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PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF PAKISTAN
Ministry of National Health Services, Regulations and Coordination
Drug Regulatory Authority of Pakistan

NOTIFICATION

Islamabad, the 12th November, 2021

S.R.O. 1472(I)/2021.— In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, is pleased to make the following rules, namely: -

1. Short title and commencement.— (1) These rules shall be called the Ethical Marketing to Healthcare Professionals Rules, 2021.

(2) They 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) “company” means organization including its agents, affiliates, contractors and outsources entities etc. that develop, manufacture, sell, market or distribute therapeutic goods and medical technologies in Pakistan;
- (c) “demonstration product” means product that is used for training of healthcare professionals or patient education;
- (d) “evaluation Product” means product provided for human use, either as free samples of single-use products, or loans of reusable products or capital equipment;
- (e) “gift” means item provided to individual healthcare professional that do not fit into any of the category set out in these rules. These might be

tangible or intangible in nature, have monetary value and include but are not limited to cash, gift cards, food, gift baskets, courtesy gift, flowers or any type of branded promotional items;

- (f) “healthcare professional” means any member of the medical, dental, pharmacy, nursing professions, any allied health professional or any other person who in the course of his professional activities may prescribe, recommend, purchase, supply, sell or administer a therapeutic goods including medical technologies as registered or enlisted by the Authority;
- (g) “healthcare industry” comprises of providers of diagnostic, preventive, remedial and therapeutic services such as doctors, nurses, hospitals and other private, public, and voluntary organizations. It also includes medical equipment and therapeutic goods manufacturers and health insurance firms. The key sectors of healthcare industry can be broadly classified into following four sub-segments, namely:-
 - (i) pharmaceuticals and therapeutic goods manufacturers;
 - (ii) medical devices, equipment and hospital supplies manufacturers;
 - (iii) health care services and facilities; and
 - (iv) medical insurance, medical services and managed care;
- (h) “institution” means healthcare institution either public, private, non-profit organization and International Non-governmental Organizations which provide 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;
- (i) “medical technology” means product, technology, related service and therapy used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities;
- (j) “outsourcing” means any type of interaction between healthcare professionals and the companies, in order to promote, sell, market or distribute their therapeutic goods, allied medical technologies, demonstration products and evaluation products through third party arrangements;
- (k) “promotion” means any activity undertaken, organized or sponsored by a company which is directed at healthcare professional to promote the prescription, recommendation, supply, use, purchase, administration or consumption of its therapeutic good or medical technology through all methods of communications including the internet; and
- (l) “representative” means a representative of healthcare industry calling on healthcare professionals and administrative staff in relation to the promotion of therapeutic goods.

(2) The words and expressions used but not defined herein shall have the same meanings as assigned to them in the Act.

3. Benefits of ethical interactions.– Ethical interactions between companies and healthcare professionals shall be for the purposes to facilitate ethical interactions between companies having marketing authorization of therapeutic goods and healthcare professionals in Pakistan and also to-

- (a) ensure that medical decisions are made in the best interest of the patient;
- (b) increase public confidence in the medical device and diagnostic industry;
- (c) enhance patient access to safe and effective use of medical technologies and ensuring appropriate training of healthcare professionals by companies and therapeutic goods industry;
- (d) promote innovation and development of medical technologies through legitimate and transparent collaboration; and
- (e) facilitate open and transparent business environment, free from extravagant expense, enhancing the ability of companies to participate in global markets, activities and conferences etc.

4. Interaction of healthcare industry and healthcare professionals.– Interaction between industry and healthcare professionals shall be based on principles that-

- (a) neither misused by influence through improper advantages, purchasing decisions nor should such interactions be contingent upon sales transactions or use or recommendation of therapeutic goods and medical technologies by the companies and healthcare industry;
- (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 under any agreement must be substantiated and evidenced by activity reports. The adequate documentation such as the agreement, related reports, invoices etc. must be retained by the company for a period of five years to support the need for, and materiality of the services as well as the reasonableness of the remuneration paid.

5. 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, 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 be based on following conditions, namely:-

- (a) a legitimate need and purpose for the services shall be identified clearly in advance with proper justification for selecting any specific healthcare professional;
- (b) only the healthcare professional or technical assistant or helper of relevant field, required to perform such services shall be engaged;
- (c) healthcare professionals shall be selected on the basis of qualification and experience 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 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, which shall be declared in the recipient's annual income tax statement;
- (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 by the healthcare professional, 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 professionals on recommendation or approval by the

institution, rather than providing reimbursement to the healthcare professionals;

- (d) 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; and
- (f) companies shall not fund or reimburse any international trip of healthcare professional unless a no objection letter is received from the employer of that particular healthcare professional.

