Recommendations of the SEC (Endocrinology & Metabolism) made in its 85th meeting held on 17.03.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	X-11026/301/2021-BD Insulin glargine	M/s. Sanofi Limited	In light of earlier SEC recommendations of the committee in its meeting dated 21.12.2021 & 26.10.2021, the firm presented that the protocol no. mentioned in the minutes may be corrected. After detailed deliberation, the committee recommended for correction in the protocol no. of the study and the earlier other recommendation of the committee remains the same.
2.	X-11026/261/2021-BD Insulin glargine	M/s. Sanofi Limited	The firm presented their proposal for conduct of retrospective study before the committee. After detailed deliberation, the committee recommended for grant of approval for the study.
SND Division			
3.	SND/MA/20/000386 Cholecalciferol Chewable Tablets 60,000 IU	M/s. Macloeds Pharma	The firm presented the proposal along with BE study report. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Cholecalciferol Chewable Tablets 60,000 IU, for the treatment of Vitamin D_3 deficiency.
4.	SND/MA/22/000082 Levothyroxine sodium tablets 62.5mcg	M/s. ACME Formulations	The firm presented the proposal for the additional strengths of Levothyroxine sodium tablets 62.5mcg. After detailed deliberation, the committee recommended for grant of permission to manufacture Levothyroxine sodium tablets 62.5mcg for the already approved indication.
5.	SND/MA/22/000065 Levothyroxine sodium tablets 125mcg, 137mcg and 150mcg	M/s. ACME Formulations	The firm presented the proposal for the additional strengths of Levothyroxine sodium tablets 125mcg, 137mcg and 150mcg. After detailed deliberation, the committee recommended for grant of permission to manufacture Levothyroxine sodium tablets 125mcg, 137mcg and 150mcg for the already approved indication.

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6.	SND/MA/21/000525 Liraglutide 6mg/ml solution for injection in Pre-Filled pen 3ml	M/s. Biocon Pharma Limited	In light of earlier SEC recommendation dated 20/01/2022, the firm presented the revised BE study protocol. After detailed deliberation, the committee recommended for grant of permission for conduct of bioequivalence study as per the amended protocol presented.
FDC Division			
7.	FDC/MA/22/000013 Linagliptin 2.5mg/5mg + Metformin1000mg/1000mg tablets	M/s. MSN	The firm presented their proposal along with BE Study report before the committee. The committee noted that the proposed FDC is already approved in USA. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with condition that Phase IV clinical trial is required to be conducted. Accordingly, the firm should submit Phase IV clinical trial protocol within 03 months from date of approval to CDSCO for review by committee.
8.	FDC/MA/22/000034 Vildagliptin 50mg/50mg/100mg/100mg/Dapagliflozin 5mg/10mg/5mg/10mg tablets	M/s. Theon Pharmaceuticals Ltd	The firm presented their proposal before the committee. During the presentation, the firm requested for deferring the presentation to next meeting.
9.	FDC/MA/21/000235 Vildagliptin SR 50mg/50mg + Metformin (SR)500mg/1000mg)	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm didn't turn up for presentation.
10.	FDC/MA/21/000090 Vildagliptin (as sustained release) 100mg/100mg + Dapagliflozin Propanediol eq.to Dapagliflozin 5mg/10mg tablets.	M/s. Exemed Pharmaceuticals	In light of the earlier SEC recommendation dated 18.02.2022, the firm presented 16 weeks data of Phase III clinical trial report and BE study report. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing with the condition to continue the study for remaining study period and present the results before the committee.
11.	FDC/MA/22/000063 Sitagliptin IP 50mg/50mg/50mg/50mg + Metformin	M/s. Macleods Pharmaceuticals Ltd.	The firm presented their proposal along with BE and phase III study protocol before the committee.

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	Hydrochloride IP 500mg/500mg/1000mg/1000mg + Glimepiride IP 1mg/2mg/1mg/2mg tablet		The committee noted that firm is proposing phase III clinical trial study of only one strength i.e. FDC of Sitagliptin 50mg+Metformin (ER) 1000mg+ Glimepiride 1mg tablet. After detailed deliberation, the committee recommended for grant of permission for conducting the BE study and phase III clinical trial with the condition that 1. Phase III clinical trial should be double blinded. 2. Drop out rate should not be more than 20%. Accordingly, the revised phase III clinical trial protocol should be submitted to CDSCO. Further the committee also recommended that the firm should initially present the data on 75 patients before the committee for assessing the safety and efficacy as well as approvability of this FDC before considering the continuation of the study on the remaining patients. As regard to other strengths, the committee opined that decision may be taken based on the outcome of the phase III clinical trial study results.
GCT Division			
12.	CT/152/21 Semaglutide	M/s. Novo-Nordisk	In light of earlier SEC recommendation dated 20.01.2022, the firm presented their justification before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with following conditions- 1. Echocardiography and digital X-Ray of foot should be mandatory and should be performed for all subjects during screening visit. 2. The clinical study team in each site should comprise of an Endocrinologist and an Internal medicine specialist/Cardiologist.
13.	CT/93/20 Taliglucerase Alfa	M/s. Novotech Clinical Research	The firm presented their proposal for protocol amendment WI22302, version 5.0 dated 10-Dec-2021 for increase of

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			subjects from 08 to 15 from India. After detailed deliberation, the committee recommended for grant of permission to increase the subjects in India to achieve global sample size of 15 subjects. However the rationale presented for increase in no of subjects should be submitted to CDSCO by sponsor and clinical trial sites investigator in India.
BABE Division			
14.	12-09/2022/BABE/Misc-04/DC Vildagliptin 50mg, Metformin HCL 500mg, Pioglitazone 15mgTablets	M/s. Ajanta Pharma Limited, Kandivli (India)-400067	The firm didn't turn up for presentation.