Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)
*****

Islamabad, the 21st November, 2022.

NOTIFICATION

The following draft of the Therapeutic Goods (Advertisement) Rules, 2022, which is proposed to be made by the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, in exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), is hereby published for the information of all persons likely to be affected thereby and notice is hereby given that objections or suggestions thereon, if any, may, for consideration of the Federal Government, be sent within fourteen days of the publication of this Notification.

Any objections or suggestions which may be received from any person in respect of the said draft before expiry of the aforesaid period shall be taken into consideration by the Federal Government.

DRAFT THERAPEUTIC GOODS (ADVERTISEMENT) RULES, 2022

1. Short title and commencement.- (1) These rules shall be called the Therapeutic Goods (Advertisement) Rules, 2022.

(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) **"advertisement"** means anything that is aimed or designated to promote the supply, availability, 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; and

(c) **"Committee"** means the Committee on Advertisement notified under rule 4.

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

3. Conditions of Advertisement:- (1) The Committee on Advertisement (CoA) may allow the advertisement of a therapeutic good, or a remedy as specified in Schedule A or offer of a treatment for any disease, approve the contents of such advertisement and specify conditions subject to which such advertisement shall be made:

Provided that the Committee on Advertisement may, if in its opinion the public interest so requires, withdraw the approval granted to any advertisement or modify or alter any condition subject to which the advertisement was approved.

(2) An application for advertisement of a therapeutic good or offer of treatment for any disease shall be made on Form-I, accompanying all necessary documents addressed to the Chairman of the Committee on Advertisement. There shall be made a separate application for each advertisement.

(3) An application under sub-rule (2) shall be accompanied by the fee as specified by the Authority, from time to time, with the approval of the Policy Board.

(4) Approval of advertisement shall be granted on Form-II.

(5) Advertisement referred to in Schedule-II (B) of the DRAP Act, 2012 may be made to the medical, pharmacy and allied health professions, without referring to the Committee on Advertisement, through medical representatives or through professional journals and publications which are meant for circulation exclusively amongst the members of the medical, pharmacy and allied health professions.

Provided that the Committee on Advertisement may, after giving an opportunity of being heard, prohibit the publication of any advertisement in any such journal as it is found to violate any of the conditions specified under these rules.

(6) Advertisement under sub-rule (5) shall be subject to the following conditions, namely:

(i) All claims shall be made in accordance with those approved for registration of that therapeutic good.

(ii) Where the usual information on indications and dosage is provided, that advertisement material shall also contain information on contra-indications, side effects, awareness on reporting adverse drug reactions to pharmacovigilance centres and other necessary precautions as applicable.

(7) Advertisement of a therapeutic good referred to in Schedule-II(B) of the Act, may be advertised to the medical, pharmacy and allied health professions through a documentary film.

(8) No advertisement under these rule shall contain any direct or indirect comparison in any way with any other therapeutic good or remedy for any disease for the purpose of attracting customers or with a view to discredit other such product.

(9) Advertisement shall be presented with courtesy and good taste. Words and phrases implying urgency, uniqueness or such expressions which are absolute in character, such as "the most potent", "the most rapid", "the most efficacious", or which make exaggerated claims or to general claims, such as "effective in all cases" or "effective against all complaints" or superlatives shall be avoided.

(10) Advertisement of a therapeutic good shall include information on risks and precautions as may be necessary for the protection of public health, awareness on reporting adverse drug reactions to pharmacovigilance centres and maximum retail price.

(11) No therapeutic good shall be advertised in a manner which encourages self-medication, chronic use or use to the extent that it endangers health.

(12) No therapeutic good or any remedy, treatment or offer of treatment of any disease specified in Schedule B shall be advertised except as provided under these rules.

(13) Reminder publications for the medical, pharmacy and allied health professions shall 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".

