ADVERTISEMENT OF THERAPEUTIC GOODS GUIDELINES

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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 Industry)

This is a guide for Manufacturers, Importers, Wholesalers, Distributors, Retailers and those involved or wishing to be involved in promotional activities of therapeutic goods. This guide covers the advertisement of therapeutic goods (drugs, traditional, herbal, other alternative medicines and any other products promoted for therapeutic use), procedure to apply for approval of advertisement, exemptions, prohibitions and other information related to advertisement of therapeutic goods.

Note: This guideline currently does not cover the conditions and procedures for advertisement of ***medical device as*** **given in accordance with the Medical Devices Rules 2018**.

The guide may also be used for information of Drug Regulatory Authority of Pakistan and the Inspectorate mandated to perform market surveillance and advertisement monitoring.

PURPOSE

Advertising is to make any representation by any means 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.

Sub-section x of section 7 of the DRAP Act 2012, provides regulations, enforcement and monitoring of advertisement rules and ban on false advertisement.

The current guideline describes the mode of advertisement, allowing exceptions for trade, business or profession and directed advertisement (facilitating public about any recall of therapeutic good in its safety issue), while disallowing certain categories of the diseases, treatments and remedies prohibited for advertisement in any media for all categories of therapeutic goods.

These guidelines should neither be taken as a complete or definitive statement of the law nor replace or constitute formal decision of the Authority.

ABBREVIATIONS

DRAP	**Drug Regulatory Authority of Pakistan**
SRO	**Statutory Regulatory Order**
CoA	**Committee on Advertisement**
OTC	**Over the Counter**
PEMRA	**Pakistan Electronic Media Regulatory Authority**
Drugs (L, R & A) Rules	**Drugs (Licensing, Registering & Advertising) Rules**
STO	**Statistical Treasury Officer**
DAC/HAC	**Disease Awareness Campaigns / Health Awareness Campaigns**
FIDs	**Federal Inspectors of Drugs**

DEFINITIONS

Act	means the Drug Regulatory Authority of Pakistan Act 2012.
Advertisement	means forms of advertising, whether in publication or by display of any notice or sign board or by means of any catalogue, price list, letter (whether circulated or addressed to any particular person) or any document or by words inscribed on any article, or by exhibition of photograph or a cinematograph film or by way of sound recording or sound broadcasting or television or in back drops projections of conferences or in any other way and any reference to the issue of an advertisement shall be construed to. It also means anything that is aimed or designated to promote the supply, sale or use of a product whether or not for financial gain and it includes a notice, circular, label wrapper or other document and an announcement made orally or by means of producing or transmitting light or sound.
Applicant	means a person seeking approval to promote a therapeutic good / goods.
Authority	means the Drug Regulatory Authority of Pakistan.
General Public	means a person other than those involved in the healthcare profession.
Healthcare Professional	in case of human medicines includes professionals from medical, dental, pharmacy, nursing and allied health professions including but not limited to tibb, hikmat & homeopathy and any other person who in the course of their professional activities may prescribe, recommend, purchase, supply, sell or administer therapeutic goods. In case of veterinary medicines, it includes veterinarians.
Medical advertisement	relating to or likely to cause any person to believe that it relates to any therapeutic good or any device, instrument, apparatus or contrivance used or represented to be used for a medicinal or therapeutic purpose.
Medical claim	includes any statement that conveys information about a disease state or the attributes of a product in respect of its therapeutic use or in connection with diagnosis, treatment, mitigation or prevention of a disease, disorder abnormal physical or mental state.
Sales promotion	means medical advertisement in the form of sale campaign (including

	door to door sale, price discount, peddling & hawkery), an exhibition, a competition or any other activity meant to introduce, publicise or raise the profile or public awareness or visibility of a therapeutic good.
Therapeutic goods	include drugs or alternative medicine or medical devices or biologicals or other related products as may be notified by the Authority.
Material Benefits	means a benefit, direct or indirect, which may not be cash but has a monetary value.

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1. INTRODUCTION:

Advertisement and Promotion are an important means of disseminating information and a means to update the public about latest advances and rational use of therapeutic goods. Now a days various medias and modes of communication are used for readily disseminating information, advertisement and promotional activities like internet social and digital media, these media also become a source of false and misleading information. If misused these become means of wrong information regarding safety, quality and efficacy of therapeutic goods and poses a health threat to potential users consequently.

