MINUTES OF 53rd MEETING OF THE TECHNICAL COMMITTEE HELD ON 17.07.2025 AT 4:30.P.M. UNDER THE CHAIRMANSHIP OF DGHS FOR SUPERVISING CLINICAL TRIALS ON NEW CHEMICAL ENTITIES IN LIGHT OF DIRECTIONS OF THE HON'BLE SUPREME INDIA COURT OF 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. Hemant Kumar Goel** Professor & HOD, Department of Urology & Renal Transplant, Ram Manohar Lohia Hospital, New Delhi.	**Member**
5.	**Dr. Adarsh Kumar** Professor & HOD, Dept. of Toxicology, AIIMS- Delhi, New Delhi.	**Member**
6.	**Dr. Nikhil Tandon** Professor & Head, Dept. of Endocrinology & Metabolism, AIIMS, New Delhi.	**Member**
7.	**Dr. Ram Pratap Saini** Professor, Dept. of Medicine, Vardhman Mahavir Medical College & Safdarjung Hospital Ansari Nagar, New Delhi.	**Member**
8.	**Dr. Chandra Mohan Kumar** Professor, Dept. of Haematology, AIIMS Patna, Bihar.	**Member**
9.	**Rajeev Singh Raghuvanshi** Drugs Controller General (India)	**CDSCO**

The chairman welcomed the members of the Committee for 53rd Technical Committee meeting. Thereafter, 04 proposals were placed before the Committee for deliberation. The Committee discussed the proposals one after another and gave its recommendation.

Minutes of 53rd meeting of the Technical Committee held on 17.07.2025 at 4:30.p.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

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1	E-37709 Fixed Ratio Combination of Insulin Glargine and Lixisenatide (100 U + 50 mcg/ 33 mcg) Soliqua solostar®	M/s. Sanofi Healthcare India Pvt. Ltd.	The firm presented the proposal for removal of restriction of obesity from the approved indication of the drug Fixed Ratio Combination of Insulin Glargine 100U/mL + Lixisenatide 50 mcg/mL/33mcg/mL approved "for the treatment of adults patients with Obesity with insufficiently controlled type 2 diabetes mellitus to improve glycemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT2 inhibitors, when this has not been provided by metformin alone or metformin combined with another oral glucose lowering medicinal product (sulfonylurea, glinide, DPP-4 inhibitors or gliptins, and Sodium-glucose cotransporter 2 (SGLT2) inhibitors or gliflozins) or with basal insulin or with glucagon-like peptide-1 (GLP-1) receptor agonist" to align with the indication approved by other global regulatory authorities including USFDA, EMA and Japan. The committee noted that no such restriction of obesity is implied in any other country and other GLP-1 RAs approved in India. Further, the safety and efficacy data submitted by firm for approval of this drug established a favorable benefit/risk profile beyond this restricted use to adult people with obesity. After detailed deliberation, the committee recommended for approval of firm's proposal for removal of obesity from the approved indication.