Recommendations of the SEC (Endocrinology & Metabolism) made in its 94th meeting held on 19.10.2022 & 20.10.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000124 Imeglimin HCI Sustained Release Tablets 500mg/100mg	M/s. Synokem Pharmaceutical Ltd.	The firm presented their proposal along with Phase III CT as well as BE study protocol for the Imeglimin Hydrochloride Sustained Release Tablets 500mg & 1000mg. After detailed deliberation, the committee opined that the firm should conduct BE study as per the protocol presented and submit the BE study results before the committee for further consideration.
2.	ND/MA/22/000113 Imeglimin HCI & Vildagliptin Tablets 1000mg/50mg	M/s. Exemed	The firm presented their proposal of grant of permission to manufacture and market FDC of Imeglimin HCI & Vildagliptin Tablets 1000mg/50mg along with BE and Phase III clinical trial before committee. The committee observed that permission to manufacture and market of Imeglimin tablet was granted recently. After detailed deliberation, the committee recommended that the firm should complete Phase IV clinical trial with Imeglimin tablet and present it before the committee for further consideration.
3.	ND/MA/22/000133 FDC of Vildagliptin and Imeglimin 50mg/1000mg	M/s. Dr. Reddy	The firm presented their proposal for grant of permission to manufacture and market FDC of Imeglimin HCI & Vildagliptin Tablets 1000mg/50mg along with BE and Phase III clinical trial before committee. The committee observed that permission to manufacture and market of Imeglimin tablet was granted recently and the clinical experience with drug Imeglimin is very less. After detailed deliberation, the committee did not recommend the conduct of the proposed with BE and Phase III clinical trial with FDC of Vildagliptin and Imeglimin 50mg/1000mg.
4.	ND/MA/22/000112	M/s. Exemed Pharmaceuticals	The firm presented their proposal of grant of permission to manufacture and market FDC of Imeglimin Hydrochloride +

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	FDC of Imeglimin Hydrochloride + Sitagliptin Phosphate Monohydrate IP Tablets (1000mg + 50 mg)		Sitagliptin Phosphate Monohydrate IP Tablets (1000mg + 50 mg) along with BE and Phase III clinical trial before committee. The committee observed that permission to manufacture and market of Imeglimin tablet was granted recently. After detailed deliberation, the committee recommended that the firm should complete Phase IV clinical trial with Imeglimin tablet and present it before the committee for the further consideration.
5.	ND/MA/22/000130 FDC of Imeglimin Hydrochloride 500mg/1000mg + Sitagliptin Phosphate 50mg + 50 mg	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal of grant of permission to manufacture and market FDC of Imeglimin Hydrochloride 500mg/1000mg + Sitagliptin Phosphate 50mg + 50 mg along with BE and Phase III clinical trial before committee. The committee observed that permission to manufacture and market of Imeglimin tablet was granted recently. After detailed deliberation, the committee recommended that the firm should complete Phase IV clinical trial with Imeglimin tablet and present it before the committee for the further consideration.
6.	ND/MA/22/000131 FDC of Imeglimin Hydrochloride 500mg/1000mg + Vildagliptin 50mg/50mg	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal of grant of permission to manufacture and market FDC of Imeglimin Hydrochloride 500mg/1000mg + Vildagliptin 50mg/50mg along with BE and Phase III clinical trial before committee. The committee observed that permission to manufacture and market of Imeglimin tablet was granted recently. After detailed deliberation, the committee recommended that the firm should complete Phase IV clinical trial with Imeglimin tablet and present it before the committee for the further consideration.
7.	ND/MA/21/000169 Imeglimin Tablets 1000mg	M/s. Exemed	The firm presented their proposal of grant of permission to manufacture and market Imeglimin Tablets 1000mg along with justification and data before the committee.

