

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

**RAJYA SABHA
UNSTARRED QUESTION NO. 914
TO BE ANSWERED ON 11.02.2025**

STEPS TO ENSURE THE QUALITY OF MEDICAL GASES

914 SHRI JAGGESH:

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

- (a) whether it is a fact that during Covid, a significant number of people who needed external oxygen support acquired a fungal infection and lost their eyesight;
- (b) whether ensuring and prioritizing the quality of medical gases is critical and needs attention with mandatory inspections of facilities that produce medical oxygen;
- (c) whether the Prime Minister's Office has written to the Ministry to take necessary action regarding the labelling of oxygen cylinders to differentiate between Industrial and Medical oxygen; and
- (d) if so, the details thereof, and the steps taken by the Ministry for mandatory labelling of oxygen cylinders?

ANSWER

**THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE
(SHRI PRATAPRAO JADHAV)**

(a) Fungal infections like Mucormycosis are usually seen as an opportunistic infection in persons who have low underlying immunity either due to a disease like diabetes, cancers, etc. or as a side effect of irrational use of certain drugs like steroids, immunosuppressive drugs etc. While a spurt in fungal infections like Mucormycosis was noted during COVID-19 pandemic, there is no evidence at present to indicate that external oxygen support during COVID-19 directly led to such fungal infections or loss of eyesight, as a complication of the same.

(b) to (d): Medical oxygen is categorized as 'Drug' under the ambit of Section 3(b)(i) of the Drugs and Cosmetics Act, 1940. While, license to manufacture medical oxygen and other medical gases is issued by the concerned State Licensing Authorities, Central Drugs Standard Control Organization (CDSCO) in an advisory issued to all States/UTs has clarified that medical oxygen cylinders are distinct from the industrial oxygen cylinders with regards to the size and the colour of the cylinder. The CDSCO requested Drug Controllers in all State/UTs to carry out

periodic inspection of medical oxygen and other medical gases manufacturing facilities under their respective jurisdictions to verify its compliance with the Good Manufacturing Practices (GMP) and labeling requirements as per the Drugs and Cosmetics Rules, 1945.

Further, Petroleum and Explosives Safety Organization (PESO) vide a circular has clarified that as per Rules 8(1) of Gas Cylinder Rules 2016, every person filling any cylinder with any compressed gas, before it is stored or dispatched, shall ensure that the cylinder is painted with appropriate identification colours specified in IS:3933 for medical cylinders. PESO has also directed all Medical Oxygen Cylinder Filling Plants to ensure compliance of Rules 8(1) of Gas Cylinder Rules 2016 for clear identification of medical oxygen cylinders and to differentiate medical oxygen cylinders from other cylinders filled with gases. Similarly, all Medical Oxygen Cylinder Manufacturers have been directed to ensure that all medical oxygen cylinders manufactured by them are properly painted as per IS: 3933 standards prior to dispatch to the consignee.
