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

Islamabad, the 9th June, 2023.

S.R.O. 678(I)/2023.– In pursuance of sub-clause (vii) of clause (c) 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 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:-

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

"(xi) "essential drugs and biologicals" for the purposes of this Policy means the drugs and biologicals included in the list of essential medicines as published by the World Health Organization (WHO) and notified by the Ministry of National Health Services, Regulations and Coordination and as updated or revised from time to time, subject to the following conditions, namely:-

(a) all strengths of a particular dosage form of drug and biological shall be considered as essential, if any of the strength of that dosage form is present in notified WHO Model List of Essential Medicines (MLEM);

(b) Dosage forms mentioned below in each row shall be considered as interchangeable with each other in the same row and essential if any of the strength in one dosage form is present in WHO MLEM;

(i) Tablets and capsules;
(ii) Oral suspension, syrup, solution, emulsion, elixir and other oral liquids;
(iii) Cream, ointment, gel, lotion and paste;
(iv) Eye and ear drops;
(v) Nasal drops and nasal spray;
(vi) Liquid inhaler, dry powder inhaler and rotacap inhaler;
(vii) Intravenous, intramuscular, subcutaneous and other injectable forms; and
(viii) Injection, vial and ampoule and pre-filled syringe and pen cartridge;

(c) if any biological drugs is present in WHO MLEM, it shall be considered as essential irrespective of its source (human, animal, microbial etc.) and process or technology;

(d) for combination formulations of vaccines and biologicals, if all of combo ingredients are individually labelled and categorized as essential in WHO MLEM, the combination in all strengths shall be considered as essential; and

(e) If primary drug or biological present in WHO MLEM is not registered in Pakistan, the alternative(s) mentioned against that particular molecule shall be considered as essential in that dosage form.

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