GOVERNMENT OF PAKISTAN

MINISTRY OF NATIONAL HEALTH SERVICES REGULATIONS & COORDINATION

(**Drug Regulatory Authority of Pakistan**)

NOTIFICATION

Islamabad, the , 2018.

The following draft of Ethical Marketing to Healthcare Professionals Rules, 2018 proposed to be made in exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with clause (q) of section 7 thereof, is hereby published, for the information of all persons likely to be affected thereby and notice is hereby given that the draft will be taken into consideration after **fifteen** days of its publication.

Any suggestion or input, which may be received in respect of the said draft, before the expiry of the said period, will be considered by the Drug Regulatory Authority of Pakistan.

1. Short title and commencement. - (1) These rules may be called the Ethical Marketing to Healthcare Professionals Rules, 2018.

(2) These shall come into force at once.

2. Definitions. – (1) In these rules, unless there is anything repugnant in the subject or context, -

(a) "Act" means the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012);

(b) "Companies" mean organizations that develop, manufacture, sell, market or distribute therapeutic goods including Medical Technologies in Pakistan;

(c) "Demonstration Products" mean products that are used for training of healthcare professionals or patient education;

(d) "DRAP" means the Drug Regulatory Authority of Pakistan;

(e) "Evaluation Products" mean products provided for human use, either as free samples of single-use products, or loans of reusable products or capital equipment;

(f) **"Gifts"** mean items provided to individual healthcare professionals that do not fit into any of the categories set out in these rules and gifts include cash, gift cards, food, gift baskets, flowers or any type of branded promotional items;

(g) **"Healthcare Professionals"** mean individuals and entities that purchase, lease, recommend, use or arrange for the purchase or 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 who influences purchasing decisions;

(h) **"Healthcare Industry"** means the global industry classification standard and the industry classification benchmark divide the industry into two main groups, namely: -

(i) healthcare equipment and services, comprise of companies that provide medical equipment, medical supplies and healthcare such as hospitals, home healthcare providers and nursing homes, ambulatory care specialists and general medical practitioners; and

(ii) comprise sectors of companies that produce biotechnology, healthcare and miscellaneous scientific services. healthcare biotechnology and related life sciences;

(i) **"Institution"** means healthcare institution either public or non-profit organization which provides healthcare and related services, including but not limited to the provision of inpatient and outpatient care, diagnostic or therapeutic services, laboratory services, medicinal drugs, nursing care, assisted living, elderly care and housing, including retirement communities, and equipment used or useful for the provision of healthcare and related services;

(j) **"Medical Technologies"** mean products, technologies, related services and therapies used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities;

(k) **"Outsourcing"** means type of interaction between healthcare 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; and

(l) **"Representative"** means a representative of healthcare industry calling on healthcare professionals and administrative staff in relation to the promotion of medicines.

(2) All words and expression used in these rules but not defined, have the same meaning as in the Act.

(3) The purpose of these rules is to facilitate ethical interactions between companies having marketing authorization of therapeutic goods and healthcare professionals in Pakistan.

3. Conditions for Outsourcing. – (1) The practice of having a certain job function done outside a company instead of having an in-house department or employee handle them subject to the following conditions, namely:-

(a) the act of outsourcing shall be permissible up to five percent and inclusive of the total marketing expense; and

(b) companies shall submit annual expenditure statement of marketing expenses incurred in various activities upon closure of each financial year as set out in Annexure-I.

4. Benefits of ethical interactions. – (1) Ethical interactions between companies and healthcare professionals shall have the following benefits, namely: -

(a) ensure 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 and ensuring appropriate training of healthcare professionals by companies and therapeutic goods industry;

(d) promoting innovation and development of medical technologies through legitimate and transparent collaboration; and

(e) facilitating open and transparent business environment, free from high prices, enhancing the ability of companies to participate in global markets, activities and conferences etc.

5. Interaction of healthcare industry and healthcare professionals.– (1) Interaction between industry and healthcare professionals shall be-

(a) neither misused by influence through improper advantages, purchasing decisions nor should such interactions be contingent upon sales transactions or use of recommendation of companies' products;

(b) 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; and

(c) where services are performed by a healthcare professional for or 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.

(2) To the extent that any provision of these rules 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.

6. Consulting arrangements with healthcare professionals.– (1) Companies shall engage healthcare professionals to provide services which support research and development in medical science, new technologies, improve existing products and services, awareness of safe and effective use of company products or enhance the quality and efficacy of patient care.

