed:

- Host country regulations should permit such an arrangement;
- The meeting should be a truly international, scientific Event with a significant proportion of the speakers and attendees from countries other than the country where the Event takes place;
- Promotional material (excluding promotional aids as described in Article 7.5.1.2) for a pharmaceutical product not registered in the country of the Event should be accompanied by a suitable statement indicating the countries in which the product is registered and make clear that such product is not available locally;
- Promotional material which refers to the prescribing information (indications, warnings, etc.) authorized in a country or countries other than that in which the Event takes place but where the product is also registered, should be accompanied by an explanatory statement indicating that registration conditions differ internationally; and
- An explanatory statement should identify the countries in which the product is registered and make it clear tha

7.1.4. Appropriate Venue

All Events must be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. Companies must avoid using renowned or

extravagant venues. The additional requirements set forth in Article 7 of this Code also apply accordingly.

7.1.5. Limits

Refreshments and/or meals incidental to the main purpose of the Event can only be provided:

- exclusively to participants of the Event; and
- If they are moderate and reasonable as judged by local standards.

7.1.6. Entertainment

No entertainment or other leisure or social activities should be provided or paid for by member companies.

7.1.7. Guidance from Member Associations

Member associations are encouraged to provide written guidance on the meaning of the terms "renowned" and "extravagant" as used in Article 7.1.4 of this Code, and the meaning of the terms "moderate" and "reasonable", as used in Article 7.1.5 of this Code. As a general rule, the hospitality provided must not exceed what participants would normally be prepared to pay for themselves.

7.2. Sponsorships

Member companies may sponsor HCPs to attend Events provided such sponsorship is in accordance with the following requirements:

- The Event complies with the requirements in this Code as described in 7.1;
- Sponsorship to HCPs is limited to the payment of travel, meals, accommodation and registration fees;
- No payments are made to compensate HCPs for time spent in attending the Event; and
- Any sponsorship provided to individual HCPs must not be conditional upon an obligation to prescribe, recommend, purchase, supply, administer or promote any pharmaceutical product.

7.3. Guests

Companies must not pay any costs associated with individuals accompanying invited HCPs, except in cases of medical necessity.

7.4. Fees for Services

HCPs may be engaged as consultants and advisors 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 arrangements 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 directly related to the identified need and the consultants must have the expertise necessary to provide the service;
- 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; and
- the compensation for the services must be reasonable and reflect the fair market value. The compensation arrangement may include reimbursement of reasonable expenses including travel, meals and accommodation.

7.5. Gifts and Other Items to Healthcare Professionals

Items in this section, where permissible, must never constitute an inducement to prescribe, recommend, purchase, supply, sell or administer a pharmaceutical product.

7.5.1. Gifts and Promotional Aids

7.5.1.1. Prohibition of Gifts

Gifts for the personal benefit (such as sporting or entertainment tickets, electronics items, social courtesy gifts, etc.) of HCPs (either directly or through clinics and institutions) are prohibited. Providing or offering cash, cash equivalents or personal services is also prohibited. For these purposes, personal services are any type of service unrelated to the HCP's profession and that confer a personal benefit to the HCP.

7.5.1.2. Promotional Aids

A promotional aid is a non-monetary item given for a promotional purpose (which does not include promotional materials as defined in Articles 5 and 6). Providing or offering them to HCPs in relation to the promotion of prescription- only medicines is prohibited.

Promotional aids of minimal value and quantity may be provided or offered to HCPs solely for the promotion of over-the-counter medicines if relevant to the practice of the HCP.

7.5.2. Items of Medical Utility to enhance the Provision of Medical Services and Patient Care

Items of medical utility may be offered or provided by member companies if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care.

They should not be offered on more than an occasional basis, even if each individual item is appropriate.

Items of medical utility can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

7.5.3. Informational or Educational Items that enhance Patient Care

Informational or educational items provided to HCPs for their education or for the education of patients on disease and its treatments may be offered by member companies provided that the items are primarily for educational purposes and do not have independent value.

These informational and educational items can include the company name, but must not be product branded, unless the product's name is essential for the correct use of the item by the patient.

