Recommendations of the SEC (Endocrinology & Metabolism) made in its 107th meeting held on 19.10.2023 & 20.10.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000054 Lobeglitazone sulphate 0.5mg + Glimeperide 1mg Tablet	M/s. Glenmark Pharmaceuticals Ltd.s	The firm presented their proposal for waiver of Phase IV clinical trial before the committee. After detailed deliberation, the committee opined this is new combination that is first time introduced in the country. Therefore, it is required to generate sufficient safety and efficacy data and hence the firm should submit Phase IV clinical trial protocol as per the conditions of market authorization before the committee for further review.
Biological Division			
2.	BIO/CT18/FF/2023/37242 Somapacitan	M/s. Novo-Nordisk	The firm presented their proposal for grant of permission for import and marketing of drug Somapacitan Injection (Sogroya®) 5mg/1.5mL, 10mg/1.5mL, 15 mg/1.5 mL solution for injection in pre-filled pen with local clinical trial waiver based on the global clinical trials including Indian patients in both adult and pediatric population and the drug falls under the orphan drug category. The committee noted thatglobal clinical study conducted by the firm includes limited number of Indian patients both adult and pediatric population. After detailed deliberation, the committee recommended for grant ofpermission to import and marketing of drug Somapacitan Injection (Sogroya®) 5mg/1.5mL, 10mg/1.5mL, 15 mg/1.5 mL solution for injection in pre-filled penwith local clinical trial waiver with the condition that the firm should conduct Phase IV study for the proposed indication in India. Accordingly, the firm should submit Phase IV protocol within three months of approval of additional indication.
3.	4-35/Reliance/PAC-R-Denosumab (60)/2023-BD Denosumab 60mg/mL	M/s. Reliance	The firm presented the proposal for amendment in the warning statement for already approved drug productDenosumab 60mg/mL (PFS and vial)from current warning statement “To

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			be sold by retail on the prescription of a Rhematologist and Orthpaedicians only" to "To be sold by retail on the prescription of an **Endocrinologist**, Rhematologist and Orthpaedicians only". After detailed deliberation, the committee recommended for the proposed amendment in the warning statement.
4.	BIO/CT04/FF/2023/38054 Biphasic Isophane Insulin Injection 100U/ml	M/s. Regenix Drugs Ltd.	The firm presented their proposal to conduct Phase-III clinical trial titled "Prospective, Multi-center, Randomized, Double blind, Parallel-group, Active-controlled, Phase III Study to Compare the Efficacy, Safety and Immunogenicity of Regenix Biosciences Limited, India, (Investigational drug) - Regenix insulin 30/70 with Eli Lilly's, India, bacteria based Human Insulin Basal Bolus Huminsulin® 30/70 (Reference drug) in Type I and Type II Diabetes patients" vide Protocol No. CT22-008, Version 03 dated 26.05.2023. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented by the firm
5.	BIO/CT21/FF/2023/37380 Insulin Glargine Injection	M/s. Virchow Biotech	The firm presented the results of PK/PD study along with their proposal to conduct Phase-III clinical trial titled "Comparative study on the safety and efficacy of VB70G insulinglargine and Lantus in combination with oral antihyperglycemic drugs in patients with type 2 diabetes mellitus". After detailed deliberation, the committee opined that objective of the proposed Phase-III study with/without OAD's may be clarified to CDSCO and the number of evaluable patients should atleast be 100 on the test arm and accordingly firm should submit revised protocol for re-deliberation in the committee.
6.	BIO/CT04/FF/2019/17660 Insulin Aspart Mix 30 (100IU/mL)	M/s. Bio Genomics Limited	In light of earlier SEC recommendation dated 20.02.2020, the firm presented the results of PK/PD study along with their proposal to conduct Phase-III clinical trial titled "A Phase III, Multi-center, Open-Label, randomized, Parallel Group Study to Compare Efficacy Safety and Immunogenicity of Recombinant Insulin

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			Aspart Mix 30 (Manufactured by BioGenomics Limited) with NovoMix® 30 (Manufactured by Novo Nordisk), in Diabetes Mellitus Patients" After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented by the firm.
SND Division			
7.	SND/MA/23/000070 Cholecalciferol Granules 60000IU (Mouth dissolving Granules)	M/s. Tirupati Medicare	In light of earlier SEC recommendation dated 18.07.2023 & 19.09.2023, the firm presented specific justification and data along with published literatures in support of Bioequivalence study and Phase-III clinical trial waiver before the committee. The committee informed again that CDSCO has approved Cholecalciferol 60000 IU orally disintegrating strips (in 2017), Cholecalciferol oral drops 800 IU/ml (in 2021), Cholecalciferol 2000 IU orally disintegrating strips (in 2015), Cholecalciferol 60000 IU chewable tablets (in 2022) and Cholecalciferol 60000 IU Oral solution (in 2022). After detailed deliberation, the committee recommended for grant of permission to manufacturing and marketing of Cholecalciferol Granules 60000IU (Mouth dissolving Granules) with BE & CT waiver subject to condition that the firm should conduct Phase-IV clinical trial study. However, the firm should fulfil the requirements of CMC data before approval of the product. Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval of drug for further review by the committee.
8.	SND/MA/22/000297 Imeglimin HCl SR Tablets 500mg & 1000mg	M/s.Exemed Pharmaceuticals	In light of earlier SEC recommendation dated 24.11.2022. The firm presented Bioequivalence Study Report and Phase III Clinical Trial Report before the committee for the manufacturing and marketing of Imeglimin HCl SR Tablets 500 mg & 1000mg. After detailed deliberation, the committee recommended for grant of permission to manufacturing and marketing of Imeglimin HCl SR Tablets 500 mg & 1000 mg for

