GOVERNMENT OF INDIA MINISTRY OF CHEMICALS AND FERTILIZERS DEPARTMENT OF PHARMACEUTICALS

LOK SABHA UNSTARRED QUESTION NO. 5603 TO BE ANSWERED ON 4th APRIL, 2025

Self-injectable Epinephrine Autoinjectors

5603. Shri G M Harish Balayogi:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

- (a) whether it is a fact that self-injectable epinephrine autoinjectors are currently unavailable in India and patients have to carry pre-drawn epinephrine syringe for emergency use, if so, the reasons thereof;
- (b) whether the Government has undertaken steps to make the said self-injectable epinephrine autoinjectors available to the public, if so, the details thereof and if not, the reasons therefor;
- (c) whether the Government has plans to include self-injectable epinephrine autoinjectors under the Pradhan Mantri Bharatiya Janaushadhi Pariyojana (PMBJP), if so, the details thereof and if not, the reasons therefor;
- (d) whether the Government has undertaken any steps/initiatives to promote the domestic manufacturing of self-injectable epinephrine autoinjectors, if so, the details thereof and if not, the reasons therefor; and
- (e) the details of the domestic pharmaceutical companies that are currently in the process of manufacturing self-injectable epinephrine autoinjectors?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a) to (e): As per information received from the Ministry of Health and Family Welfare, self-injectable epinephrine autoinjectors are presently not being manufactured in India. However, epinephrine injectables, such as ampoules and vials, are readily available and are being produced by companies in India.

Under the Production Linked Incentive Scheme for Pharmaceuticals, financial incentive is provided to 55 selected applicants for manufacturing identified products, which include epinephrine autoinjectors. One of the selected applicants has filed an application with the Central Drugs Standard Control Organisation (CDSCO), for manufacturing and marketing permission for epinephrine autoinjector, which, as per input received from CDSCO, is at the stage of review. As an approved product, manufacturing and sale of epinephrine autoinjector, upon commercialisation, is eligible for incentive at the rate of 10% of sales.

Since manufacturing and marketing permission for epinephrine autoinjector is at the stage of review in CDSCO, and only approved products may be considered for inclusion in the product basket of Pradhan Mantri Bhartiya Janaushadhi Pariyojana scheme, epinephrine autoinjectors is currently not included in the scheme product basket.
