

To be published in the extra ordinary Gazette of Pakistan, Part-II

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

Islamabad, the 19th January, 2018.

NOTIFICATION

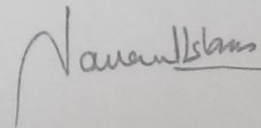
S.R.O...⁴¹.../(I)/2018. - In exercise of the powers conferred by clause (a) of section 7 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with section 12 of the Drugs Act, 1976 (XXXI of 1976), the Drug Regulatory Authority of Pakistan (DRAP) with the approval of the Federal Government is pleased to fix maximum retail prices subject to the conditions specified herein, namely:-

Maximum Retail Prices of drugs may be increased as per para 8 of Drug Pricing Policy-2015, namely:-

- (a) 2.08% for scheduled drugs,
- (b) 2.91% for non-scheduled drugs; and
- (c) 4.16% for lower priced drugs.

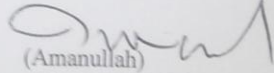
2. The maximum retail prices (MRPs) shall be subject to the following conditions, namely:-

- (a) the price increase shall not be applicable on the batches manufactured before affecting the increase of authorized rates by the Federal Government. No recall of drugs of already marketed batches shall be allowed;
- (b) the revised MRPs shall be printed on the label in the manner prescribed by the Drugs (Labeling and Packing) Rules, 1986;
- (c) no manufacturer, importer, retailer, hospital, clinic, wholesaler or distributor shall be allowed to affix stickers, overlapping or masking of prices;

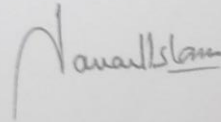


- (d) calculations of revised MRPs, duly signed and stamped by the Managing Director or Managing Partner or CEO or any authorized person on their behalf, shall be intimated to the Authority (Division of Costing and Pricing) at least 15 days prior to affecting the increase;
- (e) revised price list shall be submitted in hard copy and uploaded on the DRAP website or as prescribed by the Authority from time to time;
- (f) evidence for authenticity of the existing approved prices shall be submitted with declaration that the calculation have been made in accordance with the provisions of the Drug Pricing Policy-2015 and the approved increased rate by the Federal Government; and
- (g) if after 4.16% increase in MRP of any lower priced drug, its MRP comes out to be more than the threshold as given under para 11 of the Drug Pricing Policy-2015, such drug shall be excluded from lower priced category and shall be given price increase in future as per scheduled drug or non-scheduled drug whichever is applicable.
3. This notification shall not be applicable on all subjudice cases related to pricing issues including Notification No11-2/2013-DDC(P) dated 29th November, 2013 till final adjudication of such cases.

[No.F.11-17/2017-DD (P) (Vol-I)]


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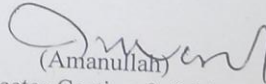
Islamabad, the 19th January, 2018

NOTIFICATION

F.No.11-17/2017-DD(P)(Vol-I) .- In pursuance of sub-clause (vii) of clause section 7 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with sub-paragraph (2) of paragraph of 11 of the Drug Pricing Policy-2015, the Federal Government is pleased to make the following amendments in sub-paragraph (1) of the above said paragraph, as under:-

“11. Lower priced drugs.- (1) The drugs whose MRPs are less than the following threshold shall be deemed to be non-scheduled drugs even otherwise falling under the scheduled category to encourage their production:

- (i). Rs.3.11/- per tablet / capsule / respule / caplet
- (ii). Rs.3.11/- 5ml of syrup /suspension/elixir
- (iii). Rs.3.11/- per patch
- (iv). Rs.6.21/- per sachet
- (v). Rs.15.53/- per injection
- (vi). Rs.3.11/- per 1 gm of cream/ ointment/ gel (non sterile) subject to maximum pack size of 20gm.
- (vii). Rs.4.14/- per 1 gm of cream/ ointment/ gel (sterile) subject to maximum pack size of 20gm.
- (viii). Rs.4.14/- per ml of eye/ ear /nasal drops /nasal spray / inhalation solution (sterile) subject to maximum pack size of 10ml.”


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