The value of books and subscriptions must be reasonable. Other informational or educational items must be of modest value.

7.5.4. Guidance on Values

Member associations shall provide guidance using local currency, on acceptable monetary amounts for the following:

- "minimal value" for promotional aid items;
- "modest value" for items of medical utility and informational & educational items;
- "reasonable value" for scientific books & journal subscriptions

8. Samples

8.1. Samples

In accordance with local laws and regulations, free samples of a pharmaceutical product may be supplied to HCPs authorized to prescribe that product in order to enhance patient care. Samples should be marked as such so that they cannot be resold or otherwise misused.

8.2. Control and Accountability

Companies should have adequate systems of control and accountability for samples provided to HCPs including how to look after such samples whilst they are in possession of medical representatives.

9. Clinical Research and Transparency

9.1. Transparency

Companies are committed to the transparency of clinical trials which they sponsor. It is recognized that there are important public health benefits associated with making clinical trial information more publicly available to healthcare practitioners, patients, and others. Such disclosure, however, must maintain protection for individual privacy, intellectual property and contract rights, as well as conform to legislation and current national practices in patent law.

Companies disclose clinical trial information as set out in the Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases (2009, with minor revisions as of January 15, 2018) and the Joint Position on the Publication of Clinical Trial Results in the Scientific Literature (2010, with minor revisions as of October 30, 2017) issued by the IFPMA, the

European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA) and the Pharmaceutical Research and Manufacturers of America (PhRMA).

9.2. Distinct from Promotion

All human subject research must have a legitimate scientific purpose. Human subject research, including clinical trials and observational studies, must not be disguised promotion.

10. Support for Continuing Medical Education

Continuing medical education (CME) helps ensure that HCPs obtain the latest and most accurate information and insights on therapeutic areas and related interventions that are critical to the improvement of patient care and overall enhancement of the healthcare system. The primary purpose of an educational meeting must be the enhancement of medical knowledge and therefore financial support from companies is appropriate.

When companies provide content to CME activities and programs, such material must be fair, balanced and objective, and designed to allow the expression of diverse theories and recognized opinions. Content must consist of medical, scientific or other information that can contribute to enhancing patient care.

Companies must follow Article 7 of the IFPMA Code where applicable.

11. Interactions with Patient Organizations

11.1. Scope

The pharmaceutical industry has many common interests with patient organizations. All interactions with patient organizations must be ethical. The independence of patient organizations must be respected.

11.2. Declaration of Involvement

When working with patient organizations, companies must ensure that the involvement of the company and the nature of that involvement is clear from the outset. No company may require that it be the sole funder of the patient organization or any of its programs.

11.3. Written Documentation

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.

11.4. Events

Companies may provide financial support for patient organization meetings provided that the primary purpose of the meeting is professional, educational, and scientific in nature, or otherwise supports the mission of the patient organization. When companies hold meetings for patient organizations, companies must ensure that the venue and location is appropriate and conducive to informational communication. In addition, any meals or refreshments provided by a company must be modest as judged by local standards.

12. Company Procedures and Responsibilities

12.1. Procedures

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

12.2. Training

Companies should also ensure that relevant employees receive training appropriate to their role.

12.3. Responsibilities for Approving Promotional Communications

A designated company employee with sufficient knowledge and appropriate qualifications should be responsible for approving all promotional communications. In the alternative, a senior company employee(s) could be made responsible provided that he or she receives scientific advice on such communications from adequately qualified scientific personnel.

13. Infringement, Complaints, and Enforcement

13.1. Complaints

Genuine complaints relating to infringements of the AIPM BH Code are encouraged. Detailed procedures for complaints and the handling of complaints (including the respective roles and jurisdiction of AIPM BH and member associations) will be added.

13.2. Measures to Ensure and Enforce Compliance

Each member association should strongly encourage its member companies to adopt procedures to assure adherence to its national code. While strong local legal and regulatory mechanisms and vigorous government enforcement may obviate the need for compliance mechanisms in some countries, member associations are encouraged, where appropriate, to include provisions intended to assure compliance with their national codes. The AIPM BH recognizes, however, that local laws and practices vary widely and will affect the types of compliance provisions, if any, which may be adopted.