(2) Consulting arrangements between companies and healthcare professionals shall fulfil with the following conditions, namely: -

(a) a legitimate need and purpose for the services shall be identified in advance;

(b) only a reasonable number of healthcare professionals, required to perform the services, shall be engaged;

(c) healthcare professionals shall be 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 consultants shall be for the services actually performed;

(e) compensation shall be paid after the services have been performed and upon sufficient evidence of performance of services, retainer fees or other advance payments shall not be permitted;

(f) compensation shall be paid by cheque or electronic bank transfer, not in cash;

(g) the services and compensation to be paid, if any, shall be in written agreement prior to the services to be performed; and

(h) consulting arrangements shall 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 such cases disclosure shall be made in accordance with the applicable laws, regulations or rules.

(3) If it is necessary for the healthcare professional consultant to travel for official services, companies shall pay for or reimburse reasonable expenses of travel, accommodation and meal, subject to the following conditions, namely: -

(a) The expenses shall be limited to those that are necessary for the healthcare professionals to perform the services;

(b) no expenses shall be paid for spouses or other guests accompanying the healthcare professional;

(c) Companies shall make travel bookings directly on behalf of the healthcare professional on recommendation or approval by the institution, rather than providing reimbursement to the healthcare professional;

(d) If direct bookings are not possible, reimbursement shall be only made for actual cost incurred, and upon submission of original receipts or other adequate proof of payment;

(e) reimbursement shall be made by cheque or electronic bank transfer;

(f) companies shall not fund any international trips of the healthcare professional consultant directly. It shall be provided to institution, which shall choose among the medical professionals of relevant field with the purpose to provide exposure to maximum individuals.

7. Third party educational conferences.– (1) Third party educational conference, sponsored or conducted by or on behalf of a professional association shall be independent of an educational, scientific, policy-making nature and for the purpose of promoting scientific knowledge, medical advancement or delivery of effective healthcare.

(2) Companies may support such conferences through grants to conference organizers or to institutions to support individual attendance at the conference or other appropriate methods:

provided that such support preserves-

(a) the independence of medical education and must not be used as a means of inappropriate inducement;

(b) the grants shall 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 does not bring the industry's reputation into disrepute;

(d) the support shall be consistent with relevant guidelines established by the conference organizer and any accrediting body;

(e) the conference organizer shall independently control and be responsible for the selection of program content, faculty, educational methods and materials;

(f) the funding provided shall be 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; and

(i) the conference must be held within the country.

(3) Where consistent with the conference organizer's guidelines, companies may sponsor or organize appropriate meals in connection with conferences, provided that:-

(a) such meals shall be modest in cost;

(b) shall not include entertainment or recreational activities;

(c) shall be subordinate in time and focus on the scientific or educational purpose of the conference; and

(d) only provided to healthcare professional attendees of the conference.

(4) Companies may purchase advertisements and lease booth space for company displays at conferences.

(5) Companies may also sponsor satellite symposia at conferences and provide content and faculty for these symposia, provided that the arrangements shall be 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.

8. Company-sponsored training and educational meetings.– (1) Companies may provide training and education of healthcare professionals on the safe and effective use of company products, including hands-on training sessions, cadaver workshops, wet lab sessions, live surgeries, lectures and presentations.

(2) Companies may provide reasonably priced meals in connection with training and education meetings.

(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 professionals' 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.

(4) For outdoor 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 shall be limited to those necessary for the healthcare professionals to attend the training;

(b) no costs shall be 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 shall make travel bookings directly for, on behalf of, the healthcare professionals, rather than providing reimbursement to the healthcare professionals;

(d) when direct booking is not possible, reimbursement shall only be made for actual and appropriate cost incurred, and upon submission of original receipts or other adequate proof of payment;

(e) reimbursement shall be made by cheque or electronic bank transfer;

(f) companies shall not fund healthcare professionals' vacation or other personal activities such as private side trips; and

(g) companies shall not fund any international trip for healthcare professionals.

9. Business meetings.– (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 shall be subject to the following rules:

(a) meetings shall be nearer to the healthcare professionals' place of business, such discussions may take place at another mutually convenient location:

Provided it shall be conducive to the business discussion;

(b) meals must be modest and incidental to the business discussion;

(c) entertainment shall not be provided; and

(d) expenses shall 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.