Drug Regulatory Authority of Pakistan is empowered under Schedule II(B) of the DRAP Act 2012 to control advertisement of therapeutic goods.

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.

Control of advertisement and promotion of therapeutic goods aims at ensuring that the public and healthcare professionals receive correct information, which ultimately will help them in making informed decision on the choice and use of products.

Those involved or wishing to be involved in any of the above activities are required to abide to these requirements. It is an offence for any person or institution to breach any of the requirements of these guidelines. In case of any breach, immediate warnings, sanctions and penalties will be imposed as per decision of the Committee on Advertisement.

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)
- 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. TYPE OF ADVERTISEMENT:

a). Advertisement using light and sound projection: This category includes advertisement in video and or 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. EXEMPTIONS:

Exemptions are allowed for the following categories of advertisements and sales promotion activities:

(a). Medical advertisements are made through medical representatives or through professional journals and publications, which are meant for circulation exclusively amongst the members of the medical and allied professions including pharmaceutical field. One copy of each issue of such journal or publication may be sent to the Drug Regulatory Authority of Pakistan. Advertisement can also be made through a documentary film.

All claims made in medical advertisements should be in accordance with claims approved for registration or enlistment of that therapeutic good.

Medical advertisements should include information on indications, dosage, contra-indications, side effects and necessary precautions applicable on the therapeutic good.

Medical advertisements also include reminder publications for the medical, pharmaceutical and allied professions, include the name of the therapeutic good and its exact composition, the price, the name and address of the manufacturer and a statement to the effect that "Full information is available on request".

Such advertisements can be prohibited if they are found to violate the law and conditions of advertisement.

(b). Directed advertisement are force measure arrangements, about recalls, safety concerns and availability of therapeutic goods under directions by Committees, Boards or Authority (DRAP).

(c). Other exceptions A therapeutic good or any substance can be advertised through press if it is merely intended to inform the public of the availability or the price of such therapeutic good. These advertisements can be prohibited, if required in the public interest.

Prohibition: Promotion in the form of financial or material benefits shall not be offered to or sought by healthcare professionals to influence them in the prescription of therapeutic goods. Therapeutic efficiency of preferences from other brands shall not be claimed under such advertisement.

5. DISEASES, DIRECT TO CONSUMER ADVERTISEMENT FOR TREATMENT OF WHICH IS PROHIBITED IN ANY MEDIA:

- Venereal diseases.
- Sexual impotence.
- Amenorrhoea metrorrhagia, menorrhagia, metrosalpingitis, ovaritis, fibromas, cysts.
- Bright's disease, cataract, glaucoma, epilepsy, [...] locomotive ataxia, multiple sclerosis, lupus, paralysis, blindness.
- Complaints requiring surgical operation (e.g., appendicitis, stomach ulcers, prostatic disorders, hernias, sinusitis, mastoiditis.
- Serious illness liable to endanger the life of the patient (e.g., pneumonia, pleurisy, abscess of the lungs).
- Gripe Waters and Cough Preparations

6. ADVERTISEMENT BY PLACES OF TREATMENT

All advertising of therapeutic goods or related services is subject to the control of advertisement administered by the DRAP Act 2012. Advertisement by places of treatment should be to the extent of the services being provided and not promote therapeutic goods. This covers all websites and social media for consumers, which provide services that may lead to the prescription and supply of Prescription Only Medicines. Such sites must also comply with the prohibitions of advertisement given under the DRAP Act 2012.

Any mention of the availability of a named prescription only medicine from a clinic in social media is likely to be considered as an advertisement which is prohibited.

Proprietors of clinics, dawakhanas and other such places providing healthcare can submit application for advertisement which will be as per given provisions and schedules related to advertisement and promotion.

7. PRE-REQUISITES FOR ADVERTISEMENT / SALES PROMOTION AUTHORIZATION:

i). Advertisement seeker should have valid authorization (registration or enlistment of the product) and evidence of registration/enlistment of therapeutic good.

ii). Application should be on prescribed form **(Annex-I)**, along with prescribed fee as notified by Authority.

iii). Copies in duplicate of publicity material, including print, audio visual categories etc. Scientific data to support the claims made in the advertisement specimen along with authorization of concerned board / committee.

iv). Any other information required by the Chairman Committee on Advertisement (CoA).

8. RESPONSIBILITY:

Drug Regulatory Authority of Pakistan, along with other functions, as defined under the DRAP Act 2012, regulates the advertisement of therapeutic goods through its statutory Boards or committees.

