MINUTES OF 54th MEETING OF THE TECHNICAL COMMITTEE HELD ON 09.02.2026 AT 11:00. A.M. UNDER THE CHAIRMANSHIP OF DGHS FOR SUPERVISING CLINICAL TRIALS ON NEW CHEMICAL ENTITIES IN LIGHT OF DIRECTIONS OF THE HON'BLE SUPREME COURT OF INDIA ON 03.01.2013

Present:

1.	**Prof. (Dr.) Sunita Sharma** Director General of Health Services, Ministry of Health and Family Welfare.	**Chairman**
2.	**Dr. Taru Dewan** Professor & Head, Dept. of Ophthalmology, Ram Manohar Lohia Hospital, New Delhi.	**Member**
3.	**Dr. Kaushal Kalra** Head of the Department, Dept. of Medical Oncology, Vardhman Mahavir Medical College & Safdarjung Hospital Ansari Nagar, New Delhi.	**Member**
4.	**Dr. Vibhu Mediratta** Professor, Dept. of Dermatology, LHMC, New Delhi	**Member**
5.	**Dr. Adarsh Kumar** Director, Forensic Science Laboratories, Uttar Pradesh	**Member**
6.	**Dr. K. H. Reeta** Professor, Dept. of Pharmacology, AIIMS Delhi.	**Member**
7.	**Dr. Annam Visala** Joint Drugs Controllers (India)	**CDSCO**

The chairman welcomed the members of the Committee for 54th Technical Committee meeting. Thereafter, 01 proposal was placed before the Committee for deliberation. The Committee discussed the proposal and gave its recommendation.

Minutes of 54th meeting of the Technical Committee held on 09.02.2026 at 11:00 AM under the chairmanship of DGHS for supervising clinical trials on new chemical entities in light of directions of the Hon'ble Supreme Court of India on 03.01.2013

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/IMP/24/000080 Abrocitinib tablets 50 mg, 100 mg & 200 mg	M/s. Pfizer Products India Private Limited	The firm presented proposal for grant of waiver to condition no. (X) to allow conduct of Active surveillance study in lieu of Phase IV CT study for Abrocitinib Tablets 50 mg, 100 mg, 200 mg in adolescents before the technical committee. After detailed deliberation, the committee recommended for waiver of Phase IV clinical Trial study and firm should conduct Active PMS study in adolescent patients with the following conditions: a) The Active PMS study should include minimum 50 evaluable adolescent patients. b) The duration of proposed Active PMS study should be for 4-5 years for long term safety in patients 12 years to 16 years of age and 16 years to 18 years in a stratified manner and firm should submit interim report on annual basis to CDSCO along with bone safety findings data, creatine phosphokinase elevation data and latent tuberculosis infection monitoring in comparison with base line data. c) At least 50% of the adolescent population shall be provided the drug free of cost for the duration of treatment. Accordingly, firm should submit detailed structured active PMS protocol to CDSCO for review by Subject Expert Committee.