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.	BIO/CT18/FF/2023/39717 Atezolizumab injection (1875 mg/15 ml vial) (Tecentriq) by new route of administration i.e., subcutaneous route.	M/s. Roche Products (India) Private Limited	The firm presented the proposal for grant of permission to import and market the drug product Atezolizumab injection (Tecentriq®) 1875 mg/15 mL vial for subcutaneous administration for the following indications with the request of local Phase III clinical trial waiver and commitment to conduct a Phase IV trial in India. 1. Atezolizumab is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy. 2. Atezolizumab as monotherapy for the first line treatment of patients of metastatic NSCLC whose tumors have a PD L1 expression ≥ 50% tumor cells or greater than or equal to 10% tumor infiltrating immune cells and who do not have EGFR or ALK genomic tumor aberrations. 3. Atezolizumab, as a single agent, as adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II to IIIA non-small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on ≥ 1% of tumor cells. The committee noted the PK/PD results of Asian & Non-Asian population from the Global clinical study IMscin001 for the ethnic differences in the PK parameters in the study. The Committee further noted that firm has received the USFDA approval for the SC route on

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			12.09.2024. After detailed deliberation, the committee recommended for the grant of approval to import and market the drug product Atezolizumab injection (Tecentriq®) 1875 mg/15 mL vial for subcutaneous administration with a condition that firm should conduct a Phase IV clinical trial in India including patients from all the applied three indications of NSCLC. Accordingly, firm should submit Phase IV clinical trial protocol to CDSCO within three months of grant of marketing authorization.
2.	BIO/CT18/FF/2023/40657 Elranatamab Solution for Injection; 44 mg/ 1.1 mL (40 mg/mL) and 76 mg/1.9 mL (40 mg/mL)	M/s/ Pfizer Products India Private Limited	The firm presented the proposal for grant of permission to import and market the drug product Elranatamab Solution for injection 44 mg/1.1 ml (40 mg/ml), 76 mg/1.9 ml (40 mg/ml)for the indication "As monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy" with a request of local Phase III clinical trial waiver and commitment to conduct a Phase IV trial in India. The committee noted that the firm received accelerated approvals based on the Phase II data in USA and other countries including EU, UK, Japan, Australia, Canada, etc. and the additional data presented by the firm of the Phase 2 global study, MagnetisMM-3. Further, committee noted that firm has committed to provide the results of the ongoing Global clinical study. The committee also noted that there is an ongoing global phase III clinical trial of the same drug in the similar indication

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			where India is one of the participating countries. After detailed deliberation, the committee recommended for the grant of permission to import and market the drug product Elranatamab Solution for injection 44 mg/ 1.1 ml (40 mg/ml), 76 mg/ 1.9 ml (40 mg/ml) with a condition that the proposed drug to be prescribed for relapsed/ refractory multiple myeloma in patients who have received at least four prior therapies, including an anti-CD38 monoclonal antibody, a Proteasome inhibitor and an anti-CD38 antibody. Further, the firm should conduct a Phase IV clinical trial in India. Accordingly, firm should submit Phase IV clinical trial protocol to CDSCO within three months of grant of marketing authorization.
3.	37709 Fixed Ratio Combination of Insulin Glargine and Lixisenatide 100 U + 50 mcg/ 33 mcg) Soliquasolostar®	M/s Sanofi Healthcare India Pvt. Ltd.	Under Discussion.
New Drugs Division			
4.	ND/MA/23/000094 Erdafitinib Tablet 3 mg, 4 mg & 5 mg.	M/s Natco Pharma ltd.	The firm presented its proposal for grant of permission to manufacture and market of Erdafitinib Tablet 3 mg, 4 mg & 5 mg along with the justification for local Phase-III Clinical Trial waiver, before the technical committee. After detailed deliberation, the committee opined that there is an unmet medical need for the proposed indication in the country. Accordingly, the committee recommended for the grant of permission to manufacture and market of the drug Erdafitinib Tablet 3 mg, 4 mg & 5 mg with local Phase III clinical trial waiver. Further committee recommended that firm should conduct Phase IV clinical trial of the approved product and

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			indication for which the protocol should be submitted to CDSCO within 3 months of approval of the drug for review by the SEC committee.