9. COMMITTEE ON ADVERTISEMENT (CoA)

9.1. Composition of the Committee:

Sr. No.	Designation of the Member	Position in the Committee
1.	Director (Pharmacy Services), Drug Regulatory Authority of Pakistan, Islamabad.	Chairman (*Ex-Officio*)
2.	Representative from Directorate of Health and OTC Products, not below an officer of BPS-18. Drug Regulatory Authority of Pakistan	Member
3.	Representative from Directorate of Pharmaceutical Evaluation and Registration, not below an officer of BPS-18. Drug Regulatory Authority of Pakistan	Member
4.	Representative from Directorate of Medical Devices and Medicated Cosmetics, not below an officer of BPS-18. Drug Regulatory Authority of Pakistan	Member
5.	Representative from Pakistan Electronic Media Regulatory Authority (PEMRA), not below an officer of BPS-18.	Member
6.	Representative from Health Services Academy, not below an officer of BPS-18.	Member

7.	A Co-opted expert in the field related to a specialty case before the committee to be nominated by the Chairman of Advertisement.	Member
8.	Deputy Drugs Controller, Pharmacy Services, Drug Regulatory Authority of Pakistan.	Secretary of the Committee (*Ex-Officio*)

9.2. Terms of References of Committee on Advertisement:

The terms of reference of the Committee are as under; --

(i). To evaluate application preferred under Rule 31 of the Drugs (L, R & A) Rules 1976 and to approve the advertisement in accordance with the said rule and with such other conditions, as may be required in public interest;

(ii). To regulate the advertisements of therapeutic goods or a remedy or a treatment or offer of a treatment for any disease and to enforce regulations for the advertisement;

(iii). To monitor and investigate the complaints received from various quarters and issue orders 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 Federal Inspectors;

(iv). To call any person for personal hearing to adduce evidence before the Committee; and

(v). To issue guidelines with the prior approval of the Drug Regulatory Authority of Pakistan for regulating the advertisement of therapeutic goods.

10. PROCEDURE FOR PHARMACEUTICALS AND ALTERNATIVE THERAPEUTIC GOODS

(Under rule 31-Conditions of Advertising):

10.1. Procedure for Submission of Application:

10.1.1. Where to apply?

The application for approval of advertisement should be submitted to:

The Chairman Committee on Advertisement (CoA),
Division of Pharmacy Services,
Drug Regulatory Authority of Pakistan,
3rd Floor, T.F Complex,
6 – Mauve Area, Sector G-9/4,
Islamabad.

10.1.2. Who can apply?

The manufacturers and importers of therapeutic goods can apply for approval of advertisement for their registered/enlisted products.

10.1.3. Application processing fee

Each application for approval of advertisement shall be accompanied with non-refundable processing fee specified in Schedule "F" as updated vide SRO 1117(I)/2012 dated 10th September 2012. The fee shall be deposited in the Head of Account of DRAP given as under:

Allied Bank (Civic Centre Islamabad), Branch Code: 0117, Account No: 0010008463700018

or any other branch specified by DRAP in other cities.

Note: The application shall not be processed till the deposition of prescribed fee in the Head of Account of DRAP and verification of the challan/deposit slip to this effect by Statistical Treasury Officer (STO) DRAP.

10.1.4. Application requirements

Application for advertisement of therapeutic goods shall be made on Form 8 (Annex-I). A separate application shall be made for each product and each advertisement. Following information is the pre-requisite for the application: -

- Evidence / validity of registration or enlistment issued by DRAP.
- Original Fee deposit slip duly verified by STO, DRAP.
- Publicity material/specimen of advertisement for which permission is required as follows:

  i. For Electronic media advertisement (TV, Cinema, Radio & Audio), soft copy in CD and printed story board of advertisement/script for radio & audio.

  ii. For Print media advertisement, specimen of promotional material. Mode of print media advertisement along with dimensions, are also required to be specified on the specimen.

(Video clips and audio clips should be provided in formats compatible with windows media player)

Note: Same advertisement specimens in two different languages will be considered as two separate advertisement. Moreover, same specimens of advertisement but for advertisement through different modes of print media will be considered as separate advertisements.

10.2. Processing of application

On receipt of application, the application shall be evaluated on preliminary basis by the Division of Pharmacy Services for completion of pre-requisites. Deficiencies are communicated to the applicant for completion of application. Complete applications are technically evaluated in light of conditions specified in Rule 31 and relevant Schedules and are processed for inclusion as agenda.