6. Third party educational conference.– (1) Third party educational conference, sponsored or conducted by or on behalf of a national professional association or organization, shall be 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 conference through grants to conference organizers or institutions to support individual attendance at the conference, provided that-

- (a) such support preserves 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 or company, including sufficient information to allow the conference organizer or institution or 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 and may be reimbursable via checks or electronic bank transfer;
- (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; and
- (j) organizing committees of third-party conferences must publish sponsorship tariffs that are applicable to all the sponsors, subsequently, must publish an audited statement of expenses and sponsorship fees.

(3) Where consistent with the conference organizer's guidelines, companies may sponsor or organize appropriate meals in connection with conference, 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) shall only be provided to healthcare professional attendees of the conference.

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

(5) Companies may also sponsor satellite symposia at conferences and provide content and facility for these symposia:

Provided that the arrangements shall be disclosed in writing of all materials relating to the satellite event. If healthcare professional consultant engaged for these symposia, the provisions relating to healthcare professional consultants also apply.

7. 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, town or city, that is logistically sensible considering the location of the majority of participants and those providing the educational learning, an exception may be for technologies not locally available;
- (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) cost shall not 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) companies may 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, except any exception provided under these rules.

8. Business meetings.— Company representatives may meet from time to time with healthcare professionals to discuss therapeutic risk and benefit, pharmaco-kinetic or pharmaco-dynamic features and other related information supported with valid scientific data or evidence. Such meetings shall be subject to-

- (a) place of business of the healthcare professionals, 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.

9. Educational items.— (1) Companies may provide educational items to institutions, 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 educational items may be permissible, such as textbooks, anatomical models and other therapeutic goods information sources which may be higher in cost but not be extravagant.

10. Gifts and entertainment.– (1) Companies shall not provide gifts to individual beneficiary healthcare professionals in any shape whatsoever.

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

11. Grants and donations.– Companies may provide research, educational, charitable grant and donation. The company shall-

- (a) adopt objective criteria for providing grants and donation 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 decision for grant and donation but they may provide input to help evaluate the suitability of a proposed program or recipient;
- (d) not provide grant 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 *bonafide* organization or institution and not to individual healthcare professionals; and
- (g) make the payment through electronic bank transfer or cross cheques and cash grants shall not be made.

12. Demonstration and evaluation products.– Companies may provide medical technology to institution free of charge for demonstration and evaluation purposes, provided that-

- (a) they shall not be given or intended as an improper inducement;
- (b) demonstration product shall be marked "for demonstration purpose only" in visible font size or otherwise to indicate that these are solely for demonstration purposes;

- (c) evaluation product shall be provided in quantities or for a duration that is determined reasonable to enable healthcare professional for adequate evaluation;
- (d) evaluation product shall be appropriately disclosed and documented;
- (e) companies shall ensure that loaned product is retrieved or returned if not purchased by the end of the evaluation period;
- (f) drug product sample 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 patient free of cost, in compliance with other prevailing rules on the subject matter.

13. Effective implementation.– For effective implementation of these rules, each company shall ensure that-

- (a) a senior executive is appointed who is responsible overseeing the company's compliance with these rules;
- (b) practical, useful, and meaningful policies, guidance and tools are adopted which are intended to ensure compliance with these rules;
- (c) effective 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, the company's board of directors or any other governing body are expressly committed to support these rules;
- (e) institute appropriate internal monitoring and annual 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) head of the company shall provide a certification to the Authority at the end of each year annually, that the company has complied with the rules of ethical marketing.

14. Enforcement.– (1) To ascertain breach of these rules, authority shall have the power to carry out financial audit of any healthcare industry, either itself or through any external auditor appointed for the purpose under the prevailing laws.

(2) Each company shall provide a detailed summary of all expenditures incurred on institutions or healthcare professionals on account of marketing, honoraria, travel, subsistence expenses, grants and any other related financial transaction to the relevant tax authorities as well as to the Authority on annual basis as per Schedule. This summary shall include the full name, National Tax Number and National Identification Card Numbers of all individuals who have benefited from such support.

(3) Healthcare professionals shall disclose any conflict of interest, funding received and other relevant activities during the course of interaction, with companies or company representatives, to their institutions.

15. Contravention and punishment.– Whoever, himself or by any other person on his behalf contravenes any provision of these rules shall be punishable in accordance with the provisions of the Act and Schedules made there under.

16. Cognizance of offence.– (1) Cognizance of offence shall be in accordance with the provisions of the Act and Schedules made there under.

(2) In case of complaints and non-compliance of the rules by a healthcare professional or the healthcare industry, the recommendation shall be referred to concerned Division of the Federal Government, department of concerned governments, regulatory bodies or directorate to take necessary action as per prevailing laws.

(3) All such complaints shall be handled and processed by the Authority through relevant Divisions.

SCHEDULE
[see rule 14(2)]

DETAILS OF EXPENDITURE

Company Name:

Turnover:

PKR

Financial Year:

Sr.	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			
(1)	(2)		(3)	(4)	(5)	(6)	(7)		(8)	(9)	(10)

Signature & Stamp

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

DR. ABDUR RASHID,
Director (Pharmacy Services).