4. Committee on Advertisement: (1) The Authority shall notify a Committee on Advertisement consisting of the following members, namely:

(i) Director Pharmacy Services of the Authority who shall also act as ex-Officio Chairman;

(ii) Additional or Deputy Director Pharmacy Services of the Authority who shall also act as ex-Officio Secretary;

(iii) Additional or Deputy Director Pharmaceutical Evaluations & Registration, of the Authority;

(iv) Additional or Deputy Director Health and OTC Products of the Authority;

(v) Additional or Deputy Director Medical Devices & Medicated Cosmetics of the Authority;

(vi) Additional or Deputy Director Quality Assurance and Laboratory Testing of the Authority; and

(vii) Representative from Pakistan Electronic Media Regulatory Authority not below an officer of BPS-18.

(2) The Chairman of the Committee may co-opt expert(s) in the field related to a specialty.

(3) The quorum for holding a meeting of the Committee shall be simple majority of the total membership.

(4) The meeting of the Committee may be held at any time as may be deemed appropriate by the Chairman.

(5) The terms of reference of the said Committee shall be as under:-

(i) To evaluate applications referred under these rules and to approve, reject or defer the advertisement in accordance with the said rules 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 advertisement;

(iii) 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 DRAP Act, 2012 and rules made thereunder regarding advertisement matters referred to it by the Federal Inspectors of Drugs;

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

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

5. Ethical Criteria: The marketing authorization holder or his representative shall follow the ethical criteria for promotion as given in Schedule C and rules made under the DRAP Act, 2012.

6. Expenditure on Advertisement and Marketing.– No person shall spend more than five percent of the turnover on advertising, sampling and other promotional activities in respect of therapeutic goods.

Explanation: The expenditure on pay and allowances of the field force connected with the promotional activities shall not be included in expenditure for the purpose of these rules.

7. 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.

8. Removal of Anomalies.– If any difficulty arises in giving effect to any of the provisions of these rules, the Authority with the approval of the Policy Board, not inconsistent with the provisions of the Act, may make such changes as may be required.

9. Repeal.- Rule 31, Rule 33, Schedule D-I, Schedule E, Schedule G and Form-8 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 are hereby repealed.

FORM-I

APPLICATION FOR ADVERTISEMENT OF A THERAPEUTIC GOOD/TREATMENT/OFFER OF TREATMENT

[See rule 3(2)]

<table>
<tr><td>1.</td><td colspan="2">Name of applicant</td></tr>
<tr><td>2.</td><td colspan="2">Address of the applicant
Mailing/postal address (if other than):
Email:
Phone:
Registration No. of Healthcare Professional in case of advertisement of treatment or offer of treatment:</td></tr>
<tr><td rowspan="2">3.</td><td colspan="2">Purpose
Advertisement of therapeutic good ☐
Advertisement of treatment / offer of treatment ☐</td></tr>
<tr><td>i.
Name:

Marketing Authorization No:

Generic name if any:

Composition with properties of each ingredient:

Major indication (s):

Major precaution (s):

Contraindication (s):

Warning (s):

Price (MRP):</td><td>ii.
Name of place offering treatment:

Registration No. of place offering treatment:</td></tr>
<tr><td>4.</td><td colspan="2">Mode of publicity:
Print Media ☐ Electronic Media ☐
i. Print media (mention mode):
Specimen: Printed Ad. with legible fonts
ii. Electronic media (mention mode):
Specimen: verbatim/storyboard & audio(mp3) /video clip(mp4)</td></tr>
<tr><td>5.</td><td colspan="2">Fee submitted: ☐
Challan No.:</td></tr>
<tr><td>6.</td><td colspan="2">Soft copy of application, annexures & specimen of advertisement ☐</td></tr>
</table>

Signature of applicant
Stamp

FORM–II

APPROVAL TO ADVERTISE
[See rule 3(4)]