10.3. Meeting of the Committee on Advertisement

Once the application is thoroughly reviewed and evaluated by the Division, it is included as agenda for meeting of CoA for consideration. The CoA evaluates the advertisement specimens and gives recommendatory decision on each case. After the meeting, agreed upon minutes are referred to the Concerned Authority or Federal Government for final approval.

The decision on each case is communicated to stake holders after approval of minutes by the Federal Government.

10.4. Issuance of approval letters

After final approval of the advertisements of therapeutic goods by the Federal Government, the letters of approval are issued with a validity of 2 years unless earlier suspended, withdrawn or cancelled by concerned Authority.

Approval by DRAP for publishing/airing advertisement, is in addition to and not in derogation of the provisions of any other law.

Promotion should be carried out as per the approved advertisements. No changes can be made in the advertisements without approval of the Committee on Advertisement.

11. ETHICAL PRINCIPLES FOR THE CONFORMANCE OF CONTENTS:

(a). Truthfulness

Advertisements should truthfully state the nature, quality and properties of the therapeutic goods. Advertisements must not directly or indirectly mislead the viewer/listener or give rise to any unrealistic expectations with regard to the safety, quality or properties of the therapeutic good by:

- implication
- through emphasizing certain information
- omitting information
- being ambiguous
- making exaggerated claims e.g. “the only”, “longest lasting”, “works the fastest”, or
- by comparison with other categories of products

Recommendations relating to the use of the therapeutic good must be accurately stated and should be relevant to their properties as authorized by concerned Board or Committee.

(b). Substantiation of prominence

All claims or statements made in the advertisement must be substantiated/supported by facts or robust objective evidence from credible sources. Any text, emphasis, certification, award or unique feature or prominence of the advertised product must be substantiated.

Information must be presented in a balanced, objective and accurate manner and must be referenced with appropriate citations (where relevant).

Requirements for substantiation also apply to the publication of any testimonials, which include "user experience’ or “user review" for innovative pharmaceutical dosage form or packaging. Testimonials must be current, genuine, authenticated, for example, via signed testimonials and be of a typical experience i.e. results obtained by the average user of a therapeutic good/medicinal product. These testimonials must be provided as evidence upon request.

(c). Comparative claims

Medical advertisements must not denigrate or attack unfairly any other products, goods or services. There should be no comparative claims against another named product or brand in any advertisement e.g. “works faster and better than X”.

(d). Language

Direct to consumer advertising should be in simple-to-understand language, easily comprehensible and avoid confusing medical jargons. Scientific jargons and irrelevancies should not be used to make claims appear to have a scientific basis they do not possess. Any scientific terminologies used should be in a manner that is readily understood by the targeted audience.

The Advertisements must not directly or indirectly cause fear, alarm, distress in the consumers or abuse the trust, exploit the lack of knowledge of any consumer by using eye catching words or any repulsive or disturbing words or images.

(e). Use of Scientific Data

Advertisements for a therapeutic good must not misuse research results or make unnecessary quotations from technical and scientific publications. Data that the general public cannot verify or validate should not be used for exploitation purposes. Scientific data in the public domain shall be made available, on request, to prescribers and any other person entitled to receive it as appropriate to their requirements.

(f). Superlatives and exaggerating terms

Advertisement material shall be presented with courtesy and good taste. In all advertisements the following should be avoided:

- Superlatives or exaggerating terms (which imply or suggest a usage or property which the medicinal product does not possess) e.g. “miracle”, “100% safe”, “instant cures”, “clinically proven”, “increase memory power”, “improve study grades”, “effective in all cases” or “effective against all complaints” etc.
- Words and phrases implying urgency, uniqueness and or such expressions which are absolute in character, such as “the most potent”, “the most rapid”, “the most efficacious” etc.
- Promotion of traditional / alternative medicines should not suggest that:
    - the safety and efficacy of the product is due to it being “natural”.
    - Efficacy of this product has been proved due to endorsement/ enlistment by DRAP

(g). Encouraging inappropriate or excessive use

Advertisements should not directly or indirectly encourage indiscriminate, unnecessary or excessive use of a therapeutic good particularly antimicrobials. The advertiser must not

suggest or offer trial use of a therapeutic good. Claims in an advertisement shall not contain misleading, unverifiable statements, omissions likely to induce medically unjustifiable use of a therapeutic good or to give rise to under risks. The word "safe" shall not be used with respect to promotion unless properly qualified and approved. Promotional material shall not be designed so as to disguise its real nature.

