

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

**RAJYA SABHA
UNSTARRED QUESTION NO.275
TO BE ANSWERED ON 04.02.2025**

BLOOD BANKS AND HUMAN SAFETY

275 DR. AJEET MADHAVRAO GOPCHADE

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

- (a) the details of the actions taken by the Central Government in collaboration with State Governments, to implement the Supreme Court's verdict on Writ Petition (Civil) 91 of 1992 regarding critical issues related to Blood Banks and human safety, as on date; and
- (b) whether Government has received any representation for a National Blood Transfusion Act aimed at creating a comprehensive legislative framework to standardize and ensure the safety of blood services, if so, the details thereof and the steps taken to address it up to this point as on date?

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

- (a) In response to the directions of the apex court's 1996 judgment, a structure was created to implement the court's directives in letter and spirit, establishing a comprehensive framework for blood transfusion services across India. This multi-tiered system is designed to ensure the safe and efficient operation of blood transfusion services nationwide.

National Blood Transfusion Council (NBTC), State Blood Transfusion Council

(SBTC), Central Drugs Standard Control Organization (CDSCO): The NBTC, as the apex policy-making body, has been instrumental in developing national policies, strategies, standards, and technical guidelines for blood transfusion services. India has made significant strides in strengthening its blood transfusion services, ensuring safer and more readily available blood for patients nationwide. This progress reflects the Government's unwavering commitment to this critical area of healthcare. At the apex level, the Ministry of Health and Family Welfare provides overall policy direction and overarching governance. The NBTC, comprising the Governing Body, Technical Resource Group, and Standing Committee, is responsible for formulating national policies, strategies, standards, and technical guidelines for blood transfusion services. The DGHS also oversees the Blood Transfusion Services (BTS) Division, which works to implement these policies and manage the service delivery aspects. Crucially, the DCGI-FDA (Drugs Controller General of India - Food and Drug Administration) acts as the central licensing and regulatory authority for all blood banks, ensuring adherence to quality and safety standards. The Central Drugs Standard Control Organization (CDSCO), in collaboration with State Drugs

Licensing Authorities, regulates blood centers to ensure compliance with the Drugs & Cosmetics Act 1940 & Rules 1945, covering the collection, storage, and processing of blood and its components. Regular inspections are conducted, and necessary actions are taken based on observed violations. The Drugs and Cosmetics (Second Amendment) Rules, 2020, have further reinforced the National Blood Policy. The DCGI coordinates closely with its state-level arms, the DC/FDA (State Drugs Controller/Food and Drug Administration), which carry out the licensing and regulatory functions at the state level. At the state level, the State AIDS Control Societies (SACS) and State Blood Transfusion Councils (SBTCs) are responsible for implementing the national guidelines and managing blood transfusion services within their respective states. These bodies often include a State Transfusion Core Coordination Committee and a Blood Safety Division of SACS, demonstrating a focus on both coordination and safety. The operational level comprises various blood banks, including government blood banks and storage centers, as well as private, NGO, and government blood banks. All these operational blood banks are subject to licensing and regulation by the DCGI, through the state DC/FDAs, ensuring compliance with established standards.

Regulatory Oversight: The DCGI-FDA (at the national level) and State Drugs Licensing Authorities (at the state level) enforce regulations under the Drugs & Cosmetics Act, ensuring the safety and quality of blood collection, storage, and processing. The Drugs and Cosmetics (Second Amendment) Rules, 2020, have further strengthened these regulations.

Complete Ban on Professional Blood Donation: The court mandated an immediate ban on professional blood donation, aiming to eliminate the risk associated with paid donors and promote voluntary, non-remunerated blood donation.

Mandatory Testing for Five TTIs: Simultaneous with the ban on professional donors, mandatory testing of every unit of collected blood for five transfusion-transmissible infections (TTIs) was implemented. These TTIs include HIV/AIDS, Hepatitis B, Hepatitis C, Syphilis, and Malaria, significantly enhancing blood safety.

Standardization and Quality: The publication of the National Standard for Blood Centres and Blood Transfusion Services (2nd edition, 2022) and the Transfusion Medicine Technical Manual (2023) provide standardized guidance for best practices. Operational guidelines for the national external quality assessment program (issued in 2025) promote continuous quality improvement.

Expansion of Nucleic Acid Testing (NAT): NAT facilities have been expanded, particularly to prominent national and state institutions, significantly improving the detection of blood-borne infections and enhancing blood safety. Nearly half of Indian states now have at least one government facility equipped with NAT testing.

Proposed Capital Blood Centers: The government is proposing the establishment of advanced capital blood centers in each state, equipped with state-of-the-art facilities (including NAT, molecular labs, HLA labs, etc.) to centralize and modernize blood banking infrastructure in a phased manner.

National External Quality Assessment (EQA) Program Expansion: The EQA program is being expanded to all States and Union Territories, ensuring adherence to high standards in blood transfusion practices. EQA centers will also have NAT testing facilities.

Shift to Blood Components: A significant transition occurred from the transfusion of whole blood to the use of individual blood components (red cells, plasma, platelets, cryoprecipitate).

This allows for more targeted treatment, maximizing the benefit of each blood donation and reducing wastage.

Development of Plasma Derived Medicinal Products (PDMPs): Further processing of plasma has led to the production of Plasma Derived Medicinal Products (PDMPs), such as albumin, clotting factors, and immunoglobulins. These specialized products are essential for treating a variety of medical conditions.

Transition to Community-Based Approach: The blood transfusion program has evolved from a purely medical program to a community-based program. This involves active engagement of NGOs and the general public in promoting voluntary blood donation, raising awareness about blood safety, and strengthening the blood supply chain. This shift recognizes the crucial role of community involvement in ensuring a sustainable and safe blood supply.

Reaching Donors' Doorsteps: The procurement and deployment of mobile blood collection buses have extended blood donation services to the doorsteps of donors, making it easier and more convenient for individuals to contribute. This initiative has broadened community participation and helped increase voluntary blood donations.

Evolution to Transfusion Medicine and Immunohematology: The field has expanded beyond basic blood banking (collection, storage, and distribution) to encompass the specialized areas of transfusion medicine and immunohematology. This reflects a greater understanding of the complexities of blood groups, compatibility testing, and the interactions between blood components and the patient's immune system.

Shift to Clinical Specialty: Blood transfusion services have evolved from simply providing blood to becoming a clinical specialty actively involved in patient care. Transfusion medicine specialists now play a crucial role in managing complex cases, including those involving rare blood types, autoimmune hemolytic anemia, and other challenging clinical scenarios.

Collaborative Patient Care: Blood transfusion services are increasingly integrated into overall patient care, working in close collaboration with other medical specialties (e.g., surgery, oncology, haematology) to optimize treatment strategies and improve patient outcomes. This collaborative approach ensures that blood transfusions are administered appropriately and effectively as part of a comprehensive treatment plan.

(b) Yes. The Government has received a representation for National Blood Transfusion Act from Hon'ble Rajya Sabha MP Dr. Ajeet Madhavrao Gopchade aimed at creating a comprehensive legislative framework to standardize and ensure the safety of blood services.

We have sent this to our Technical Resource Group for their input.
