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GUIDELINES ON SUBMISSION OF EXPENDITURE DETAILS UNDER THE ETHICAL MARKETING TO HEALTHCARE PROFESSIONALS RULES, 2021

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Drug Regulatory Authority of Pakistan
Islamabad - Pakistan

1. HISTORY

This is the first edition of these guidelines.

2. APPLICATION -

This is a guide for Therapeutic Goods' Marketing Authorisation Holders (importers and manufacturers of therapeutic goods) to understand the procedure for reporting expenditure details related to marketing activities.

3. PURPOSE

The current guideline describes the criteria for submission of expenditure on marketing activities targeted towards healthcare professionals to the Drug Regulatory Authority of Pakistan and the mechanisms required for the same in compliance with the Ethical Marketing to Healthcare Professionals Rules 2021.

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DEFINITIONS AND ACRONYMS

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
Demonstration product	means product that is used for training of healthcare professionals or patient education
Evaluation product	means product provided for human use, either as free samples of single-use products, or loans of reusable products or capital equipment;
EMHP	Ethical Marketing to Healthcare Professionals
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;
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
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
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
Medical technology	means product, technology, related service and therapy used to diagnose, treat, monitor, manage and alleviate health conditions and disabilities
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
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
Representative	means a representative of healthcare industry calling on healthcare professionals and administrative staff in relation to the promotion of therapeutic goods

4. INTRODUCTION:

The Healthcare Industry comprising various sectors is interlinked and is highly dependent on frequent interactions, coordination, and supportive activities for a sustainable healthcare environment. Among this industry, therapeutic goods companies and healthcare professionals are two of the prime stakeholders. Their interaction is vital and prone to criticism due to its repercussions on the patients and public.

The interaction must be maintained for innovation, progress and improvement of the healthcare and healthcare products, preserving professional ethics and transparency.

As per Section 7(q) of the DRAP ACT 2012, the Authority is empowered to monitor and regulate the marketing practices, to ensure rational use of drugs, and ethical criteria for promotion of therapeutic goods in line with international practices.

In order to exercise the function in Section 7(q), DRAP notified the required Rules titled as "Ethical Marketing to Healthcare Professionals Rules 2021" vide S.R.O. 1472(I)/2021 on the 12th of November 2021. These rules state major forms of interaction between companies and healthcare professionals.

5. PRINCIPLES OF ETHICAL INTERACTION:

The interaction between healthcare industry (companies, HCPs/healthcare establishments) is based on codes of ethical interaction for marketing and promotion. These different codes are founded on three principles [4,5] which are:

i. Principle of Separation
ii. Principle of Transparency
iii. Principle of Documentation

Following these principles under Rule 4 of the EMHP Rules 2021, companies are required to not influence medical decisions and prescriptions through incentives, keep the interaction fully transparent by disclosing the purpose and scope beforehand and keep a traceable, auditable record of all interactions. The principles can be referred to in the Rules in detail.

Professional and moral ethics in marketing require the commitment of the leadership and executives for making a conducive environment within the company. Policies and procedures prepared for practice and monitoring different aspects of marketing can aid in compliance. At an individual's level, it is also necessary that the employees regular or outsourced, accept and comply with the policies in place and not exercise immoral practices

in carrying out assigned tasks, be it marketing or any other.

6. DATA AND DOCUMENT SUBMISSION TO THE DRAP:

In compliance to the EMHP Rules 2021 companies are required to submit certain documents and details which are given below:

> **Rule 13(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.*
>
> **Rule 14(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.*

6.1. Summary on Details of Expenditure

For harmonised data submission and convenience of companies, this guideline provides formats and mechanisms that cater to frequently raised queries.

For submission of compliance under Rule 13(h), the format is given at **Annexure-I**, needs to be submitted by the head of the company or a senior executive who is duly authorised for this purpose under Rule 13(a).

DRAP has prepared a template **Annexure-III** for reporting details besides the Schedule at **Annexure II** in compliance with Rule 14(2) of the Ethical Marketing to Healthcare Professionals Rules 2021. In compliance to the Rules, details of institutions and healthcare professionals is essential for the record of the company and for the record of DRAP for future reference purposes. This template has been prepared with the intent to receive uniform information and also for the convenience of the companies to be able to add the required details in a summarised manner.