(h). Guaranteed results and side effects

Advertisements must not claim or state a therapeutic good to be magical or infallible or extraordinary or guarantee the results. It must not claim or suggest that the product does not cause or is free from any side effects. All medicinal products have the potential to cause side-effects as each individual respond differently.

(i). Discourage from medical advice

Advertisements should not in any way discourage the public from seeking the advice of a healthcare professional or to consult a physician or a pharmacist e.g. by offering diagnosis or suggesting treatment by post, electronic communication or telephone etc. Advertisements should also not suggest that a surgical operation or hospitalization etc is unnecessary or that health could be affected by not taking the proposed therapeutic good.

It must not directly or indirectly, promote self-diagnoses or self-treatment of any serious disease. Serious diseases which are not allowed for direct to consumer advertisements are given in Schedule E.

(j). Recommendations and endorsements

The Advertisement must not include any recommendation by any healthcare professional to avoid the perception of professional endorsement in advertisements, for example, the feature of models in "white coats" or with stethoscopes.

Directed to consumer advertisements should not contain recommendations or endorsement from a celebrity or give the impression of advice or support from a celebrity. In this context, "recommendations" can include testimonials, support and endorsements which would include, but is not limited to any compliment, accolade or positive assessment. "Celebrity" includes persons of all fields, not limited to media, sports, politics, and culinary personalities with or without identifying the celebrity in the advertisements.

(k). Endorsement by Government or public authority

The advertisements must not reflect false or erroneous claims indicating or suggesting that

the use of a product is promoted, supported or endorsed by the Government or any public authority.

(l). Logos, Initials and Trademarks

Advertisements should not make use of names, initials, logos and / or trade service marks of other firm, company or institution. Written permissions from the concerned firm, company or institution on the use of their names, initials, logos and / or trade service marks should be availed before use. The names and / or logos of DRAP must not be used for advertisement and sales promotion of a product in any media.

(m). Samples for promotional purposes

It is prohibited under the Drugs (L, R & A) Rules 1976, to sale or supply samples of therapeutic goods to the public for promotional purposes. Free samples of therapeutic goods may be provided in modest quantities to prescribers or pharmacists, preferably on request.

(n). Refund

Any offer to refund money, either in full or partial, to users of the product must not be made. This also includes discounts or promotional offers made on therapeutic goods.

(o). Advertising using the internet, social and digital media

The promotion of therapeutic goods, treatment or offer of treatment to the public using the mobile phone, WhatsApp messages, internet, social and digital media etc is not allowed.

(p). Mandatory warning/precautionary statements in advertisements

It is mandatory to include precautionary statements which are specific to the product along with general precautionary statements, in advertisements directed at the public. Such statements should be rational and based on the safety studies of the product as approved by the respective board / committee.

(q). Advertisements in any form made to physicians and health-related professionals

The wording and illustrations in advertisements to physicians and related healthcare professionals like pharmacists, should be fully consistent with the approved scientific data sheet for the therapeutic good concerned or other source of information with similar content. The text should be fully legible.

While introducing the therapeutic good to the physician for the first time it should contain full product information, on the basis of the approved scientific data sheet or similar document and should contain, among others, the following information: -

(a) The generic name(s) of the active ingredient(s);

(b) the content of active ingredient(s) per dosage form or regimen;

(c) the generic name(s) of other ingredient(s) known to cause problem(s)

(d) the approved therapeutic uses;

(e) dosage form or regimen;

(f) side-effects and major adverse drug reactions;

(g) precautions, contra-indications and warnings;

(h) major interactions;

(i) the name and address of manufacturer or distributor; [--]

(j) reference to appropriate scientific literature ; and

(k) Price of the therapeutic good.

Reminder advertisements should include, amongst others, at least the international non-proprietary name or generic name, the name of each active ingredient and the price of therapeutic good and the name and address for the manufacturer or distributor for the purpose of receiving further information.

Promotional material should be designed to ensure that prescribers are not misled in any way by the promotional claims.

Promotional material/advertisement for dissemination to healthcare professionals should have clearly stated “for healthcare professionals only” and should be exclusively distributed to healthcare professionals.

