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

LOK SABHA
UNSTARRED QUESTION NO. 2168
TO BE ANSWERED ON 31ST JULY, 2026

INSULIN AWIQI OF NOVO NORDISK

2168. SHRI SUBBARAYAN K:
COM. SELVARAJ V:

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

(a) whether it is a fact that Danish drug producer Novo Nordisk has launched a weekly basal insulin Awiqi for adults with Type 1 and Type 2 diabetics in a dozen countries including India replacing the daily insulin, if so, the details thereof; and

(b) the opinion of the doctors about this new medicine and the response of the patients to the new insulin?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE

(SMT. ANUPRIYA PATEL)

(a) & (b): Central Drugs Standard Control Organisation (CDSCO) has granted approval to M/s. Novo Nordisk India Private Limited for import and marketing, in India, for Insulin Icodec Solution for Injection (Awiqli®) 700 U/1 mL, 1050 U/1.5 mL & 2100 U/3 mL in pre-filled pen (r-DNA origin) in accordance with the provisions of the Drugs and Cosmetics Act, 1940 and the Rules thereunder, for the treatment of diabetes mellitus in adults. As per the approved Package Insert, the drug is to be administered once weekly through the subcutaneous route and is to be prescribed only by a registered endocrinologist or physician having post graduate qualification in medicine based on the patient's clinical condition.

The aforesaid drug has been approved by CDSCO for import and marketing in India based on the recommendations of the Subject Expert Committee (Endocrinology & Metabolism) in its meeting held on 19.06.2024 and after examination of its chemical, manufacturing and control (CMC) data, including clinical efficacy and safety data generated from global clinical trials, including Indian patients. The firm has also been directed to conduct a post-marketing surveillance study in the country under real-world clinical practice settings in India as per the provisions of New Drugs and Clinical Trial Rules, 2019.

The Subject Expert Committee consists of eminent experts drawn from different organizations such as Research Institutes, Regulatory Bodies, Medical Colleges & Hospitals and other eminent institutions/organizations.

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