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

LOK SABHA UNSTARRED QUESTION NO. 1138 TO BE ANSWERED ON 05TH DECEMBER, 2025

CORNEAL TRANSPLANTATION CENTRES

1138. SHRI SURESH KUMAR SHETKAR: SHRI MANICKAM TAGORE B:

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

- (a) whether the Government has issued any notification on November 6, 2025, to remove the mandatory requirement of clinical specular microscopes in corneal transplantation centres based on the recommendation of any expert medical committee and if so, the details thereof;
- (b) whether the Government has conducted any field study or impact assessment before amending the Transplantation of Human Organs and Tissues Rules, 2025 and if so, the details thereof;
- (c) whether this relaxation is likely to compromise the quality or safety of corneal grafts, particularly in centres lacking advanced diagnostic facilities and if so, the details thereof;
- (d) whether the Government has established alternative quality-control or monitoring mechanisms to ensure donor cornea health in the absence of specular microscopy and if so, the details thereof;
- (e) whether smaller eye hospitals and rural transplant centers are being provided with financial or technical assistance under the (NOTP) following this amendment and if so, the details thereof; and
- (f) whether the Government proposes to issue uniform operating guidelines to prevent misuse of donor corneas or unethical practices in unregulated centers and if so, the details thereof?

ANSWER THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI PRATAPRAO JADHAV)

- (a) Yes. The Government has issued a Gazetted notification dated 6 November, 2025 amending Form-15 under the Transplantation of Human Organs and Tissues Rules, 2014, wehreby the requirement of a clinical specular microscope for registration of corneal transplantation centres has been made optional.
- (b) The aforesaid amendment has been made based on the recommendations of technical experts, program experts and other stakeholders.

- (c) & (d) Such relaxation is not likely to compromise the quality or safety of corneal grafts, particularly in centres lacking advanced diagnostic facilities as the corneal tissues are first processed and evaluated by a registered eye bank, where Specular Microscope is mandatory.
- (e) Under National Organ Transplant Program (NOTP), financial assistance is provided for infrastructure and equipment required for establishing biomaterial centres at the regional or state level.
- (f) The cornea donation and transplantation, is regulated under the Transplantation of Human Organs and Tissues Act, 1994 (THOTA). The Act provides for one or more Appropriate Authority to be appointed by the respective State for the purposes of the Act and to investigate any breach of provisions of the Act and Rules thereunder and take appropriate action.