(r). Advertisements in any form to the general public

Advertisements to the general public, where permissible, should help people make rational decisions on the use of therapeutic goods determined to be legally available without a prescription. Taking account people’s legitimate desire for information regarding their health, advertisement should not take undue advantage of people’s concern about their own health.

Advertisement should not generally be permitted for prescription therapeutic goods or to promote therapeutic goods for certain serious conditions that can be treated only by qualified health practitioners or to promote self-medication or quackery.

The scheduled narcotic and psychotropic drugs should not be advertised to the general public in connection with fight against drug addiction and dependency. Although health education aimed at children is highly desirable, therapeutic good advertisements should not be directed at children.

Promotional material should be factual and claims for cure, prevention or relieve of an ailment should be made only if this can be substantiated. Advertisements should also indicate, where applicable, appropriate limitations to the use of the therapeutic good.

When lay language is used the information should be consistent with the approved scientific data or other legally determined scientific basis for approval. Language which brings about fear or distress should not be used.

Taking into account the media employed, advertisements to the general public may amongst others, contain, the following information: -

(a) The generic name(s) of the active ingredient(s);

(b) major indication(s) for use;

(c) major precautions, contra-indications and warnings, if any; and

(d) name of manufacturer or distributor.

Information on price to the consumer shall be accurately and honestly portrayed.

Promotion of products in open markets, bus stands and moving vehicles (public transport) is not allowed unless approved by the Committee on Advertisement.

The displaying of posters for a specific product in public places e.g hospitals, clinics, shops etc. would be considered as promotional material aimed at the general public and is therefore not allowed unless approved by the Committee.

(s). Medical Representatives

Medical representatives should have an appropriate educational background having medical and technical knowledge. They should have adequate training to present information on products and carry out other promotional activities in an accurate and responsible manner. Employers shall be responsible for the basic and continuing training

of their representatives. The training shall include instructions regarding appropriate ethical conduct taking into consideration the W.H.O ethical criteria.

Medical representatives have to provide complete and unbiased information for the product discussed with prescribers and pharmacists, such as an approved scientific data or other source of information with similar contents.

Employers shall be responsible for the statements and activities of their medical, representatives. Medical representative should not offer inducements to prescribers and pharmacists. Prescribers and pharmacists should not solicit such inducements.

(t). Symposia and other scientific meetings

The intimation regarding scientific symposia, seminars, conferences and such meetings where sponsored by a pharmaceutical manufacturer or distributor should be clearly communicated in advance.

The invitation regarding scientific symposia, seminars, conferences and such meetings should be restricted to Healthcare Professionals, particularly medical and allied professionals and not to any family member of such medical and allied professionals.

The invitation letter should accurately reflect the presentations and discussions to be held. Entertainment or other hospitality offered to members of the medical and allied professions should be secondary to the main purpose of the meeting and should be kept to a modest level.

(u). Post-marketing scientific studies and dissemination of information

Post-marketing scientific studies and surveillance shall not be misused as a disguised form of promotion.

(v). Information for patients contained in package inserts, leaflets and booklets

Adequate information on the use of therapeutic goods shall be made available to the patients where it is necessary for rational use of a therapeutic good. In package inserts or leaflets the manufacturers or distributors shall ensure that the information reflected is correct.

The wording of the package inserts or leaflets, if prepared specially for patients, shall be in lay language subject to the condition that the medical and scientific content is properly reflected.

In addition to approved package inserts and leaflets wherever available the preparation and distribution of booklets and other information material for patients and consumer shall also comply with the ethical principles.

(w). Disease / Health Awareness Campaigns (DAC / HAC)

The primary purpose of a DAC / HAC must be to increase awareness of a disease or diseases and to provide health educational information on that disease and its management. It should not promote the use of a particular therapeutic good or category.

Health Awareness Advertisements / health educational information, if sponsored by any firm, company or institution other than the Government or INGOs, should not make use of names, initials, logos and / or trade service marks of the sponsoring firms, companies or institutions.

Campaigns which aim to stimulate demand by the public for a specific therapeutic good or category, are likely to be considered promotional, falling within the scope of Schedule II-B of the DRAP Act 2012.

A DAC may refer to the availability of treatment options, but this should not be of such a nature that an individual would be encouraged to approach a prescriber to request a particular medicinal option. The emphasis of the material should be on the condition and its recognition rather than on the treatment options. The appropriate treatment for each disease is for the healthcare professional to decide in consultation with the patient.