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			the indication "Treatment of Type 2 Diabetes Mellitus inadequately controlled with diet and exercise alone". However, the firm should fulfil the requirements of CMC data before approval of the product.
FDC Division			
9.	FDC/MA/21/000067 Dapagliflozin 5mg + Vildagliptin 50mg + Metformin HCl IP 500mg film coated tablet	M/s. USV Pvt. Ltd.	In light of earlier SEC recommendation dated 21.09.2021, the firm presented their proposal along with BE report and Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.
10.	FDC/MA/22/000276 Gliclazide SR IP + Dapagliflozin (30mg+10mg/ 60mg+10mg) tablet	M/s. Eris Lifesciences Limited	In light of earlier SEC recommendation dated 19.09.2023, the firm presented data w.r.t. ADR events reports after detailed causality assessment as per WHO scale along with details of 5 hypoglycemic cases. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.
11.	FDC/MA/23/000013 Metformin HCl (SR) IP 500mg/1000mg + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg/10mg + Linagliptin 5mg/5mg Tablets	M/s. Mascot Health Series Pvt. Ltd	In light of earlier SEC recommendation dated 22.08.2023 & 23.08.2023, the firm presented the proposal along with Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial with the condition that the inclusion criteria of CT protocol should be modified as "Patient should be on stable dose of Metformin of atleast 1gm/day for 2 months". The firm should submit Phase III clinical trial report to CDSCO for further review by the committee.
12.	FDC/MA/23/000261 Empagliflozin + Sitagliptin	M/s. Zydus Healthcare Limited	The firm presented their proposal along with Phase III CT Protocol for two strengths i.e., Empagliflozin + Sitagliptin

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	(10mg+50mg, 10mg+100mg, 25mg+ 50mg, 25mg+100mg) Film coated Tablet		(10mg+100mg, 25mg+100mg) tablet and requested for BE study waiver. After detailed deliberation, the committee considered the request for BE study waiver and recommended for grant of permission to conduct Phase III clinical trial. The results of the study should be presented before the committee for further review.
13.	FDC/MA/23/000263 Linagliptin + Glimepiride IP + Metformin Hydrochloride IP (ER) (5mg+1mg+500mg, 5mg+1mg+1000mg, 5mg+2mg+500mg & 5mg+2mg+1000mg) tablet	M/s. Exemed Pharmaceutical	The firm presented their proposal before the committee along with BE study protocol. After detailed deliberation, the committee opined the following: 1. The proposed FDC is not approved anywhere in the world. 2. There is a possibility of more hypoglycemic events with higher dose of Linagliptin proposed in the FDC. 3. The firm should present more scientific literature available from peer reviewed journal in support of co-administration of the drugs in proposed strengths in the FDC. Accordingly, the firm should submit above data for further review by the committee.
14.	FDC/MA/23/000268 Dapagliflozin + Linagliptin + Metformin Hydrochloride IP (ER)(10mg+5mg+500 mg & 10mg+5mg+1000mg) film coated tablet	M/s. Optimus Pharma Private Limited	The firm presented their proposal along with BE study protocol & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study & Phase III clinical trial. The result of the BE study should be presented for review by the SEC before initiation of the Phase III clinical trial.
15.	FDC/MA/23/000274 Dapagliflozin Propanediol	M/s. Alkem Laboratories Ltd.	The firm presented their proposal along with justification for BE study as well as Clinical Trial waiver for lower strength

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	Monohydrate eq. to Dapagliflozin 5mg + Linagliptin 5mg film coated tablet		based on their Clinical Trial report of higher strength i.e. Dapagliflozin 10 mg + Linagliptin 5 mg tablet. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC in lower strength.
GCT Division			
16.	CT/96/23 Online Submission (38908) LY3502970	M/s. Eli Lilly	The firm Presented Phase III Clinical Trial Protocol no. J2A-MC-GZGT. After detailed deliberation, the committee recommended for grant of permission to conduct the trial.
17.	CT/83/23 Online Submission (38413) Cagrilintide & Semaglutide (CagriSema)	M/s. Novo-Nordisk	The firm Presented Phase IIIa Clinical Trial Protocol no.NN9388-4896 After detailed deliberation, the committee recommended for grant of permission to conduct the trial.
18.	CT/89/23 Online Submission (38687) Deglusterol	M/s. CBCC Global Research	The firm Presented Phase II Clinical Trial Protocol no.CG-D-P02,version 2.0 dated 22 May 2023 After detailed deliberation, the committee recommended for grant of permission to conduct the trial..
19.	CT/94/23 Online Submission (38872) Deglusterol	M/s. CBCC Global Research	The firm Presented Phase II Clinical Trial Protocol no.CG-D-P03,version 1.0 dated 20 July 2023 After detailed deliberation, the committee recommended for grant of permission to conduct the trial.