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			The committee observed that the firm has completed Phase III clinical trial and BE study with Imeglimin tablet 1000 mg as per the protocol approved by the committee. After detailed deliberation, the committee recommended for the grant of permission to manufacture and market Imeglimin Tablets 1000mg subject to the condition that firm should conduct Phase IV clinical trial. Accordingly, firm should submit Phase IV clinical trial protocol to CDSCO with in the 3 months of approval.
8.	ND/IMP/21/000035 Etelcalcetide Injection 2.5mg/0.5ml, 5mg/ml	M/s Amgen Technology Pvt. Ltd.	The firm presented their proposal for import and market of drug Etelcalcetide Injection 2.5mg/0.5ml and 5mg/ml along with justification and data before the committee. The committee observed that the Etelcalcetide is approved in US for the treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease (CKD) on hemodialysis and 36 subjects from India were part of the global clinical trial wherein efficacy and safety in Indian subgroup of study appear to be consistent with the overall study. After detailed deliberation, the committee opined that there is unmet medical need in the country as secondary hyperparathyroidism is an important complication of chronic kidney disease, particularly among the patients receiving hemodialysis and recommended for the grant of permission to import and market of drug Etelcalcetide Injection 2.5mg/0.5ml and 5mg/ml.
9.	ND/MA/22/000109 Lobeglitazone Sulfate 0.5/0.5mg + Metformin Hydrochloride 500/1000mg ER Tablets	M/s Glenmark Pharmaceutical Ltd.	In light of earlier SEC recommendation dated 09.09.2022, the firm presented the clinical trial report before the committee. The committee observed that the Lobeglitazone Tablets 0.5mg is approved in India and FDC Lobeglitazone and Metformin is approved outside India (South Korea since 2015). The clinical

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			trial results demonstrate the efficacy and safety of combination treatment of Lobeglitazone and Metformin in Indian patient with Type 2 Diabetes Mellitus. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of Lobeglitazone Sulfate 0.5/0.5mg + Metformin Hydrochloride 500/1000mg ER Tablets for the proposed indication subject to the condition that the drug should be sold by retail only under the prescription of Endocrinologist or Internal Medicine specialist.
Biological Division			
10.	BIO/IMP/19/000078 Semaglutide 3 mg Tablets, 7 mg Tablets and 14 mg Tablets	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented the protocol for conduct of non interventional PMS study titled "A multicentre, prospective, non-interventional single-arm study investigating clinical parameters associated with the initiation of once-daily oral Semaglutide in a real-world adult population with type 2 diabetes in India; Protocol no.: NN9924-4960, version 1.0 dated 08 April 2022". After detailed deliberation, the committee recommended for grant of permission to conduct the study as per presented protocol.
11.	BIO/CT/19/000070 Insulin Glargine 100 IU/ml	M/s. Eli Lilly and Company (India) Pvt. Ltd.	The firm presented clinical study report of Phase IV. After detailed deliberation, the committee noted the results of the study.
12.	BIO/CT04/FF/2022/33278 Dulaglutide	M/s. Eli Lilly and Company (India) Pvt. Ltd.	The firm presented the protocol for conduct of Phase IV study titled "A 24-week multicenter, open-label, single-arm study to evaluate safety in patients with type 2 diabetes mellitus in India treated with Dulaglutide". Protocol no. H9X-IN-GBGR, H9X-IN-GBGR(a) dated 16 Sep 2022. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per presented protocol.
13.	BIO/IMP/22/000027	M/s. Pfizer Products India	The firm presented justification for thewaiver of conduct of Phase IV study,