Such campaigns should not contain materials which refers to recommendations by scientists or healthcare professionals which could encourage consumptions of therapeutic goods.

12. STAKEHOLDERS RESPONSIBILITIES

Cooperation and collaboration of all stakeholders is required to effectively manage and control promotion of therapeutic goods to attain the vision and mission of protecting and promoting public health. Stakeholders include law enforcing bodies/ personnel (DRAP, Provincial Governments/ Drug Control Administrations, Health Care Commission(s), Federal Inspectors of Drugs and Provincial Drug Inspectors), Registration holders and dealers of therapeutic goods (distributors, wholesalers, retailers), healthcare professionals, media and general public.

(a) Law Enforcers and Local Government Authorities

DRAP in collaboration with Provincial Drugs Inspectors and regional offices of DRAP is enforcing the DRAP Act 2012. Provincial Governments are independently working and are responsible for regulating post-marketing activities.

They have to work as law enforcers and are thus obliged to advocate voluntary compliance to existing laws, regulations and guidelines, specifically law enforcers are responsible to:

- Enforce the rules, regulations and guidelines for regulating promotion of therapeutic goods.
- Timely handling stakeholders complaints relating to promotion / advertisement of therapeutic goods.
- Report contraventions / defaulters who deliberately give misleading information about quality, safety and efficacy of therapeutic goods.
- Take legal action against defaulters in Drug courts.

(b) Registration Holders and dealers of therapeutic goods

They are responsible to:

- Ensure the provision of safe, efficacious and quality products having authorization from DRAP before promotion activities.
- Obtain approval of Committee on Advertisement, DRAP for carrying out direct to consumer advertising and refrain from illegal practice in this regard.
- Compliance with Rules and guidelines in preparing promotional material.
- Report any contraventions / defaulters of law to collaborate with DRAP in ensuring provision of safe efficacious and quality therapeutic goods.

(c) Healthcare Professionals

Healthcare Professionals are at the forefront of providing healthcare to the public. They play the role of promoters and are also targets audience of various promotional activities.

They are responsible to:

- Ensure rational use of therapeutic goods due to their influence and raise awareness of health issues and disease prevention.
- Report any contraventions / defaulters of law (involved in unethical promotion activities, giving misleading/false information etc.) to collaborate with DRAP in ensuring provision of safe efficacious and quality therapeutic goods.

(d) Media

Electronic and Print Media is the source used for disseminating information to various target audience. Media is extensively used for promotional activities. Media is responsible to:

- Voluntary compliance with the DRAP Act 2012 in promotional activities of therapeutic goods.
- Report any contraventions / defaulters of law to collaborate with DRAP in ensuring provision of safe efficacious and quality therapeutic goods.
- Reject airing / printing advertisements which do not have official approval from DRAP.
- Give recommendations on how to effectively and efficiently control advertisement of therapeutic goods.

(e) General Public / Consumers

Members of the community / consumers are the ultimate target of all promotional activities. Consumers have a very crucial role in ensuring that registration holders and dealers of therapeutic goods are complying with the law. They are responsible to:

- Report any promotion activities or advertisement which is misleading, illegal, unethical etc.
- Report any contraventions / defaulters of law (involved in unethical promotion activities, giving misleading/false information etc.) to collaborate with DRAP in ensuring provision of safe efficacious and quality therapeutic goods.

13. COMPLAINTS

Complaints about advertisements for therapeutic goods, treatment or offer of treatment which are in violation of the law can be made with sufficient evidence/proof, to the Drug Regulatory Authority of Pakistan.

Complaints are expected from various quarters.

i. Self-Surveillance / Federal Inspector of Drugs (as per given manual for advertisement monitoring)
ii. Complaints sent by any Boards / Committee / any other forum.
iii. Complaint sent by any person who has seen advertising for a therapeutic good that is misleading or otherwise fails to comply with the legal requirements in

his or her opinion.

To file a complaint, following procedure is required to be followed by the complainant;

i. Complaint is made in the form provided in the annexure.
ii. Details of advertisement regarding when and where it appeared along with a copy of the advertisement for effective action.
iii. Details of the concerns about advertisement with special emphasis on any adverse impact on public health, false / mis-representation or any other violation of law in the opinion of complainant.
iv. Contact details of the complainant so that any further information or clarification may be sought and to be informed / advised on the outcome of the complaint.
v. Any other information which the committee on advertisement may require for investigation of complaint.
vi. Complaints can be sent to

The Director Pharmacy Services, DRAP / The Chairman Committee on Advertisement (CoA), Division of Pharmacy Services, Drug Regulatory Authority of Pakistan, 3rd Floor, T.F Complex, 6 – Mauve Area, Sector G-9/4, Islamabad.

