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PART III

Other Notifications, Orders, etc.

GOVERNMENT OF PAKISTAN
**MINISTRY OF NATIONAL HEALTH SERVICES,
REGULATIONS AND COORDINATION
(Drug Regulatory Authority of Pakistan)**

NOTIFICATION

Islamabad, the 15th July, 2020

No. F. 11-2/2020-DD(P).—In pursuance of sub-clause (vii) of clause (c) of section-7 and clause (a) of sub-section (1) of section-11 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan, on the recommendations of its Policy Board and with the approval of the Federal Government, is pleased to direct that the following amendments shall be made in the Drug Pricing Policy, 2018, namely:—

(1057)

Price : Rs. 6.00

[5753(2020)/Ex. Gaz.]

In the aforesaid policy,—

- (a) **In paragraph 2, in sub-paragraph (1), for clause (xi), the following shall be substituted, namely:—**

“(xi) “essential drugs and biologicals” means the drugs and biologicals included in the list of essential medicines as published by the World Health Organization and notified by the Ministry of National Health Services, Regulations and Coordination and as updated or revised from time to time”;

- (b) **In paragraph 7, for sub-paragraph (2), the following shall be substituted, namely:—**

“(2) Manufacturers and importers may increase their existing MRP's of essential drugs/biologicals (excluding lower priced) equal to 70% increase in CPI (with a cap of 7%) and MRPs of all other drugs/biologicals and lower priced drugs up to increase in CPI (with a cap of 10%) subject to the following conditions, namely:—

- (i) Calculations of revised MRPs, duly signed and stamped by the Managing Director or Managing Partner or CEO or any authorized person on his behalf, shall be submitted along-with evidence for authenticity of existing MRPs to the Authority (Division of Costing and Pricing). Non intimation of MRPs shall be construed as non-revision of MRPs. The failure to submit the calculations for increase in MRPs shall tantamount to nullifying the price increase;
- (ii) if calculations of revised MRPs are in accordance with this sub-paragraph, the Authority shall issue the revised price within 30 days of submission of the correct calculations by the manufacturer or importer provided that where the Authority fails to issue revised price within the mandatory period of 30 days, such issuance shall be deemed to have been made;
- (iii) revised price list shall be submitted in hard copy and upon issuance shall be uploaded on the DRAP's website or as prescribed by the Authority from time to time;

- (iv) no manufacturer, importer, retailer, hospital, clinic, whole-seller or distributor shall be allowed to affix stickers overlapping or masking of prices;
- (v) the price increase shall not be applicable on the batches manufactured before affecting the increase under this paragraph. No recall of drugs of already marketed batches shall be allowed;
- (vi) the revised MRPs shall be printed on the label in the manner prescribed by the Drugs (Labeling and Packing) Rules, 1986; and
- (vii) if there are cogent reasons why the MRP of a drug/biological should not be increased or reduced, the Federal Government may, by notification for reasons to be recorded, declare a specific category of drugs/biological to be excluded from application of this sub-paragraph.”;

(c) **in paragraph 9, for sub-paragraph (5), the following shall be substituted, namely:—**

- “(5) All new hardship applications filed after issuance of this Policy shall be decided within 120 days of submission of the hardship case on the specified form and complete in all respect with the DRAP (Division of Costing and Pricing) in manner as specified in this Policy. In case, no response is sent to the applicant of hardship case under provisions of this paragraph within 120 days, the applicant may apply to the Authority for increase of MRP upto maximum of 10% on the existing approved MRP with evidence that a complete case was submitted with the DRAP (Division of Costing and Pricing) provided that the applicant must have sent a reminder to DRAP 30 days before the expiry of the 120 days period. The Authority shall approve and issue the increase of MRP upto maximum of 10%, subject to such increase not being more than what has been sought in the application, on the existing approved MRP as requested within 7 days of submission of application provided that where the Authority fails to issue the revised price within the mandatory period of 07 days, such issuance shall be deemed to have been made upto an extent of 10% of MRP or the relief sought, whichever is lower. Further provided that if the matter has been referred

by DRAP to the Federal Government within the aforesaid 120 days, the Federal Government shall decide the matter within 60 days of being submitted by the Authority.”; and

(d) **in paragraph 10, for sub-paragraph 2, the following shall be substituted, namely:—**

“(2) Threshold limit of lower priced drugs shall be increased by equal to CPI every year and notified by the Ministry of National Health Services, Regulations and Coordination.”

AMANULLAH,
Director (Pricing & Costing).