MINUTES OF 52nd MEETING OF THE TECHNICAL COMMITTEE HELD ON 02.05.2024 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

Present:

1.	**Prof.(Dr.) Atul Goel**, Director General of Health Services, Ministry of Health &Family Welfare, New Delhi.	Chairman
2.	**Dr. Nikhil Tandon**, Professor & Head Department of Endocrinology & Metabolism, AIIMS, New Delhi.	Member
3.	**Dr. Kamlakar Tripathi**, Former Prof., Dept of Medicine, Institute of Medical Science, BHU, Varanasi.	Member
4.	**Dr. Nandini K. Kumar,** Former Deputy Director General Sr. Grade (ICMR) President, Forum for Ethics Review Committees in India Distinguished Scientist Chair, Ministry of Ayush.	Member
5.	**Dr. B.R. Sherwal**, Medical Superintendent, VardhmanMahavir Medical Collage and Safdarjung Hospital, New Delhi.	Member
6.	**Dr. Rajeev Singh Raghuvanshi**, Drugs Controller General (India), New Delhi.	CDSCO
7.	**Dr. A. Visala**, Joint Drugs Controller (I), New Delhi.	CDSCO

The chairman welcomed the members of the Committee for 52nd Technical Committee meeting. Thereafter, 06 proposals were placed before the Committee for deliberation. The Committee discussed the proposals one after another and gave its recommendation.

Minutes of 52nd meeting of the Technical Committee held on 02.05.2024 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/Form44/FF/2019 /15236 Polatuzumab Vedotin 140 mg/vial for Injection	M/s. Roche Products(India) Pvt. Ltd.	After detailed deliberation, the technical committee recommended for approval of the drug for the indication ie.,PolatuzumabVedotin in combination with bendamustine and rituximab is indicated for the treatment of previously treated adult patients with diffuse large B-Cell lymphoma (DLBCL) who are not candidate for hematopoietic stem cell transplant to import and market the drug with waiver of Phase III and IV clinical trial in the country with following conditions: 1) The drug should be prescribed only for the patients who are not eligible for transplant procedure as certified by tumor board of the hospital. 2) The firm should conduct active PMS study to establish the safety and efficacy in Indian population. Accordingly, Active PMS protocol should be submitted to CDSCO within 3 months of the approval of the applied indication.
SND Division			
2.	SND/MA/21/000349 Pirfenidone ER Tablets 1200mg	M/s. Cipla Pvt.Ltd.	After detailed deliberation, the technical committee noted that CDSCO already approved Pirfenidone tablet 200mg, 400mg, 600mg and 267mg & 801mg. However, the proposed Pirfenidone ER Tablets 1200mg not approved anywhere in the world. The Technical committee also noted as per international prescribing information of ESBRIT capsule, there is dose titration requirement (in Initiation and maintenance) and dose modification requirement due to adverse events such as photosensitivity & rash, GI events requiring dose reduction / interruption.

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			Further, as per the published literature (Sarcoidosis vasculitis and diffuse Lung diseases Journal-2020; 37 (1); 148-157) presented by the firm, only 42.6% patients have tolerated 2403mg dose. Therefore, the Technical Committee reiterated SEC recommendations and requested the firm to conduct Phase III clinical trial to assess safety, efficacy and tolerability of proposed Pirfenidone ER Tablets 1200mg. Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for further review.
New Drugs Division			
3.	ND/MA/20/000160 Romidepsin for Injection 10mg per vial	M/s. MSN Laboratories	After detailed deliberation, the technical committee noted that USFDA has granted accelerated approval for new drug Romidepsin for injection for the treatment of cutaneous T-cell lymphoma (CTCL) and for the indication Peripheral T-cell lymphoma (CTCL) in patients who have received at least one prior systemic therapy in the year 2009 and 2011 respectively. The committee also noted that subsequently, in year 2021, innovator has withdrawn the PTCL indication from the U.S. market as the confirmatory Phase 3 study trial did not meet the primary efficacy endpoint of progression free survival. In view of the above, the committee did not recommend the grant of BE waiver and also recommended that the firm should conduct local Phase III clinical trial for proposed indication i.e. for the treatment of cutaneous T-cell lymphoma (CTCL).
4.	ND/IMP/21/000022 Gilbertinib 40mg film coated tablets	M/s. Astellas Pharma	After detailed deliberation, the technical committee opined that the relapsed or refractory acute myeloid leukaemia (AML) with a FLT3 mutation is a rare and life threatening condition. Accordingly, the committee recommended for phase IV clinical trial

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			waiver subject to the condition that the firm should conduct active post marketing surveillance study in Indian population for the approved indication and accordingly protocol to be submitted to CDSCO for further review by subject expert committee.
FDC Division			
5.	FDC/IMP/22/000025 Avibactam Sodium eq. to Avibactam 0.5gm + Ceftazidime pentahydrate eq. to Ceftazidime 2gm Powder for concentrate for solution for infusion	M/s. Pfizer Limited	After detailed deliberation, the technical committee noted that Phase III clinical trial study waiver was already considered by SEC at the time of approval of additional indication for the proposed FDC, issued on 14.10.2022 with condition to conduct Phase IV clinical trial study. After examining the matter, committee recommended that the firm should conduct Phase IV CT study in the approved additional indication. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 03 months.
GCT Division			
6.	GCT/CT04/FF/2022/ 35047 Ritlecitinib (PF -06651600) 50mg	M/s. Pfizer Limited	After detailed deliberation, the technical committee did not accept the firm request to include adolescents (12 to <18 years of age) in the study and recommended that the patients above 18 years should be recruited in the study.