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Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations and Coordination
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NOTIFICATION

Islamabad, the 27th January, 2025.

S.R.O. 68(I)/2025. –In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, is pleased to make the following rules, namely: -

1. Short title and commencement.– (1) These rules shall be called the Therapeutic Goods (Advertisement) Rules, 2025.

(2) These rules 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 shall also include a notice, circular, label wrapper or other document and any announcement made orally or by means of producing or transmitting light or sound; and

(c) "Advertisement Board" means the Advertisement Board constituted under these rules.

(2) The words and expressions used but not defined in these rules shall have the same meanings as are assigned thereto in the Act.

3. Application of advertisement.– (1) No person shall make advertisement of therapeutic goods, except with prior written permission of the Advertisement Board for which he shall be required to make application-

(a) on Form-I of Schedule-A to these rules, accompanying all necessary documents and addressed to the Secretary of the Advertisement Board; and

(b) accompanied by the fee as notified by the Authority with the approval of the Policy Board under the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules, 2022.

(2) The Advertisement Board may allow the advertisement of a therapeutic good, specified in Schedule-B to these rules and may approve the contents of such advertisement and specify conditions subject to which such advertisement shall be made.

(3) The Advertisement Board may make decision, on advertisement of health and over the counter (OTC) products (non-drugs) and medical devices, on the basis of recommendations of the Enlistment Evaluation Committee (EEC) and the Medical Devices Board (MDB) respectively.

(4) A separate application shall be made for each advertisement and product.

(5) Approval of advertisement shall be granted on Form-II set out in Schedule-A to these rules, which shall be valid for a period of two years only unless earlier withdrawn or cancelled or suspended.

4. Advertisement to healthcare professionals. – (1) Advertisement referred to in item B of Schedule-II to the Act may be made to the medical, pharmacy and allied health professions, without referring to the Advertisement Board through-

(a) medical representatives;

(b) professional journals and publications; or

(c) a documentary film,

which are meant for circulation exclusively amongst the members of the medical, pharmacy and allied health professions.

(2) The advertisement made under sub-rule (1) shall be subject to the following conditions, namely: -

(a) all claims shall be made in accordance with those approved for registration or enlistment of the therapeutic good;

(b) where the usual information on indications and dosage is provided, the advertisement material shall also contain information on contra-indications, side effects, awareness on reporting adverse drug reactions to relevant pharmacovigilance centres and other necessary precautions as are applicable; and

(c) publications for the medical, pharmacy and allied health professions shall include the name of the therapeutic good and its exact composition, the name and address of the manufacturer or marketing authorization holders and a statement to the effect that full information is available on request.

(3) On the information received under sub-rule (2), the Advertisement Board after giving an opportunity of personal hearing may pass appropriate orders in case of any violation of these rules.

5. General conditions of advertisement. – (1) No advertisement under these rules shall contain any direct or indirect comparison, in any way, with any other therapeutic good for the purpose of attracting customers or with a view to discredit other such product.

(2) 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 too general claims, such as "effective in all cases" or "effective against all complaints" or superlatives shall be avoided.

(3) Advertisement shall include information on risks and precautions as may be necessary for the protection of public health and awareness on reporting adverse drug reactions to the relevant pharmacovigilance centres.

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

(5) No therapeutic good or any remedy, treatment or offer of treatment of any disease specified in Schedule-C to these rules shall be advertised except as provided under rule 4.

(6) The marketing authorization holder or his representative shall follow the Ethical Marketing to Healthcare Professionals Rules, 2021 and guidelines as may be approved by the Authority from time to time.

(7) Expenditure on advertisement, marketing, sampling and other promotional activities in respect of therapeutic goods shall not be more than five percent of the turnover. This shall not include expenditure on pay and allowances of the field staff connected with such activities for the purpose of these rules.

6. Cancellation, suspension or variation of advertisement. – (1) Before cancellation or suspension of approval of an advertisement, the Advertisement Board shall issue a show cause notice and after giving an apportunity of personal hearing, may pass appropriate orders in case of violation of any of the conditions or contravention of any provision of the Act or these rules.

(2) The Advertisement Board may, if 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.

(3) The Advertisement Board may refer the case to Drug Courts for violation of the Act or these rules.

7. Advertisement Board.– (1) The Advertisement Board shall consists of.-

(a)	Director (Pharmacy Services), DRAP	*chairman*
(b)	Deputy Director (Pharmacy Services), DRAP as nominated by the Director (Pharmacy Services)	*ex-officio member-cum-secretary*
(c)	Representative of Directorate of Pharmaceutical Evaluations and Registration, DRAP not below BPS-18 or RO-13 or equivalent	*member*

(d) Representative of Directorate of Health and OTC Products, DRAP not below BPS-18 or RO-13 or equivalent — *member*

(e) Representative of Directorate of Medical Devices and Medicated Cosmetics, DRAP not below BPS-18 or RO-13 or equivalent — *member*

(f) Representative of Directorate of Quality Assurance and Laboratory Testing, DRAP not below BPS-18 or RO-13 or equivalent — *member*

(2) The Advertisement Board may co-opt expert related to the concerned field to attend a meeting of the Advertisament Board but such person shall have no right to vote at the meeting or delibration of the advertisement.

