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

LOK SABHA UNSTARRED QUESTION NO. 3338 TO BE ANSWERED ON 08TH AUGUST, 2025

QUALITY CONTROL ORDER (QCO) FOR MEDICAL AND SURGICAL GLOVES

3338. DR. BYREDDY SHABARI:

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

- (a) whether the Government intends to issue a Quality Control Order (QCO) for medical and surgical gloves, considering that a draft QCO was notified to the World Trade Organization (WTO) in February 2025;
- (b) if so, the details thereof alongwith the timeline by which the final notification is expected to be issued and implemented;
- (c) whether the Government is aware that several essential products such as toys, steel and footwear are already covered under mandatory QCOs and BIS certification, while critical healthcare protective items such as medical and surgical gloves remain excluded;
- (d) if so, the details thereof;
- (e) the reasons for the delay in bringing such essential healthcare items under mandatory BIS certification; and
- (f) the steps being taken by the Government to ensure that medical and surgical gloves used in infection control meet uniform safety and quality standards through ISI marking?

ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. ANUPRIYA PATEL)

(a) to (f): As informed by the Department of Pharmaceuticals, it has published a draft Quality Control Order (QCO) for medical and surgical gloves on website of World Trade Organisation (WTO) in February 2025. No timeline is set for notification of the same.

Medical and Surgical gloves are regulated in the country under Medical Devices Rules, 2017 under the Drugs and Cosmetics Act, 1940 and the said devices are required to meet the standards as per the said rule to ensure quality, safety and performance of the Medical Devices.