10. Educational items.– (1) Companies may provide educational items to healthcare professionals, that benefit patients or serve a genuine educational function for healthcare professionals.

(2) Educational items shall be unpretentious in cost, as determined by local standards.

(3) Certain permissible educational items, such as textbooks and anatomical models, may be higher in cost but not be extravagant.

11. Gifts and entertainment.– (1) Companies shall not provide gifts to individual beneficiary healthcare professionals, even if the item is of minimal value except those gifts shall be permissible which are of direct utilization or benefit to the patient or to medical institution.

(2) Companies shall not provide, organize or pay for recreational or entertainment activities for healthcare professionals, including tours, cultural or artistic activities.

12. Grants and donations. - (1) Companies may provide research, educational and charitable grants and donations in cash or in kind:

Provided that the company shall-

(a) adopt 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 professional;

(b) implement appropriate procedures to evaluate grant and donation requests against those objective criteria and to ensure that they shall not be 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 for grants and donations but they may provide input to help evaluate the suitability of a proposed program or recipient;

(d) not provide grants for inappropriate activities, such as holiday parties or entertainment activities;

(e) not link the grant or donation directly or indirectly to the purchase of medical technologies;

(f) provide the grant or donation in response to a written request from a *bona fide* organization or institution, not to individual healthcare professionals;

(g) make the payment though cross cheques and no cash grants shall be made.

13. Demonstration and evaluation products.– Companies may provide medical technologies to healthcare professionals free of charges for demonstration and evaluation purposes:

Provided that-

(a) they shall not be given or intended as an improper inducement;

(b) demonstration products shall be marked "not for human use" in visible font size or otherwise to indicate that these are solely for demonstration purposes;

(c) evaluation products shall be provided in quantities (or for a duration) that is determinedreasonable to enable adequate evaluation by the healthcare professionals;

(d) evaluation products shall be appropriately disclosed and documented;

(e) companies shall ensure that loaned products are retrieved or returned if not purchased by the end of the evaluation period;

(f) drug product samples given or supplied to medical practitioners for their clinical evaluation or support shall be subject to additional labelling requirements such as physician's samples, not for sale, reduced pack size etc. duly marked with indelible ink; and

(g) the quantification shall be based on minimum requirement allowed and shall be given to patients free of cost, in compliance with rule 33 of the Drugs (Licensing, Registering and Advertising) Rules 1976.

14. Effective implementation. - For effective implementation of these rules, each company shall ensure that:

(a) a senior executive is appointed for responsibly overseeing the company's compliance with these rules;

(b) practical, useful, and meaningful policies, guidance and tools are adopted, intended to ensure compliance with these rules;

(c) effective and ongoing training and education is provided, on the code of conduct for ethical marketing and on company policies implemented to ensure compliance with these rules;

(d) senior management and the company's board of directors or other governing body are expressly committed to support these rules;

(e) institute appropriate internal monitoring and auditing mechanisms are in effect;

(f) safe mechanisms are created for employees who raise concerns and encouragement is given;

(g) third party intermediaries, including consultants, distributors, sales agents, and brokers that may interact with healthcare professionals in connection with the company's medical technologies are required and must agree to comply with these rules; and

(h) board of directors shall provide a certification to DRAP at the end of each year annually, that the company has complied with the rules of ethical marketing.

15. Enforcement.– To ascertain breach of these rules, authority shall have the power to be carry out financial audit of any healthcare industry, either itself or through any external auditor appointed for the purpose.

16. Contravention and punishment.– Whosoever himself or by any other person on his behalf contravenes with the provisions of the Act and these rules, shall be punishable as provided for in Schedule II and III Act.

17. Cognizance of offence.– (1) Cognizance of offence shall be in accordance with Schedule IV of the Act.

(2) In case of complaints and non-compliance by the healthcare professionals, the recommendation shall be referred to concerned governments and regulatory bodies including councils etc. for necessary legal action according to law.

(3) All such complaints shall be handled and processed by the pharmacy services division, DRAP.

[F.No. 13-2/2017 DD (PS)]

(**SHEIKH ANSAR AHMED**)
Director, Pharmacy Services Division
Drug Regulatory Authority of Pakistan

Annexure-I

[*see rule 3(b)*]

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	Electronic Media					Local	Foreign			
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)

Authorized Signature and Stamp