MONITORING ADVERTISEMENT OF THERAPEUTIC GOODS

DRAFT GUIDELINES / MANUAL FOR FEDERAL INSPECTOR OF DRUGS

Document History: **1st Edition**
Effective Date:

Drug Regulatory Authority of Pakistan
GOVERNEMNT OF PAKISTAN
Telecom Foundation Complex, Sector G-9/4, Islamabad.

HISTORY

This is the first edition of these guidelines.

APPLICATION - (Guidelines for Federal Inspector of Drugs)

This is a guide for Federal Inspector of Drugs to assure control of promotion and advertisement of therapeutic goods (except medical devices) as an integral part of the overall market surveillance.

For implementation of this guide, Inspectorate is advised to seek guidance from Advertisement of Therapeutic Goods Guidelines.

PURPOSE

The current guideline describes the criteria for monitoring and screening, direct to consumer advertisement of therapeutic goods to assure compliance with the Act, Rules made thereunder and guidelines. It gives the screening mechanisms required to identify false or misleading information in promotion and advertisement of therapeutic goods in the market, via the internet, electronic media, digital media and print media.

Table of Contents

1 INTRODUCTION:

As per the DRAP ACT 2012

"**Therapeutic goods**" include drugs or alternative medicine or medical devices or biologicals or other related products as may be notified by the Authority.

Control of Advertisement:

"No person shall himself or by any other person on his behalf advertise, except in accordance with such conditions as may be prescribed: -

a) Any Therapeutic good.

b) Any substance used or prepared for use in accordance with the Ayurvedic, Unani, Homeopathic, Chinese or Biochemical system of treatment or any other substance or mixture of substances as may be prescribed.

c) Any remedy treatment or offer of a treatment for any disease."

Explanation: For the purpose of this entry "Advertise" means to make any representation by any means whatsoever for the purpose of promoting directly or indirectly the sale or disposal of a therapeutic good, a substance or a mixture of substances, a remedy or a treatment except the display of sign boards for a clinic, a dispensary or a hospital or such other institution offering treatment.

2 LEGAL PROVISIONS RELATED TO ADVERTISEMENT:

Advertisement of therapeutic goods is regulated under:

- The DRAP ACT 2012 (Schedule II Prohibitions-B)
- The Drugs Act 1976 (Section 24) Under Schedule VI of the DRAP Act 2012
- Drugs (Licensing, Registering & Advertising) Rules 1976
    - Rule 31 (Conditions of Advertising)
    - Rule 33 (Expenditure on advertisement)
    - Rule 34 (Substances required to be controlled for advertisement)
    - Schedule D-I (Permissible drugs)
    - Schedule E (Diseases for which Direct to consumer advertisement is prohibited)
    - Schedule F (Fee specified)

- Schedule G (Ethical criteria for medicinal drug promotion)

- S.R.O 983 (I)/2013 Committee on Advertisement
- S.R.O 412 (I)/2014 Alternative Medicines and Health Products (Enlistment) Rules 2014

3 TYPES OF ADVERTISEMENT:

a). Advertisement using light and sound projection: This category includes advertisement in video and audio form in television commercials, cinema documentaries, radio-broadcast, mobile messages and internet including social media or any other such mode.

b). Advertisement through still mode: This category includes advertisement in still form in print media i.e. newspaper, magazine, brochure, poster, wobbler, sticker, display stand, lighted boxes and neon signs, mail order announcement, calendars, hoarding/billboards or any other such media or static display on mobile, internet and social media.

4 MONITORING ADVERTISEMENT AND PROMOTION OF THERAPEUTIC GOODS:

As per the SRO 983 (I)/ 2013 Constitution of the Committee on Advertisement, the TORs of the Committee are:

- to regulate advertisements of therapeutic goods or a remedy or a treatment or offer of a treatment of any disease and enforce regulations for the advertisement;
- to monitor and investigate the complaints received from various quarters and issue orders as to the actions to be taken in respect of any contraventions of the Drugs Act 1976 and the DRAP Act 2012, regarding advertisement matters referred to it by the Federal Inspectors.

Monitoring of advertisement and promotion activities of therapeutic goods shall be as per criteria given in the DRAP Act 2012 and Rules thereunder

- Rule 31 Under the Drugs (Licensing, Registering & Advertising) Rules 1976
- Schedule D-I
- Schedule-E
- Rule 30 (11) Under the Drugs (Licensing, Registering & Advertising) Rules 1976
- Rule 33 Under the Drugs (Licensing, Registering & Advertising) Rules 1976
- Sub-Rule 1 of Rule 11 of Alternative Medicines and Health Products (Enlistment) Rules, 2014.