(3) The Authority with approval of the Policy Board may increase or decrease the members of the Advertisement Board.

(4) The meetings of the Advertisement Board shall be regulated in accordance with the regulations made under section 24 of the Act.

8. Appeal against the decision of the Advertisement Board. – Any person aggrieved by the decision of the Advertisement Board may prefer an appeal before the Authority within sixty days.

SCHEDULE-A
Form-I
[See rule 3(1)(a)]

Application for Advertisement of Therapeutic Good

1.	**Name of the applicant**
2.	**Address of the applicant** Mailing/postal address (if other than): Email: Phone:
3.	**Advertisement of therapeutic good** Name: Registration / Enlistment No: Generic name, if any: Composition with properties of each ingredient: Major indication (s): Major precaution (s): Contraindication (s): Warning (s):
4.	**Mode of publicity:** Print Media ☐ Electronic Media ☐ Internet/Digital Media ☐ **i.** Print media (mention mode): Specimen: Printed Ad. with legible fonts **ii.** Electronic media (mention mode): Specimen: verbatim / storyboard and audio (mp3) / video clip (mp4) **iii.** Internet / Digital Media (mention mode): Specimen: Picture / verbatim / storyboard [image (jpeg) / audio (mp3) / video clip (mp4)]
5.	Fee submitted: ☐ Challan No.:
6.	Soft copy of application, annexures and specimen of advertisement attached ☐
7.	Signature of the applicant Stamp

Form–II
[See rule 3(5)]

Ref. No:.....
Date of issuance:.....

Drug Regulatory Authority of Pakistan
Government of Pakistan

Approval for Advertisement of Therapeutic Good
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): Registration / Enlistment No.
1. This permission shall be subject to the conditions specified in the Therapeutic Goods (Advertisement) Rules, 2025 under the Drug Regulatory Authority of Pakistan 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 Advertisement Board 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. دوا کے استعمال سے مضر اثرات کی صورت میں اطلاع متعلقہ کمپنی اور ڈریپ (DRAP) کو دیں۔
6. Approved advertisement specimen enclosed.

Secretary
Advertisement Board
(Signatures)
(Stamp)

Chairman
Advertisement Board
(Signatures)
(Stamp)

Form-III

[See rule 6(3) and rule 7]

Report on Illegal Advertisement (Cognizance of Offence)		
1	Name of Therapeutic Good	
	Company	
	Advertisement Mode	
	Advertisement made (attachment)	
	Reason of concern	
	Detail of Action taken / to be taken	
2	Name of Therapeutic Good	
	Company	
	Advertisement Mode	
	Advertisement made (attachment)	
	Reason of concern	
	Detail of Action taken / to be taken	
3	Add more rows as required	

Name of Officer: _____

Designation: _____

Department/Organization: _____

_____

Contact No. / email: _____

Signatures

SCHEDULE-B

[See rule 3(2)]

Permissible list of therapeutic goods, registered or enlisted with the Drug Regulatory Authority of Pakistan, including, --

1. Analgesics in oral dosage forms (For mild aches / pain and fever):
2. Analgesics for topical use including analgesic balms.
3. Antiseptics and disinfectants (For minor cuts, wounds and abrasions).
4. Oral hygiene products.
5. Neutralizing and Physical Antacids.
6. Carminatives and laxatives (bulk forming and softening agents).
7. Oral preparations for good health, containing Vitamin(s), Mineral(s) and Vitamin(s) + Mineral(s) combination. (Restricted advertisement, not to be promoted as an alternative to natural food and its sources).
8. Oral Rehydration Solutions (ORS).
9. Probiotics and Prebiotics.
10. Lozenges for throat irritation.
11. Any other therapeutic goods as approved by the Authority.

SCHEDULE-C

[See rule 5(5)]

Medical complications, diseases and disorders, advertisement for the treatment of which is prohibited, --

1. Any psychotic condition and Psychological disorders
2. Addiction
3. Auto-immune diseases
4. Cancer
5. Cardiovascular disorders and diseases
6. Complaints requiring surgical procedures
7. Deafness
8. Diabetes
9. Diseases and disorders of the uterus
10. Diseases and disorders of the renal system
11. Diseases and disorders of the ocular system
12. Diseases and disorders of the nervous system
13. Diseases and disorders of the prostatic glands
14. Infectious diseases
15. Obesity, stature of persons, sterility and other endocrine disorders
16. Sexual dysfunctions and other related disorders
17. Venereal diseases
18. Advertisement of any other ailment which causes self-medication, is habit forming and deceives the public towards its use.
19. Cough Preparations (having pharmacological action on the CNS)
20. Antimicrobial Agents
21. Therapeutic goods containing narcotic, psychotropic, precursor and steroids.
22. Any other disease or condition or therapeutic goods as approved by the Authority.

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

AAMAR LATIF,
Additional Director (Legal Affairs).

The Manager,
Printing Corporation of Pakistan Press,
Islamabad.