Recommendations of the SEC (Endocrinology & Metabolism) made in its 83rd meeting held on 20.01.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New DrugDivision			
1.	ND/MA/21/000169 Imeglimin 500/1000 mg tablet	M/s. Exemed	The firm presented their proposal for grant of manufacturing and marketing permission of the drug Imeglimin 500 and 1000 mg tablet along with BE study results. After detailed deliberation, the committee recommended for conduct of Phase III clinical trial of the drug Imeglimin 500 and 1000 mg tablet.
Biological Division			
2.	BIO/CT04/FF/2021/29042 Insulin Glargine	M/s.Genesys Biologics Pvt.Ltd.	The firm presented the results of Phase I (PK-PD) trial alongwith the proposal for conduct of Phase III study. The committee observed that events of itching and utricaria was observed with the test drug in one of the subject which have likely relation with the drug as per the firm. After detailed deliberation, the committee recommended that the firm may generate additional safety data in healthy volunteers before consideration of proposal to conduct the Phase III clinical trial. Dr. Subhankar Chowdhury did not participate in the deliberation.
SND Division			
3.	SND/MA/19/000114 Vildagliptin Sustained Release (SR) Tablets 100 mg	M/s. Abbott Healthcare	The firm presented the PMS study protocol for Vildagliptin Sustained Release (SR) Tablets 100 mg as per the condition of Form CT-23. After detailed deliberation, the committee recommended for grant of permission for conduct of the PMS study subject to condition that the title of the study should change to active PMS study and more government site should be included.
4.	SND/MA/21/000525 Liraglutide 6mg/ml	M/s.Biocon Pharma Ltd.	The firm presented the proposal of BE protocol amendment of the product Liraglutide 6mg/ml solution for injection in PFP (18mg/3ml PFP) (Synthetic

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	solution for injection in PFP (18mg/3ml PFP) (Synthetic Peptide)		Peptide) before the committee. After detailed deliberation, the committee opined that sample size reduction may be allowed from 54 healthy subjects to 30 healthy subjects, but External syringe-aspiration technique is not acceptable in this BE study as the applied product is Liraglutide 6mg/ml solution for injection in PFP (18mg/3ml PFP). Accordingly, the firm should submit revised BE protocol to CDSCO.
FDC Division			
5.	FDC/MA/22/00001 Metformin Hydrochloride (as sustained release 500 mg/1000mg/500mg/1000 mg + Vildagliptin (as sustained release 100 mg/100mg/100mg/100mg + Dapagliflozinpropanediol monohydrate eq. to Dapagliflozin 5mg/5mg/10mg/10mg tablet	M/s. Ravenbhel Healthcare Pvt. Ltd.	The firm presented their proposal along with BE and CT protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. With regard to Phase III CT protocol, the committee noted that there are various strengths for which the firm wants to conduct the clinical trial. However, the reference arm was not found justified in view of the proposed inclusion criteria. In view of above, the committee recommended that the firm should submit the revised Phase III CT protocol with modified study arms as well as modified inclusion criteria for further consideration.
6.	FDC/MA/22/00006 DapagliflozinPropanediol monohydrate eq. to Dapagliflozin 5 mg + Metformin hydrochloride IP (Immediate Release) 500 mg tablet	M/s. Sun Pharma Laboratories Ltd.	The firm presented their proposal before the committee alongwith BE study report. The committee noted that FDC is already approved in Extended release dosage form. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed lower strength of the FDC.
GCT Division			
7.	CT/51/16 Online Submission (11876) Dulaglutide	M/s. Eli Lilly	The firm presented justification in light of earlier SEC recommendation meeting held on 25.11.21 for approval of protocol amendment H9X –MC -GBGC (e) dated

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			15- Oct -2020. After detailed deliberation, the committee noted that last patient last visit was already over in India and globally last patient last visit will be in Feb 2022 and clinical study report will be submitted around May 2022 for the study. Hence, the committee did not recommend for approval of the proposed protocol amendment.
8.	CT/152/21 Online Submission (29094) Semaglutide	M/s. Novo-Nordisk	The firm presented the Phase IIIb clinical trial protocol no NN9535-4533, Version 5.0 Date: 15 October 2021 before the committee. After detailed deliberation, the committee did not recommend for grant of permission for the proposed clinical study protocol no NN9535-4533, Version 5.0 Date: 15 October 2021 and opined that the firm should revise the protocol with following: 1. Echocardiography should be done for all patients during screening visit 2. Digital X-Ray of foot should be included during screening visit 3. All the conditions which affect walking distance like varicose vein, anaemia, COPD,etc. should be clearly defined in the protocol. The committee also opined that the study team in each site should comprise of an endocrinologist and an internal medicine specialist/cardiologist. Accordingly, the firm should submit revised protocol to CDSCO for further review by the committee.