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GOVERNMENT OF PAKISTAN

MINISTRY OF NATIONAL HEALTH SERVICES REGULATIONS & COORDINATION

(Drug Regulatory Authority of Pakistan)

NOTIFICATION

Islamabad, the --- of June, 2017

Ethical Criteria for Interaction with Health Care Professionals 2017 **“Regulation to provide Code of Conduct for Ethical Marketing to Health Care Professionals”**

S.R.O. . .(I)/2017-The following draft of (Code for Ethical Marketing) Regulations, 2017, proposed to be made, in exercise of the powers conferred by Section 24 (Chapter IV) of the Drug Regulatory of Pakistan Act, 2012 (XXI of 2012) is hereby published as, for information of all concerned likely to be affected thereby and notice is hereby given that the draft will be taken into consideration by the Policy Board after fifteen days of its publication in the Official Gazette.

Any objection or suggestion which may be received from any person in respect of the said draft before the expiry of the said period shall be considered by the Drug Regulatory Authority of Pakistan.

1. Short Title and commencement. - (1) These regulations may be called the Code of Ethical Marketing to Health Care Professionals Regulations, 2017, to provide for conduct of Ethical Marketing by the Pharma Industry to Physicians and other Healthcare professionals.

- (2) They shall enter into force following its publication in the official gazette.
- (3) The provisions of these regulations are in addition to and not in derogation of any other rules or provisions made under the Drugs Act 1976, or DRAP Act 2012.

2. Purpose

2.1 The purpose of this Code is to facilitate ethical interactions between companies having marketing authorization of therapeutic goods and Healthcare Professionals in Pakistan.

2.2 Ethical interactions between companies and Healthcare Professionals provide numerous benefits, such as:

- (a) Ensuring that medical decision-making is made in the best interest of the patient.
- (b) Increasing public confidence in the medical device and diagnostic industry.
- (c) Enhancing patient access to safe and effective use of Medical Technologies by ensuring appropriate training of Healthcare Professionals by companies.
- (d) Promoting innovation and ongoing development of Medical Technologies through legitimate and transparent collaboration
- (e) Facilitating open and transparent business environment, free from the high costs due to corruption, enhancing the ability of companies to participate in global markets, activities and conferences etc.

3. General Principles

This Code is based upon the following general principles:

The Principle of Separation:

Interaction between industry and Healthcare Professionals must neither be misused by influence through improper advantages, purchasing decisions, nor should such interactions be contingent upon sales transactions or use of recommendation of companies' products.

The Principle of Transparency:

Interaction between industry and Healthcare Professionals must be transparent and in compliance with national and local laws, regulations or professional codes of conduct. Companies shall maintain appropriate transparency by submitting a prior written notification made to the hospital administration, the Healthcare Professional's superior or other locally-designated competent authority, fully disclosing the purpose and scope of the interaction.

The Principle of Documentation:

For interaction between a company and a Healthcare Professional, such as where services are performed by a Healthcare Professional for on behalf of a company, there must be a written agreement setting out, *inter alia*, the purpose of the interaction, the services to be performed, the method for reimbursement of expenses as well as the remuneration to be paid by the company. The activities envisaged by the agreement must be substantiated and evidenced by activity reports and the like. Adequate documentation such as the agreement, related reports,

invoices etc. must be retained by the company to support the need for, and materiality of, the services as well as the reasonableness of the remuneration paid

3.1. To the extent that any provision of this Code conflicts with a provision of any law, regulation, company policy, or local medical technology industry code of ethical conduct, companies shall comply with the provision that has the highest ethical standard or legal binding.

4. Definitions

4.1 In this Code:

Companies mean organizations that develop, manufacture, sell, market or distribute therapeutic goods including “Medical Technologies” in Pakistan.

Demonstration Products means products that are used for training of Healthcare Professionals or patient education.

Evaluation Products mean products provided for human use, either as free samples of single-use products, or loans of reusable products or capital equipment.

