

Recommendations of the SEC (Endocrinology & Metabolism) made in its 17th/24 meeting held on 15.10.2024 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	E-file no. 25129 Insulin injection, Biphasic Isophane (30/70) 100 IU/ml	M/s M. J. Biopharma Pvt.Ltd.	The firm presented the Phase IV clinical trial report titled “A Prospective, Multi-center, Phase IV Study to Assess the Safety, Efficacy and Immunogenicity of BIOSULIN® 30:70 (Insulin Injection, Biphasic Isophane 100 IU/mL of M.J. Biopharm Private Limited) in treatment of Patients Diagnosed with Type 2 Diabetes Mellitus”. After the detailed deliberation the committee noted the results of Phase IV Clinical study as presented by the firm. Further, the committee recommended to revise the Package Insert of the product by including a cautionary statement regarding administration of appropriate dose of BIOSULIN® 30:70 (Insulin Injection, Biphasic Isophane 100 IU/mL) by the patient. Revised Package insert shall be submitted to CDSCO for evaluation.
2.	E-19337 Human insulin (Regular/Isophane/ Biphasic)	M/s Wockhardt Limited	The firm did not turn up for the presentation.
3.	r-DNA11011(18)/95/2024-eoffice Algalsidase Alfa (REPLAGAL®)	M/s Takeda Biopharmaceuticals India Pvt. Ltd.	The proposal should be deliberated before the specialized physician as recommended in the last SEC deliberation dated 13.08.2024.
4.	r-DNA-11011(18)/163/2024-eoffice Olipudasealfa Powder for concentrate for solution for infusion 20 mg vial	M/s Sanofi Healthcare India Pvt. Ltd.	The firm presented the proposal for update in Prescribing Information in the posology, use in special population, overdose & patient counselling information section for Xenozyme® (Olipudase alfa Powder for concentrate for solution for infusion 20 mg vial) in line with Company Core Data Sheet (CCDS) version 05 dated 01st Dec 2022 and version 06 dated 04th May 2023. After detailed deliberation, the committee recommended that the firm should submit safety data of Indian patients w.r.t. SAE's & AE's of all patients treated with the drug product along with PSUR data.

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			Further, the safety and efficacy data to be deliberated in the presence of an independent expert who is using the drug for the treatment of patients and has not been part of previous studies (PI or Co-investigator) of the proposed drug in India.
New Drug Division			
5.	ND/MA/22/000197 Trelagliptin 50mg/100mg Tablets	M/s. Pure & Cure Healthcare Pvt. Ltd.	In the light of earlier recommendation dated 16.02.2023 and 17.02.2023, the firm presented the BE study report of the drug Trelagliptin 100 mg Tablets before the committee. After detailed deliberation, the committee considered the BE study result. Further, the firm should submit and present the Published Post market safety data before the committee for further consideration.
6.	ND/CT/24/000059 Tirzepatide 2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, 10mg/0.5 mL, 12.5 mg/0.5 mL and 15 mg/0.5 mL solution for injection in a single dose prefilled pen	M/s. Eli Lilly and Company (India) Pvt. Ltd.	The firm did not turn up for the presentation.
FDC Division			
7.	FDC/MA/22/000337 Empagliflozin + Linagliptin + Metformin Hydrochloride IP (as extended release) (10mg+5mg+1000mg, 25mg+5mg+500mg, 25mg+5mg+1000mg) film coated tablet	M/s. Pure & Cure	In light of the earlier SEC recommendation dated 19.01.2023 & 20.01.2023, the firm presented BE study report of higher strength of proposed FDC (Empagliflozin + Linagliptin + Metformin Hydrochloride (ER) 25mg+5mg+1000mg) film coated tablet before the committee. The firm informed the committee that the product in strengths i.e. 1000mg + 5mg + 25mg & 1000mg + 5mg + 10mg is already approved by USFDA. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product in

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			<p>above two strengths, after submission of data including dissolution data and justification for BE waiver for lower strength (Empagliflozin + Linagliptin + Metformin Hydrochloride (ER) (10mg+5mg+1000mg) film coated tablet as per the BE Study guideline with the condition that the firm should conduct Phase IV clinical trial.</p> <p>Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC for review by the committee.</p>
8.	<p>FDC/MA/24/000217</p> <p>Empagliflozin + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin HCl IP(ER) (10mg+100mg+1000mg/25mg+100mg+1000mg) film coated bilayered tablets</p>	M/s Lupin Limited	<p>The firm presented the proposal along with BE study protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study with the condition that a trained physician (MD, Internal Medicine) should be present during study.</p> <p>Accordingly, the firm should submit BE study report along with Phase III CT protocol to CDSCO for further review by the committee.</p>