[TO BE INTERODUCED IN THE SENATE]

A

BILL

further to amend the Drug Regulatory Authority of Pakistan Act, 2012

WHEREAS it is expedient further to amend the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), for the purposes hereinafter appearing;

It is hereby enacted as follows:-

1. Short title, extent and commencement. - (1) This Act may be called the Drug Regulatory Authority of Pakistan (Amendment) Act, 2025.

(2) It shall extend to the Islamabad Capital Territory.

(3) It shall come into force at once.

2. Amendment of section 7, Act XXI of 2012.- In the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), in section 7,-

(i) in clause (c), for paragraph (vii), the following shall be substituted, namely:-

"(vii) regulation for pricing and mechanism for fixation of prices including Maximum Retail Price (MRP) of the generics and essential medicine products; medicines sold under the health and over the counter products; various therapeutic goods and all the drugs:

Provided that the method of cross-national price comparisons shall also be used to set an average price level for different medications in this regard;".

(ii) in clause (u), for the semi colon, ";" occurring at the end a colon ":" shall be substituted and thereafter the following new proviso shall be inserted, namely:-

"Provided that the registration board shall clearly define the maximum time limit for the registration procedure of the medicines along with the formation of standards to be observed for determining the quality medicines and methodology to be adopted for taking laboratory tests of medicines manufactured by local and multinational companies;".

STATEMENT OF OBJECTS AND REASONS

There are many lacunas in DRAP law on account of which prices of medicines often soar in the country. For example, in 2014 a Statutory Regulatory Order (SRO) was issued under which DRAP started enlisting medicines rather than fixing its prices. Because of such steps, prices of the medicines increased by manifolds. In some cases, if a registered drug was available for Rs 100, its enlisted rate went up to Rs 2,000 due to which companies stopped selling registered medicines.

There are a number of anomalies in prices such as medicines of same formula being sold at different rates. In the past, DRAP had started enlistment of medicines without fixation of prices due to which the medicines were sold at exorbitant rates under the health and over the counter (HOTC) products. Though a number of products fell in the category of drugs, they were sold as vitamins and nutrition due to which their prices were not fixed. Non-fixation of maximum retail prices (MRPs) of vitamins and other ingredients with monographs led to the exorbitant price hike of HOTC products.

Besides, the price comparison with Bangladesh and India only on new medicines shall not have the desired effect of bringing medicine prices down in Pakistan. It is unfair that old registered medicines continue to be sold for higher prices. The prices comparison (based upon cross-national medicine prices' comparison method) with Bangladesh and India should be made mandatory for all medicines. In addition, the provision should be retrospectively applied as majority of medicines have already been registered in Pakistan.

It has also been observed that the Registration Board of DRAP mostly takes an unusually long time to take up cases of registration of medicines. There is an immediate requirement on the part of DRAP to take corrective measures for timely registration of medicines and fixing of responsibility besides framing a comprehensive methodology to be adopted to take laboratory tests of the medicines. De-controlled prices of medicines through SROs, is one of the factors behind a surge in their prices. For example, SRO 471(1)/93 dated 6th July, 1993 provided a list of 821 medicines and gave blanket approval for rest of medicine prices to be decontrolled. The majority of medicines in market stand de-controlled as a result of this SRO. Only their price increases are being monitored by DRAP whereas their original high prices stay and DRAP is unable to lower them. It is against spirit of Drugs Act, 1976 that not all prices of drugs were controlled. SRO prima facie is in violation of Act which calls for price fixation. Every medicine should fall under domain of price control of DRAP.

The above amendments have been proposed in order to eradicate above factors behind soaring prices of medicines in the country.

The bill has been designed to achieve the aforementioned purpose.

SENATOR DR. ZARQA SUHARWARDY TAIMUR
MEMBER IN CHARGE