Healthcare Professionals include individuals and entities that purchase, lease, recommend, use or arrange for the purchase/lease of or prescribe therapeutic goods including “Medical Technologies” as registered by DRAP. This also includes clinical and non-clinical individuals including physicians, pharmacists, dentists, nurses, biostatisticians, microbiologists, biochemists, medical technologists, traditional practitioners of therapeutic goods etc. who make product-related decisions of the type described above and anyone with material influence over purchasing decisions.

Health Care Industry means the Global Industry Classification Standard and the Industry Classification benchmark divide the industry into two main groups:

- a) **Health care equipment & services** comprise of companies that provided medical equipment, medical supplies and health care such as hospitals, home health care providers and nursing homes, ambulatory care specialists and general medical practitioners (GPs).
- b) **Healthcare biotechnology & related life sciences** comprise sectors, companies that produce biotechnology, healthcare and miscellaneous scientific services.

Medical Technologies mean products, technologies, related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities.

Outsourcing means type of interaction between Health care professionals and the establishments in order to promote, sell, market or distribute their therapeutic goods, allied medical technologies, demonstration products and evaluation products through third party arrangements. Outsourcing is defined as:

“The practice of having a certain job function done outside a company instead of having and in house department or employee handle them; function can be outsourced to either a company or an individual”

- 1) Conditions of outsourcing are:
 - i. The act of outsourcing will be inclusive of the total marketing expense as permissible under the rules which is up to 5%.
 - ii. Companies will submit annual expenditure statement on marketing expenses. Incurred in various activities upon closure of each financial year as per annex-I.
 - iii. **Permission for outsourcing ethical marketing:** No permission for outsourcing will be granted from the DRAP, but it will be the sole responsibility of the companies/establishments/entities as defined under the regulation.

Representative means a representative of Health Care Industry calling on Health Care Professionals and administrative staff in relation to the promotion of medicines.

5. Consulting Arrangements with Healthcare Professionals.

5.1 Companies may engage Healthcare Professionals to provide services that support research and development to advance in medical science, develop new technologies, improve existing products and services, educate on the safe and effective use of company products or enhance the quality and efficacy of patient care.

5.2 Consulting arrangements between Companies and Healthcare Professionals must comply with the following:

- (a) A legitimate need and purpose for the services is identified in advance;
- (b) Only a reasonable number of Healthcare Professionals needed to perform the services are engaged;
- (c) Healthcare Professionals are selected on the basis of qualification to perform the services and not on the basis of volume or value of business generated or potentially generated by them;
- (d) Compensation to be paid to a Healthcare Professional consultant must be consistent with fair market value for the services actually performed;
- (e) Compensation is paid after the services have been performed and upon sufficient evidence of performance of services (retainer fees or other advance payments are not permitted);
- (f) Compensation is paid by cheque or electronic bank transfer. Payment must not be by cash;
- (g) The services and compensation to be paid (if any) are documented in a written agreement in advance of the services to be performed; and
- (h) Consulting arrangements should be disclosed in advance and in writing to the Healthcare Professional consultant's institution or employer, unless applicable laws, regulations or institutional rules specifically require disclosure to a different body, in which case disclosure should be made in accordance with the applicable laws, regulations or rules.

5.3 When it is necessary for the Healthcare Professional consultant to travel in order to perform the services, companies may pay for or reimburse reasonable expenses of travel, accommodation and meal, provided that:

- (a) The expenses are limited to those that are necessary for the Healthcare Professional to perform the services;
- (b) No expenses are paid for spouses or other guests accompanying the Healthcare Professional; (An exception may be for spouses working at the same entity and assigned by the supervisor of the Healthcare Professional to join the event).
- (c) Whenever possible, companies may make travel bookings directly on behalf of the Healthcare Professional on recommendation/approval by the Institution, rather than providing reimbursement to the Healthcare Professional;
- (d) When direct bookings are not possible, reimbursement is only made for actual and appropriate cost incurred, and upon submission of original receipts or other adequate proof of payment;
- (e) Reimbursement is made by cheque or electronic bank transfer. Payment must not be by cash;
- (f) Companies must not fund the Healthcare Professional consultant's vacation or other personal activities such as private side trips.
- (g) Companies must not fund any international trips of the Healthcare professional consultant directly. It should be provided to institution, which may chose among the medical professionals of relevant field with the purpose to provide exposure to maximum individuals.

