

**GOVERNMENT OF INDIA  
MINISTRY OF HEALTH AND FAMILY WELFARE  
DEPARTMENT OF HEALTH AND FAMILY WELFARE**

**LOK SABHA  
UNSTARRED QUESTION NO. 1867  
TO BE ANSWERED ON 29<sup>TH</sup> NOVEMBER, 2019**

**USE OF SHORT EXPIRY MEDICINES IN GENERIC MEDICINES**

**1867. DR. ALOK KUMAR SUMAN:**

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

- (a) whether it is a fact that short expiry medicines are being used in the preparation of generic medicines by various pharmaceutical companies;
- (b) if so, the details thereof;
- (c) the total number of cases registered in this regard along with the action taken therein; and
- (d) the corrective measures being taken by the Government to prevent such malpractice?

**ANSWER  
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND  
FAMILY WELFARE  
(SHRI ASHWINI KUMAR CHOUBEY)**

(a) to (c): There is no definition of 'generic drugs' prescribed in the Drugs & Cosmetics Act, 1940 and Drugs & Rules, 1945 made thereunder. However, generic medicines are generally those which contain same amount of same active ingredient(s) in same dosage form, and are intended to be administered by the same route of administration as that of branded medicine.

For manufacture of drugs, manufacturers are required to comply with Good Manufacturing Practices (GMP) prescribed under Schedule M of the said Rules.

As per schedule M, only raw materials which have been released by the Quality Control Department and which are within their shelf-life shall be used. It shall be ensured that shelf life of formulation product shall not exceed that of active raw materials used.

Further, the manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945 thereunder through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take stringent action against violation of provisions of the Act and Rules.

Central Drugs Standard Control Organisation under the Ministry of Health & Family Welfare which is responsible for ensuring safety, efficacy & quality of drugs, has not received any such report that the short expiry medicines are being used in the preparation of generic medicines by various pharmaceutical companies.

(d): The Government is committed to ensuring that the quality, safety and efficacy of drugs are not compromised. With this in view, the Government has taken a series of measures including strengthening of legal provisions, workshops and training programmes for manufacturers and regulatory officials and measures such as risk based inspections.

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