The complaint received is pre-evaluated by the Pharmacy Services Division in light of the provisions related to advertisement. The possible violation of related laws such as un-approved advertisement, changes in the approved contents, false advertisement or mis-representation of contents is investigated or verified from record of approved advertisements.

After initial investigation, an anonymous copy of the complaint or necessary details of the complaint are sent to the advertiser with request to give response on raised issues along with any relevant material and explain the reasons thereof if any.

Where required at any stage, the complaint may be referred to any other division for provision of information or to the Quality Assurance and Lab Testing Division for further investigation of the complaint through its inspectorate with directions to submit complete report.

Complaint cases are assessed by Committee on Advertisement which if establishes a violation of related laws, rules and guidelines with respect to misleading or mis-representation of the contents may request to

i. Suspend and/or Withdraw the Advertisement approval
ii. Amend the advertisement
iii. Issue a corrective statement
iv. Submit future advertisement contents to the Committee on Advertisement for review and approval before issue
v. Any other action which the committee may consider necessary

In case, severe violation of law is established as illegal/ unapproved advertisement, unapproved/false claims, statutory action is taken as per defined law, rules and provision.

DRAP attempts to complete investigation of advertisement complaint within 30 days but the timelines may extend where a discussion with company/advertiser is required, investigation from Inspectorate is required or where a statutory action is taken.

14. REFERENCES

a. The DRAP Act, 2012
b. The Drug Act, 1976
c. The Drugs (Licensing, Registering & Advertising) Rules, 1976
d. The Blue Guide, Advertising and Promotion of Medicines in the UK, Third Edition, July 2019.
e. WHO Guideline on Advertising of Medicines and Medicinal Products to General Public: 2015

15. ATTACHMENTS

a. Form 8
b. Checklist
c. Complaint form

ANNEXURE-I

FORM-8
(See rule 31 (1-A)

APPLICATION FORM FOR APPROVAL TO ADVERTISE A DRUG/TREATMENT/OFFER OF TREATMENT FOR ANY DISEASE

1. Name and address of the applicant. :

2. Name of Drug. :

3. Registration No. of drug(s) if any :

4. If is a Homeopathic, Unani or any other drug not requiring registration:

   (i) Composition with properties of each ingredient:

   (ii) Indications:

   (iii) Contra-indications, if any:

   (iv) Side-effects, if any:

   (v) Precautions for use, if any

   (vi) Registration Number and address of the Hakim or Homeo Doctor Supervising its manufacture with copy of the Registration Certificate Issued under the UAH, 1965:

5. Publicity material, with video cassette if the publicity is intended through television or like media:

Note --- In case of an application for institutional publicity or offer of treatment only name and address of applicant with copy of the Registration Certificate, issue under the UAH, 1965, shall be provided:

Signature of applicant

ANNEXURE-II

CHECKLIST FOR APPLICATION OF ADVERTISEMENT APPLICATION

i. Application on Form-8
ii. Fee for advertisement
    a. Per advertisement for Print Media Rs. 10,000/-
    b. Per advertisement for Radio/Audio Rs. 15,000/-
    c. Per advertisement for TV/Cinema. Rs. 25,000/-
iii. Evidence of registration of the therapeutic good (registration letter, renewal status)
iv. Specimen of advertisement
    a. Print media specimens 2 copies
    b. Electronic media (radio) advertisement audio clip in CD, two copies script
    c. Electronic media (TV/Cinema) advertisement video specimen in CD, two copies storyboard

Note:

- You are requested to go through Rule 31 of the Drug (Licensing, Registering & Advertising) Rules, 1976 and relevant Schedules to prepare your advertisement accordingly.
- Font size of statements should be legible.
- Mode of print media advertisement should be mentioned (newspaper, poster, standee, bill board etc.)
- Precautionary statements relevant to the product should be included.

ANNEXURE-III

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:**	

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Send this information to:

The Director Pharmacy Services, DRAP,
Division of Pharmacy Services,
Drug Regulatory Authority of Pakistan,
3rd Floor, T.F Complex,
6 – Mauve Area, Sector G-9/4, Islamabad
Email: drap.pharmacy@gmail.com