6. Third Party Educational Conferences

6.1 A third party educational conference is a conference sponsored or conducted by or on behalf of a professional association that is independent, of an educational/scientific/policy-making nature and for the purpose of promoting scientific knowledge, medical advancement or delivery of effective healthcare.

6.2 Companies may support such conferences through grants to conference organizers, grants to institutions to support individual attendance at the conference, or other appropriate methods, provided that:

- (a) Such support should preserve the independence of medical education and should not be used as a means of inappropriate inducement;
- (b) The grants should be made only, following a written request from the conference organizer or institution, including sufficient information to allow the company to evaluate the scientific and educational merit of the conference as well as the appropriateness of the venue and agenda;
- (c) The conference venue and agenda do not bring the industry's reputation into disrepute;

- (d) The support is consistent with relevant guidelines established by the conference organizer and any accrediting body,
- (e) The conference organizer should independently control and be responsible for the selection of program content, faculty, educational methods and materials;
- (f) The funding provided is proportionate to the overall costs of the conference;
- (g) Companies must not directly pay for, or reimburse, the expenses of any individual Healthcare Professional delegates to attend the conference and grants must not inappropriately benefit individual Healthcare Professional or provide for side trips, recreation, entertainment or lavish meals or accommodations;
- (h) All grant arrangements must be appropriately documented.
- (i) The conference must be held within the country.

6.3 Where consistent with the conference organizer's guidelines, companies may sponsor or organize appropriate meals in connection with conferences, provided that such meals are:

- (a) Modest in cost;
- (b) Don't include entertainment or recreational activities;
- (c) Are subordinate in time and focus to the scientific or educational purpose of the conference; and
- (d) Only provided to Health care Professional attendees of the conference.

6.4 Companies may purchase advertisements and lease booth space for Company displays at conferences.

6.5 Companies may also sponsor satellite symposia at conferences and provide content and faculty for these symposia, provided that the arrangements are disclosed in writing in all materials relating to the satellite event. If Healthcare Professional consultants are engaged for these symposia, the provisions relating to Healthcare Professional consultants also apply.

7. Company-Sponsored Training and Educational Meetings

7.1 Companies may provide training and education of Healthcare Professional on the safe and effective use of Company products, including "hands-on" training sessions, cadaver workshops, wet lab sessions, live surgeries, lectures and presentations.

7.2 Companies may provide reasonably-priced meals in connection with training and education meetings.

7.3 Training and education meeting must:

- (a) Be held in a location (e.g. town or city) that is logistically sensible considering the location of the majority of participants and those providing the educational learning.

- (b) Be held in appropriate venues such as the Healthcare Professional's premises, company's premises, clinical, laboratory, educational or conference facilities (including hotel meeting rooms) that enable effective learning;
- (c) Be conducted by qualified personnel, which may include sales personnel with appropriate technical expertise;
- (d) Follow a robust educational agenda that limits free time to that necessary for reasonable breaks and meals; and
- (e) Not include or facilitate entertainment or other inappropriate activities.

7.4 When it is impractical or inefficient to provide training at or close to a Healthcare Professional's place of business (such as for plant tours or demonstrations of non-portable equipment), companies may pay the reasonable travel and accommodation costs, provided that:

- (a) The costs are limited to those necessary for the Healthcare Professional to attend the training.
- (b) No costs are paid for spouses or other guests that are not legitimate attendees in their own right; (An exception may be for spouses working in the same entity and assigned by the supervisor of that Healthcare Professional to join the event.)
- (c) Whenever possible, companies may make travel bookings directly on behalf of the Healthcare Professional, rather than providing reimbursement to the Healthcare Professional;
- (d) When direct booking are not possible, reimbursement is only made for actual and appropriate cost incurred, and upon submission of original receipts or other adequate proof of payment; and
- (e) Reimbursement is made by cheque or electronic bank transfer. Payment must not be by cash.
- (f) Companies must not fund Healthcare Professional's vacation or other personal activities such as private side trips.
- (g) Companies must not fund Healthcare Professional international trip.

