Recommendations of the SEC (Endocrinology & Metabolism) made in its 80th meeting held on 26.10.2021 at CDSCO HQ, New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/CT21/FF/2021/26119, Liothyronine 5 mcg & 20 mcg tablets	M/s. Acme Generics Pvt. Ltd	The firm presented their proposal of manufacturing and marketing of the drug Liothyronine 5 & 20 mcg tablets with local clinical trial waiver justification. The committee noted that there is unmet medical need of the drug in the country. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the drug in the country with waiver of local clinical trial subject to the following condition:- 1) The firm should conduct Phase-IV clinical trial with the drug for which the protocol should be submitted to CDSCO within three months of the approval of the drug for review by the committee. 2) The drug should be sold by retail on prescription of Endocrinologists/Internal Medicine specialists only. 3) The firm should present the proposed prescribing information containing the details of the indication, contraindication, warning, precautions etc including the measures need to be taken to address the risk associated with use of the drug in pregnancy, before the committee.
2.	ND/MA/21/000157, Imeglimin 500mg and 1000mg Tab	M/s. Synokem Pharma Ltd.	The firm presented their proposal of manufacturing and marketing of the drug Imeglimin 500 mg and 1000 mg Tablet along with Phase III clinical trial protocol and BA/BE study protocol before the committee. After detailed deliberation, the committee opined that the firm should submit the following and present the same before the committee for further consideration. 1. Detailed non-clinical and clinical data of safety and efficacy of the drug. 2. Justification for the proposed clinical trial with the drug including 1000mg Tab, since this strength is not approved anywhere in the world & regulatory status of the drug in other countries.

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3.	ND/IMP/21/000035, Etelcalcitide 2.5mg/0.5ml and 5mg/ml	M/s. Amgen	In light of earlier SEC recommendations dated 24-08-2021 and 25-08-2021, the firm presented their proposal of Etelcalcitide Injection with local clinical trial waiver along with details on SAEs related to hematological, gastrointestinal along with their analysis before the committee. After detailed deliberation committee noted that the available data on dialysis patients presented by the firm was inadequate for considering local clinical trial waiver as per the requirements. In view of the above, the committee recommended that the firm should submit Phase III clinical trial protocol for further review by the committee.
Biological Division			
4.	X-11026/261/2021-BD, Insulin Glargine (100 IU OR 300 IU)	M/s. Sanofi Healthcare India Pvt. Ltd.	The firm presented their proposal to conduct Phase IV or post marketing observational study with Insulin glargine vide protocol LANTUL0944 version no 1 After detailed deliberation, the committee recommended that the firm should submit evidence of similar studies done outside India, financial disclosures and information related to switching/interchangeability of the drug, before the committee for further consideration of the matter.
5.	BIO/CT04/FF/2021/26832, Basal or Bolus human Insulin (Wosulin R, Wosulin N and Wosulin 30/70)	Wockhardt Limited	The firm presented their proposal to conduct Phase IV CT vide protocol no WOC/WOS/CT-37/14 version no 02 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV study as per the protocol subject to the condition that – (1) Safety should be the primary objective for the proposed study (2) The firm should submit an interim analysis after completion of six months study. Accordingly, revised protocol with necessary amendments should be submitted to CDSCO for consideration.
SND Division			

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6.	SND/MA/21/000453, Cholecalciferol Sachets 60,000 IU	M/s. Akums Pharmaceuticals	The firm didn't turn up for presentation.
FDC Division			
7.	FDC/MA/18/000070 Evogliptin 5mg + Metformin hydrochloride SR 1000mg tablet	M/s. Alkem Laboratories Ltd.	The firm presented their proposal along with results of active PMS study before the committee. After detailed deliberation the committee noted the results of the study conducted as per the condition of permission.
8.	FDC/MA/21/000225 Dapagliflozin propanediol to monohydrate eq to Dapagliflozin 5mg/5mg Sitagliptin 50mg/50mg +Metformin Hydrochloride 500mg/1000mg tablets	M/s. Sun Pharma Laboratories Ltd.	The firm presented Phase III CT protocol along with request for BE waiver before the committee. After detailed deliberation, the committee recommended for conducting the Phase III CT study along with the condition that more government sites should be included in the CT study. The study reports should be presented before the committee for further consideration.
9.	FDC/MA/21/000239 Pioglitazone Hydrochloride IP+Teneligliptin Hydrobromide Hydrate IP +Metformin Hydrochloride IP (15mg+20mg+1000mg & 15mg +20mg +500mg) tablets	M/s. Macleods Pharmaceuticals	The firm presented their proposal before the committee. After detailed deliberation, the committee noted that Phase III clinical trial study is already on going for FDC of Pioglitazone Hydrochloride +Teneligliptin. Considering the risk of QT prolongation & heart failure, the committee recommended that firm should submit the status and results of Phase III trial data of two drug combination for further consideration on the proposed triple drug combination
10.	FDC/MA/21/000228 Remogliflozin etabonate 100mg +Teneligliptin 10mg + Metformin hydrochloride IP 500mg/1000mg tablets	M/s. Glenmark	The firm presented their proposal before the committee along with request for Phase III CT and BE waiver (based on BCS classification). The firm presented the result of Clinical study conducted with FDC of Remogliflozin 100mg + Teneligliptin 10mg when administered alongwith Metformin in Indian patients with type 2 diabetes mellitus. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC with the condition to conduct Phase IV CT study in significant number of patients. Accordingly, the firm should submit Phase IV CT protocol within 03 months from the date of approval.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
11.	FDC/MA/21/000105 Metformin Hydrochloride as an extendedrelease form + Sitagliptin Phosphate eq to Sitagliptin (1000mg/500mg + 100mg/100mg) Tablet	M/s. Alkem	In light of earlier recommendation dated 15.06.2021 & 16.06.2021, the firm presented their proposal along with BE study results before the committee. After detailed deliberation, the committee recommended for manufacturing and marketing of the proposed FDC.
12.	FDC/MA/21/000247 Metformin Hydrochloride (as sustained release) 500mg/1000mg/1000mg + Sitagliptin Phosphate monohydrate eq to Sitagliptin 50mg/50mg + 100mg Tablets	M/s. Akums	The firm presented their proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study. The results of the study should be presented before the committee for further consideration.
GCT Division			
13.	CT/51/16 Online Submission (11876) dated 29/06/2021 Dulaglutide	M/s. Eli Lilly	The firm didn't turn up for presentation.