5 SCREENING MECHANISM:

Screening of the advertisements and promotional activities is done on the basis of given provisions and Schedules related to advertisement, which are given in detail.

5.1 Approved Advertisements & Promotional Material

The Division of Pharmacy Services after approval of applications for advertisement of therapeutic goods, sends a copy of the approval letters along with the approved promotional material, to the following:

i. Secretaries, Provincial Departments of Health
ii. Additional Director/Officer In-charge, DRAP Regional Offices
iii. Area Federal Inspector of Drugs &
iv. General Manager (Operations), PEMRA, Islamabad

The Division can be contacted for information on approvals granted to therapeutic goods and the linked promotional material.

Currently as per the Rules, approvals are given for advertisement on Electronic media (Radio, TV, Cinema) and Print media.

Internet, social media, mobile phones and emails etc. are not the permissible media for advertisement of therapeutic goods.

Approval of Advertisement is granted only for **Direct to Consumer Advertising**

No approval is required for advertising to Healthcare professionals irrespective of the category of therapeutic good and also if the advertisement is merely for informing the public of the availability or price of the therapeutic good through newspapers.

5.2 Evaluation of Advertisement during Surveillance

Content of advertisements being made by the therapeutic goods industry on any media can be evaluated on the basis of Rule 31 and Schedules under the Drugs (Licensing, Registering & Advertising) Rules 1976.

Advertisements have to be evaluated on the following criteria / checklist:

i. Approval letter by Division of Pharmacy Services, DRAP was granted?

ii. Promotional material was approved by DRAP?

iii. Media / Mode of advertising is the one for which approval was given?

iv. Content of advertisement is in compliance with the conditions given in Rule 31 and Schedules thereunder?

v. Advertisement is made within the validity time of approval (i.e. 2 years from the date of approval)?

vi. Promotional activities by a therapeutic goods company is within the limit as given under Rule 33 of the Drug (Licensing, Registering & Advertising) Rules 1976?

vii. Advertisement made to healthcare professionals is not in violation of the conditions given under Rule 31 and Schedules thereunder?

viii. Promotional activities are in compliance with Schedule G (ethical criteria for medicinal drug promotion)?

ix. Advertisement content is misleading or may have any serious adverse impact on public health.

x. Any other observation at the time of screening?

5.3 Investigation

Wherever a contravention to the Rules and the Act is observed the inspectorate investigates the matter on given criteria and collects sufficient evidence for preparation of the case. If any complaint is received, its status is verified after sufficient investigation. Case regarding illegal advertisement / advertisement in contravention of the Act and the Rules, is required to contain following minimum information:

- Name & contact details of the person/company involved
- Place of evidence / source of evidence (i.e. when & where)
- Evidence material
- Reason of concern

The Inspector may seize the stock or not to dispose of the stock or both if considered appropriate on observation of a contravention to the Rules and the Act.

The inspectorate is also required to establish any offence if found and convey cognizance as per Schedule-II (Prohibitions), Schedule-III (Offence) and Schedule-IV (Cognizance of Offences) of DRAP Act, 2012.

The complete case is to be sent to the Chairman Committee on Advertisement (Director Pharmacy Services) for decision in the Committee.

6 REFERENCES

The DRAP Act 2012

The Drugs Act 1976

The Drugs (Licensing, Registering & Advertising) Rules 1976

7 ATTACHMENTS

Format for submission of investigation / complaint to Committee on Advertisement.

ANNEXURE-I

COMPLAINT FORM

Format for submission of investigation / complaint (against advertisement of therapeutic goods / remedy / treatment / offer of treatment) to Committee on Advertisement

1. Complainant / Reporter (for follow up and feedback)	
Name of person / company / institution	
Address	
Email	
Phone no.	
2. Product details	
Brand name:	
Manufacturer	
3. Advertisement details	
Place of advertisement	
Media used (type of advertisement)	
4. Details of Person / entity involved	
Name	
CNIC / Any License no. of entity	
Address	
5. Supporting information	
Copy of advertisement	
Reason of your concern (what made you report it?)	
Any other information	
Signatures of complainant reporter: **Date:**	

****

For further information, please contact:

Pharmacy Services Division,
Drug Regulatory of Pakistan,
TF Complex,
7 Mauve Area, Sector G-9/4,
Islamabad.
Phone No. 051-9107299
Email: dir.ps@dra.gov.pk
Website: www.dra.gov.pk