Recommendations of the SEC (Endocrinology & Metabolism) made in its 84th meeting held on 18.02.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/21/000157 Imeglimin tablet 500mg/1000mg	M/s. Synokem Pharmaceuticals Ltd.	In light of earlier recommendation of SEC dated 24.11.2021 and 25.11.2021, the firm presented the BE study report along with proposed Phase III clinical trial before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the proposed protocol.
Biological Division			
2.	BIO/CT/21/000002 Insulin injection 100 IU/ml	M/s. Hinge Clinica	In light of the recommendations made in the SEC meeting dated 21.12.2021, the firm presented revised protocol for conduct of Phase III clinical trial study along with results of Phase I clamp study generated overseas before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the proposed protocol.
3.	05/Phase/IV/Shire/19-BD Velaglucerase Alfa	M/s. Shire Biotech India Pvt. Ltd.	The firm presented the proposal for amendment in the PMS study (observational) to enroll patients with Type III Gaucher disease before the committee. The committee observed that the drug is not yet approved in the country for indication of Type III Gaucher disease. After detailed deliberation, the committee did not recommend for approval of the amendment in the PMS protocol.

4.	BIO/CT04/FF/2021/29042 Insulin Glargine	M/s. Genesys Biologics Pvt.Ltd	In light of the earlier recommendations in the SEC meeting dated 20.01.2022, the firm presented justification for the AEs reported in the subjects before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of Phase III clinical trial subject to the condition that the firm should constitute an independent DSMB to monitor the patient safety during the clinical trial and submit the reports of the DSMB to CDSCO. (Note: Dr. Subhankar Chowdhury did not participate in the deliberation)
SND Division			
5.	SND/MA/20/000277 Teneligliptin tablets 10 mg	M/s. Akums	The firm presented the proposal along with BE study report before the committee. After detailed deliberation, the committee opined that the firm should submit the detailed therapeutic justification for Teneligliptin tablets 10 mg bid vs Teneligliptin tablets 20 mg, in the light of the BE study results presented and the published literature for further consideration.
FDC Division			
6.	4-56/2018-DC Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg/20mg + Pioglitazone Hydrchloride eq. to Pioglitazone 15mg/30mg film coated tablets	M/s. Synokem Pharmaceuticals	The firm presented their proposal along with Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of the proposed FDC.
7.	FDC/MA/22/000010 Empagliflozin 5mg/10mg/12.5mg/25 mg + Metformin 1000mg/1000mg/ 1000mg/1000mg	M/s. MSN	The firm presented their proposal along with BE study report and justification for clinical trial waiver before the committee. The committee noted that the proposed FDC is approved in US and also the FDC of Empagliflozin 5mg/5mg/5mg/12.5mg/ 12.5mg/12.5mg + Metformin HCl 500mg/850mg/1000mg/500mg/850mg /1000mg tablets in immediate release form was already approved in the

			country. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of the proposed FDC with the condition that the firm should conduct Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 monthss of approval for further review by the committee.
8.	FDC/MA/21/000300 Sitagliptin 50mg/50mg/100 + Metformin HCl (SR) 500mg/1000/1000mg tablets	M/s. Cipla Ltd.	The firm presented their proposal alongwith BE study report and justification for clinical trial waiver before the committee. The committee noted that the proposed FDC is approved in US And also FDC Sitagliptin 100mg/100mg+ Metformin HCl (SR) 500mg/1000 tablets and FDC of Sitagliptin (as phosphate) 50mg + Metformin HCl. 500mg/1000mg immediate release tablets was already approved in the country After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of the proposed FDC
9.	FDC/MA/21/000093 Remogliflozinetabonate 100mg/100mg+ Vildagliptin 50mg/50mg+Metformin Hydrochloride 500mg/1000mg tablet	M/s. Glenmark Pharmaceuticals Ltd.	In light of the earlier SEC recommendation, the firm presented the revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase IV clinical trial.
10.	FDC/MA/21/000090 Vildagliptin (as sustained release) 100mg/100mg+Dapagliflozin Propanediol eq. to Dapagliflozin 5mg/10mg tablets	M/s. Exemed Pharmaceuticals	The firm presented their request to present the Phase III clinical trial data after completion of 16 weeks of study duration for seeking manufacturing and marketing permission. The committee noted that similar treatment duration has been recommended for FDC of Dapagliflozin + Sitagliptin and FDC of Dapagliflozin + Teneligliptin tablets. After detailed deliberation, the committee agreed to the request for presenting the results of Phase III clinical trial on completion of 16 weeks for further

			review.
11.	FDC/MA/21/000247 Metformin Hydrochloride (as sustained release) IP + Sitagliptin Phosphate monohydrate eq. to Sitagliptin IP (500mg + 50mg, 1000mg + 50mg & 1000mg + 100mg) tablets	M/s. Akums Drugs	The firm presented their proposal along with BE study report and justification for clinical trial waiver before the committee. The committee noted that the proposed FDC is approved in US and also FDC Sitagliptin 100mg/100mg+ Metformin HCl (SR) 500mg/1000 tablets and FDC of Sitagliptin (as phosphate) 50mg + Metformin HCl 500mg/1000mg immediate release tablets are already approved in the country After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of the proposed FDC with the condition that the firm should submit in-vitro dissolution data of the test product vs innovator FDC.
GCT Division			
12.	CT/42/18 Semaglutide Submission (12567) Semaglutide	M/s. Novo-Nordisk	The applicant presented protocol version 6.0 dated 04/01/2021. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment. The committee also suggested that the applicant should include more Govt. sites.
13.	CT/50/19 Online Submission (12031) dated 19.07.21 Semaglutide	M/s. Novo-Nordisk	The firm presented clinical trial protocol amendment version 3.0 dated 17 Nov 2020 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment. The committee also suggested that the applicant should include more Govt. sites.