8. Meals Provided During Business Meetings

8.1 Company representatives may meet from time to time with Healthcare Professionals to discuss product features, conduct contract negotiations, or discuss sales terms. Such meetings are subject to the following rules:

- (a) Meetings should generally occur at or near the Healthcare Professional's place of business, although occasionally such discussions may take place at another mutually convenient location, provided it is conducive to the business discussion;

- (b) Meals must be modest and incidental to the business discussion;
- (c) Entertainment may not be provided; and
- (d) Expenses may not be paid for spouses or other guests of Healthcare Professionals that do not have a legitimate business interest in attending the meeting. (An exception may be for spouses working in the same entity and assigned by the supervisor of that Healthcare Professional to join the event.).

9. Educational Items

9.1 Companies may occasionally provide items to Healthcare Professionals that benefit patients or serve a genuine educational function for Healthcare Professionals. Items those are capable of use by Healthcare Professionals (or their family members, office staff or friends) for non-educational or non-patient related uses are inappropriate.

9.2 Educational items should be modest in cost, as determined by local standards, and should not be provided in excess.

9.3 Certain permissible educational items, such as textbooks and anatomical models, may be higher in cost but nonetheless, they should not be extravagant.

10. Gifts and Entertainment

10.1 Gifts are items that are provided to individual Healthcare Professionals that do not fit into any of the categories set out in this Code. Gifts include cash, gift cards, food, gift baskets, flowers or any type of branded promotional items.

10.2 Companies must not provide gifts to Healthcare Professionals even if the item is of minimal value.

10.3 Companies must not provide, organize or pay for recreational or entertainment activities for Healthcare Professionals, including (without limitation) tours, cultural or artistic activities, or leisure activities.

10.4 Only those gifts shall be permissible which are of direct utilization/benefit to the patient.

10.5 Gifting should be permissible for Medical Institution and not for individual beneficiary Health Care Professionals.

11. Grants and Donations

11.1 Companies may provide research, educational and charitable grants and donations provided that the company:

- (a) Adopts objective criteria for providing grants and donations that do not take into account the volume or value of purchase made by, or anticipated from, the grant recipient or affiliated Healthcare Professionals;

- (b) Implements appropriate procedures to evaluate grant and donation requests against those objective criteria and to ensure that they are not used as a condition of purchase of the Company's products or to improperly obtain any other form of advantage;
- (c) Ensure that sales representatives do not control or unduly influence decisions around grants and donations although they may provide input to help evaluate the suitability of a proposed program or recipient;
- (d) Does not provide grants for inappropriate activities, such as holiday parties or entertainment activities;
- (e) Does not link the grant or donation directly or indirectly to the purchase of Medical Technologies;
- (f) Provides the grant or donation in response to a written request from a bona fide organization or institution;
- (g) Provides the grant or donation to the requesting institution or organization and not to individual Healthcare Professionals;
- (h) Documents the grant or donation provided.
- (i) Makes the payment through cross cheques and no cash grants are made.

11.2 In addition to the rules set forth above, the following rules apply to the particular types of grants and donations specified:

- (a) Charitable Donations (monetary or in-kind):
 - (i) Companies may make monetary and in-kind donations to support bona fide charitable organizations, missions and non-profit organizations for charitable purposes, such as supporting indigent care, patient education, public education or the sponsorship of events where the proceeds are intended for charitable purposes.
 - (ii) In rare instance, donations may be made to individuals engaged in genuine charitable activities for the support of a bona fide charitable mission, but it is the obligation of the Company providing such donation to ensure that the mission is bona fide and that such individual will not personally benefit, directly or indirectly, from the donation provided.
- (b) Educational Grants:
 - (i) Companies may provide grants to support legitimate educational purposes, such as the medical education of Healthcare Professionals or medical students/residents/fellow and education of patients & the public about important healthcare topics.
 - (ii) Grants may not exceed the value necessary to achieve the educational purpose.

