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

LOK SABHA UNSTARRED QUESTION NO. 2246 TO BE ANSWERED ON 01ST AUGUST, 2025

PATHOLOGY LABORATORIES

†2246. SMT. MANJU SHARMA:

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

- (a) whether a large number of illegal/unauthorised Pathology Laboratories are being run in an uncontrolled manner across the country;
- (b) if so, the details thereof;
- (c) whether the Government proposes to set up any regulatory body in this regard;
- (d) if so, the details thereof; and
- (e) the other steps being taken by the Government as per the directions of the Apex Court against these unauthorised, Pathology Laboratories?

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

(a) to (e): 'Health' being a State subject, it is the primary responsibility of State/UT Governments to take note of illegal/unauthorised pathology laboratories being operational. The data and details, in this regard, are not maintained centrally.

Furthermore, the Government of India enacted the Clinical Establishments (Registration and Regulation) Act, 2010 to provide for registration and regulation of Government as well as private clinical establishments (except those of Armed Forces), including pathology laboratories, belonging to recognized systems of medicine. As per the Act, the pathology laboratories are required to fulfil the conditions of minimum standards of facilities and services, minimum requirement of personnel, maintenance of records and reports and other conditions. This Act empowers registering authority at District level under the chairmanship of District Collector / District Magistrate to take actions including imposing penalties in respect of violation of its provisions. The States / UTs which have adopted the CE Act are primarily responsible for regulating their pathology laboratories as per provisions of the Act and Rules thereunder.
