

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

Islamabad, the 18th March, 2022.

NOTIFICATION

The following draft of further amendments in the Drugs (Licensing, Registering and Advertising) Rules, 1976, 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), read with clause (a) of section 7 thereof and section 43 of the Drugs Act, 1976 (XXXI of 1976), is hereby published for the information of all persons likely to be affected thereby and, as required by sub-section (3) of section 43 of the said Act (XXXI of 1976), 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 AMENDMENTS

In the aforesaid Rules, Schedule D-1 shall be substituted with the following, namely.—

“SCHEDULE D-1
[See rule 31(1)]

Household remedies including—

1. Analgesics:
 - (i) Aspirin, Ibuprofen 200mg, Paracetamol, Paracetamol+Caffeine [in tablet and liquid forms (For mild aches / pain and fever)];
 - (ii) Analgesic for topical use; and
 - (iii) Analgesic balms/plasters.
2. Antiseptics and disinfectants for household use, excluding those containing hormone and antibiotics (For daily use as sanitizers. For minor cuts, wounds and abrasions).
3. Antidandruff preparations.
4. Dental preparations, mouthwash.
5. Antacid and carminatives:
Compound effervescent salts, milk of magnesia, aluminium hydroxide / magnesium hydroxide (in combination or separate use).
6. Laxatives containing bulk forming agents (bran, psyllium), stool wetting agents (magnesium hydroxide, paraffin).

7. Supplements to remedy malnutrition: (Restricted advertisement, not to be promoted as an alternate to natural food and its sources, not permitted to be marketed for the purpose of treating, diagnosing, preventing, or curing diseases)
 - (i) Iron supplements;
 - (ii) Calcium;
 - (iii) Ascorbic acid;
 - (iv) Folic acid;
 - (v) Calcium and vitamin-D; and
 - (vi) Vitamins.
8. Contraceptives.
9. Miscellaneous:
 - (i) Probiotics & prebiotics; and
 - (ii) Fish liver oil and its equivalents.

Application for advertisement of enlisted products for household remedies shall be decided by the Committee on Advertisement after seeking comments of the Division of Health & OTC products on:

- (i) Enlistment status;
- (ii) Composition quantity RDA level; and
- (iii) Verification with safety list.”

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



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