Annexures contain text in black and red font colour. Red font indicates either a statement for guidance or requires substitution with the company's response. The company may add further details in the empty tables. More rows or pages can be added for filling the information in Annexures II and III.

Explanatory notes of the Annexure II are as follows:

1.	Advertising Public & Healthcare Professionals (HCPs)	Electronic All medias with TV, radio, internet and digital Print With promotional claims not including medical literature and research articles or

		scientific articles
2.	Physician's samples	
3.	Promotional printed material	Printed material not used as advertisement to HCPs
4.	Give aways	Educational items Items given during other modes of interaction under these rules Give aways do not include gifts which are not allowed under these rules
5.	Seminar, Conference, Workshop, Exhibition	Educational training Business meeting
6.	Sponsorship/ Third party education conference	Local Foreign (if any)
7.	Outsourcing activities	Consulting arrangements with HCPs Any other outsourced activities which result in interaction with HCP, promotion of therapeutic good or other such activities under the rules
8.	Miscellaneous expenditure	Grants and donations Demonstration & evaluation products Other not fitting into the rows above

6.2. Formats for Submission

Formats given in annexures are required to be submitted as in soft copy excel format (Annexure II & III) and signed plus scanned copy with a title page or starting page including the following:

Prepared by: Name of Senior Executive given the responsibility
Contact details: email, phone
Signed Attachments: Annexure-I. II. III
Verified by: Owner / Head of the Company

1.	Certificate of Compliance	Scanned soft copy via email (pdf)
2.	Schedule "Details on Expenditure"	Soft copy via email (excel)
3.	Details of Beneficiaries	Soft copy via email (excel)

6.3. Timeline for Submission

The schedule under the EMHP Rules 2021 is also given at **Annexure-II** for summarised data submission and a format is available for the submission of details as required under Rule 14(2).

Companies are required to submit the details on marketing expenditure after closure of their respective financial/calendar year i.e July to June, or January to December, in soft via email at DRAP's designated email address, within 3 months (by 30th September or 31st March as the case may be), however, in exceptional circumstances communicated by the applicant, the time may be extended to 6 months for this submission.

7. REFERENCES

1. The DRAP Act 2012
2. Ethical Marketing to Healthcare Professionals Rules 2021
3. The Drugs (Licensing, Registering & Advertising) Rules 1976
4. IFPMA Code on Ethical Marketing and Promotiosn. https://www.ifpma.org/wp-content/uploads/2018/09/2023_IFPMA-Code-Interactive.pdf
5. MECOMED Code of Ethics https://www.mecomed.com/ethical-practices/

ANNEXURE-I

Certificate of Compliance to SRO 1472(I)/2021

We hereby undertake that we are compliant to the Ethical Marketing to Healthcare Professionals Rules, 2021 **(SRO 1472(I)/2021)** and that the provided data for the year ----- is correct to the best of our knowledge and belief.

The report containing disclosure of transfer of values in compliance to Rule 14(2) verified by the undersigned is enclosed.

Yours sincerely,

(Company name)

Signatures
(Name)
Head of the company or senior executive authorised for this purpose.
(Designation)

Stamp

ANNEXURE-II

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.											

Signature & Stamp

ANNEXURE-III

Details of Beneficiaries

As per Rule 14(2)

Details of beneficiary healthcare establishments/Institutes and healthcare professionals during the year---------given in table A and B

A. Healthcare Professionals

Sr#	Name of Healthcare Professional & address	National Identification number &/or Tax Number	Registration number (from respective councils/ regulatory bodies)	Benefit category (marketing, honoraria, travel, subsistence expenses, grants and any other related financial transaction)	Amount (Rs)
1.					

B. Healthcare Establishments/ Institutes

	Healthcare Institute & address	License number (from respective healthcare commission/ regulatory authority)	Tax Number	Benefit category (*marketing, honoraria, travel, subsistence expenses, grants and any other related financial transaction)*	Amount (Rs)
1.					

Annexures are to be attached as scanned copies of original signed documents.

Note: Documents such as correspondence / agreements / notifications / activity related reports / invoices etc. should be kept for detailed reference and audit when required.

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