(c) Research Grants:

(i) Companies may provide research grants other than mandatory contribution of CRF fund under rules to DRAP to support independent medical research with scientific merit for the purpose of advancing in scientific and clinical information, improving clinical care, promoting improved delivery of healthcare or to otherwise benefit patients.

(ii) Sponsored research should have well-defined objectives and milestones that are documented in a research protocol or similar document.

(iii) Payments should only be made upon evidence of satisfactory completion of the research activities or at agreed milestones as documented in the research protocol.

(iv) Company-initiated or directed research involving a company's medical technologies is not covered by this section and should be evaluated under the provisions addressing consulting arrangements.

12 Demonstration and Evaluation Products

12.1 Companies may provide Medical Technologies to Healthcare Professionals free of charge for demonstration and evaluation purposes, provided that:

- (a) They are not given or intended as an improper inducement;
- (b) Demonstration Products should be marked "not for human use" or otherwise to indicate that they are solely for demonstration purposes;
- (c) Evaluation products are provided in quantities (or for a duration) that is reasonable determined to enable adequate evaluation by the Healthcare Professionals.
- (d) Evaluation Products should be appropriately disclosed and documented; and
- (e) Companies should ensure that loaned products are retrieved or returned if not purchased at the end of the evaluation period.
- (h) Drug product samples given /supplied to Medical Practitioners for their clinical evaluation/support are subject to additional labeling requirements e.g. Physicians samples; not for sale, reduced pack size etc. duly marked with indictable ink.
- (h) The quantification should be based on minimum requirement and be given to patient free of cost in compliance with Rule 33 of the Drugs (Licensing, Registering & Advertising) Rules 1976.

13. Ensuring Effective Code Implementation

13.1 In order to ensure effective implementation of Code principles, each company should take the following concrete steps.

- (a) Appoint a senior executive responsible for overseeing the company's compliance with this Code;
- (b) Adopt practical, useful, and meaningful policies, guidance and tools intended to ensure compliance with the Code;
- (c) Provide effective and ongoing training and education on the Code and on company policies implemented to ensure Code compliance;
- (d) Ensure that senior management and the company's board of directors or other governing body are expressly committed to support the Code;
- (e) Institute appropriate internal monitoring and auditing mechanisms;
- (f) Create safe mechanisms for , and encourage, employees who raise concerns;
- (g) Require that third party intermediaries (including consultants , distributors, sales agents, and brokers) that may interact with healthcare Professionals in connection with the company's Medical Technologies agree to comply with this Code; and
- (h) Board of Directors shall provide a certification to DRAP at each annual year end that the company has complied with this Code of Ethical Conduct.

14. Update and Review of Regulation:

DRAP may update or revise its regulations as and when required based on international best ethical practices.

15. Contravention and Punishment:

Whosoever himself or by any other person on his behalf contravenes with the provisions of the DRAP Act 2012 and regulations made there under shall be punishable as provided for in Schedule II and III of the DRAP Act 2012.

16. Cognizance of Offence:

16.1 Cognizance of offence shall be in accordance with Schedule IV of the DRAP Act 2012.

16.2 In case of complaints and non compliance by the Health Care Professionals, the recommendation shall be referred to the concerned governments and regulatory bodies including councils etc. for necessary legal action as per their legal jurisdiction in the Court of Law.

Annexure-I

Detail of Expenditure under Rule 33 of the Drugs (Licensing, Registering & Advertising) Rules, the Drugs Act 1976 and the DRAP Act 2012

Company Name:

Turnover: PKRS.Financial Year:

| Sr No. | Advertising | | Physician's Sample | Promotional Printed Material | Give Aways | Expenditure on Seminar, Conference, Workshop, Exhibition | Sponsorship | | Any Outsourcing Activities | Miscellaneous Expenses under the Rules | Total |
|--------|------------------|-------------|--------------------|------------------------------|------------|--|-------------|---------|----------------------------|--|-------|
| | Electronic Media | Print Media | | | | | Local | Foreign | | | |
| | | | | | | | | | | | |

Authorized Signature and Stamp