No: ……

Drug Regulatory Authority of Pakistan
Government of Pakistan

Reference No.:	Dated:
M/s..... is/are hereby permitted to advertise _____in_____mode(s) of_____media for a period of two years from the date of issuance unless earlier suspended or cancelled.	
Permission of Advertisement granted for (Name): Marketing Authorization / Registration No.	
1. This permission shall be subject to the conditions specified in the Therapeutic Goods (Advertisement) Rules, 202X under the DRAP Act, 2012.	
2. The advertisement shall be made according to the approved advertisement material/story board (attested copies enclosed) without alteration or modification.	
3. The Committee on Advertisement may withdraw the approval granted or modify or alter the conditions subject to which the advertisement has been approved.	
4. This approval is valid for a period of two years only, from the date of issuance of this approval.	
5. The Reference No of the advertisement and following additional cautionary statements should also be printed in prominent font size and if aired should be clearly communicated/perceived or understood. i. تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ ii. طبیعت زیادہ خراب ہو تو ڈاکٹر سے رجوع کریں۔ iii. طبیعت میں خرابی کی صورت میں مضر اثرات کی اطلاع دیں	
6. Approved advertisement specimen enclosed	

Date of issuance: ……..

Secretary CoA (Signatures)

(Stamp)

Chairman CoA (Signatures)

(Stamp)

SCHEDULE-A

[See rule 3(1)]

PERMISSIBLE LIST FOR ADVERTISEMENT

Therapeutic goods registered with DRAP, including—

1. Analgesics:
   (i) Aspirin, Ibuprofen 200 mg, Paracetamol, Paracetamol+Caffeine [in tablet and liquid forms (For mild aches / pain and fever)]; and
   (ii) Analgesics for topical use including analgesic balms.

2. Antiseptics and disinfectants for household use, excluding those containing hormones and antibiotics (For minor cuts, wounds and abrasions).

3. Antidandruff preparations for external use, excluding steroidal preparations.

4. Oral hygiene products.

5. Antacids:
   Compound Effervescent Salts, Calcium carbonate, Milk of Magnesia, Aluminium hydroxide / Magnesium hydroxide (in combination or segregated).

6. Carminatives.

7. Laxatives containing bulk forming agents (Bran, Psyllium), stool wetting agents (Magnesium hydroxide, Paraffin).

8. Oral preparations to remedy malnutrition, containing vitmain(s), Mineral(s) & Vitamin(s) + Mineral(s) combination. (Restricted advertisement, not to be promoted as an alternative to natural food and its sources).

9. Probiotics & Prebiotics

SCHEDULE-B

[See rule 3(12)]

MEDICAL COMPLICATIONS, DISEASES AND DISORDERS FOR WHICH ADVERTISEMENT IS PROHIBITED

1. Acute psychotic conditions and Psychological disorders (including dementia, depression, anxiety, stress etc.)

2. Addiction

3. Auto-immune diseases (lupus etc.)

4. Cancer

5. Cardiovascular disorders and diseases (like arteriosclerosis, hypertension, heart failure, myocardial infarction etc.)

6. Complaints requiring surgical procedures (like appendicitis, GIT ulcers, hernias, sinusitis, mastoiditis etc.)

7. Deafness

8. Diabetes

9. Diseases and disorders of the uterus (like Amenorrhoea, metrorrhagia, menorrhagia, metrosalpingitis, ovaritis, fibromas, cysts etc.)

10. Diseases and disorders of the renal system (like nephritis, kidney disorders, kidney stones etc.)

11. Diseases and disorders of the ocular system (like Blindness, cataract, glaucoma etc.)

12. Diseases and disorders of the nervous system (like epilepsy and convulsions, locomotive ataxia, multiple sclerosis, paralysis etc.)

13. Diseases and disorders of the prostatic glands

14. Infectious diseases

15. Obesity, stature of persons, sterility and other endocrine disorders

16. Serious illness liable to endanger the life of the patient (e.g., pneumonia, pleurisy, abscess of the lungs etc.).

17. Sexual dysfunctions (like impotence) and other related disorders

18. Venereal diseases

19. Advertisement of any other ailment which causes self-medication, is habit forming and deceives the public towards its use.

20. Cough Preparations

SCHEDULE-C

[See rule 5]

ETHICAL CRITERIA FOR PROMOTION

1. Promotion.- (1) For the purposes of this Schedule, "promotion" means all informational and persuasive activities by the marketing authorization holder or his representative, the effect of which is to induce the prescription, supply, purchase and/or use of therapeutic goods.

(2) All claims concerning a therapeutic good for the purposes of promotion shall be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste. Such claims shall not contain misleading, unverifiable statements, or omissions likely to induce medically unjustifiable use of a therapeutic good or to give rise to potential risks. The word "safe" shall not be used with respect to promotion unless properly qualified. Promotional material shall not be designed so as to disguise its real nature.

(3) Scientific data in the public interest shall be made available on request to prescribers and any other person entitled to receive it as appropriate to their requirements. 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.

2. Advertisement to healthcare and allied professionals.- (1) The wording, content and illustrations in advertisements to healthcare professionals shall be fully consistent with the approved scientific data for the therapeutic goods concerned or other sources of information with similar content. The text of the advertisement shall be fully legible.

(2) While introducing the therapeutic goods to the healthcare professional for the first time it shall contain full product information, on the basis of the approved scientific data and shall 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 marketing authorization holder;
(j) reference to appropriate scientific literature;
(k) mechanism of reporting adverse drug reactions to pharmacovigilance centres; and
(l) Price of the therapeutic good.

(3) Reminder advertisements shall 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 marketing authorization holder for the purpose of receiving further information.

3. Advertisement to the general public.- (1) Advertisement to the general public, where permissible, should help people to make rational decisions on the use of therapeutic goods legally available without a prescription. While advertisements shall take into account

people's genuine desire for information regarding their health they shall not take undue advantage of people's concern about their own health.

(2) Advertisement shall not generally be permitted for prescription therapeutic goods or to promote therapeutic goods for certain serious conditions that can be treated only by qualified healthcare professionals.

(3) The scheduled narcotic and psychotropic drugs shall not be advertised to the general public in connection with fight against drug addiction and dependency.

(4) Although health education aimed at children is highly desirable, therapeutic goods advertisements shall not be directed at children.

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

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

(7) 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);
(c) major precautions, contra-indications and warnings, if any;
(d) name of marketing authorization holder; and
(e) mechanism of reporting adverse drug reactions to pharmacovigilance centres

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

4. Medical Representatives.- (1) Medical representatives shall have an appropriate educational background. They shall be adequately trained so as to possess sufficient medical and technical knowledge and integrity 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 ethical marketing and promotion criteria.

(2) Medical representatives shall make available to prescribers, pharmacists and healthcare professionals complete and unbiased information for each product discussed, such as approved scientific data or other sources of information with similar contents.

(3) Employers shall be responsible for the statements and activities of their medical representatives. A medical representative shall neither offer any inducements nor shall such inducements be solicited.

5. Free samples of prescription therapeutic goods for promotional purposes.- Free samples of therapeutic goods may be provided in modest quantities to prescribers, preferably on request.

6. Free samples of non-prescription therapeutic goods to the general public for promotional purposes. - There shall be no free sampling of non-prescription therapeutic goods to the general public for promotional purposes.

7. Post-marketing scientific studies, surveillance and dissemination of information.- (1) Post-marketing scientific studies and surveillance shall not be misused as a disguised form of promotion.

(2) Substantiated information on risks and hazards associated with the therapeutic goods shall be reported to the Division of Pharmacy Services, DRAP as a priority.

8. Packaging and labelling.- Provision of appropriate information is important to ensure the rational use of therapeutic goods. All packaging and labelling material shall provide information consistent with that approved by the Registration Board and if no such approval is available it shall be, consistent with that approved by the regulatory authority of the country from which the therapeutic good is imported or other reliable sources of information with similar content. Any wording and illustration on the package and label shall conform to the principles of ethical criteria of marketing and promotion.

9. Information for patients contained in package inserts, leaflets and booklets.- (1) Adequate information about the therapeutic goods shall be made available to the patients for rational use. In package inserts or leaflets, the marketing authorization holder shall ensure that the information reflected is correct. If package inserts or leaflets are used for promotional purposes, these shall comply with the ethical criteria for marketing and promotion. 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.

(2) In addition to approved package inserts and leaflets wherever available the preparation and distribution of booklets and other information material for patients and consumers shall also comply with the ethical criteria for marketing and promotion.

(3) Information on reporting adverse drug reactions for patients and healthcare professionals shall also be included.

[No. F.4-22/2016-DD(PS)]

AAMAR LATIF,
Additional Director (Legal Affairs).