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	Somatrogon 24mg and 60mg in prefilled pen	Private Limited	which was mentioned as the condition for import and marketing permission of the drug with request for conduct of active surveillance study. The committee noted that the drug is designated as orphan drug in countries like EU, UK etc. After detailed deliberation, the committee recommended that, firm should submit active surveillance study protocol for further review by the committee.
14.	BIO/IMP/22/000023 Biphasic Insulin Aspart Injection IP 100 Units/mL	M/s. Sanofi India Ltd.	The firm presented proposal for grant of permission to import and market the drug. with results of global clinical trial including study data on Indian patients. After detailed deliberation, the committee recommended for grant of approval to import and market the drug with condition that the firm should conduct Phase IV study and protocol should be submitted to CDSCO within three months of import and marketing approval.
SND Division			
15.	SND/MA/22/000235 Alpha Lipoic Acid Injection 25 mg/ml (600 mg/24ml) (intravenous Infusion)	M/s La Renon	The firm presented their proposal for grant of permission to manufacture Alpha Lipoic Acid Injection 25mg/ml (600 mg/24ml) (Intravenous Infusion) for the treatment of symptoms of peripheral (sensomotor) diabetic polyneuropathy with therapeutic rationale of the proposed additional dosage form and local CT waiver before the committee. After detailed deliberation, the committee opined that there is no systematic study reported or available in support of effect of Alpha Lipoic Acid for proposed indication. The committee recommended that the firm should submit proper justification and supportive documents for proposed indication for further review by the committee.
FDC Division			
16.	FDC/MA/22/000249	M/s. Innova Captab Ltd.	The firm presented their proposal along with Phase III CT protocol as well as BE study protocols.

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	Metformin HCl ER 500mg/500mg/1000mg/1000mg/1000mg + Glimepiride 1mg/2mg1mg/2mg/1mg/2mg + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/5mg/5mg/5mg/10mg/10mg tablets		After detailed deliberation, the committee recommended for grant of permission for conducting the Phase III CT study on the highest strength with the condition that active treatment duration should be 16 weeks. Further committee also recommended for conducting the proposed BE study for FDC of Metformin HCl ER 1000mg + Glimepiride 2mg + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg.
17.	FDC/MA/22/000264 Sitagliptin Phosphate monohydrate 100mg+ Pioglitazone HCl IP 15mg film coated tablets	M/s. Synokem	The firm presented their proposal along with Phase III CT protocol as well as BE study protocol. After detailed deliberation, the committee recommended for grant of permission for conducting the proposed BE and Phase III CT studies.
18.	FDC/MA/22/000276 Gliclazide SR 30mg/60mg + Dapagliflozin 10mg/10mg tablets	M/s. Eris Lifescience Ltd.	The firm presented their proposal along with Phase III CT protocol as well as BE study protocols. After detailed deliberation, the committee recommended for grant of permission for conducting the Phase III CT study on the highest strength with the condition that active treatment duration should be 16 weeks. Further the committee also recommended for conducting the proposed BE study for FDC of Gliclazide SR 60mg + Dapagliflozin10mg tablets.
19.	FDC/MA/22/000288 Metformin Hydrochloride (as SR) 500mg +Vildagliptin (as SR) 100mg + Dapagliflozin Propanediol 10mg tablets	M/s. Exemed	Inlight of earlier SEC recommendation dated 18.05.2022 the firm presented the BE study report on the higher strength of the FDC. Further, the firm also presented Phase III clinical trial report conducted with FDC of Vildagliptin + Dapagliflozin tablets with Metformin as background therapy. Further, firm also presented justification for the proposed lower strength. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing the proposed FDC with the condition that Phase IV clinical trial should be conducted.

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			Accordingly, Phase IV CT protocol should be submitted to CDSCO within 3 months from the date of approval for review by the committee.
20.	FDC/MA/22/000135 Metformin Hydrochloride (as SR) 1000mg +Vildagliptin (as SR) 100mg + Dapagliflozin Propanediol 10mg tablets	M/s. Exemed Pharmaceuticals	Inlight of earlier SEC recommendation dated 18.05.2022,the firm presented the BE study report on the higher strength of the FDC. Further, the firm also presented Phase III clinical trial report conducted with FDC of Vildagliptin + Dapagliflozin tablets with Metformin as background therapy. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing the proposed FDC with the condition that Phase IV clinical trial should be conducted. Accordingly, Phase IV CT protocol should be submitted to CDSCO within 3 months from the date of approval for review by the committee.
21.	FDC/MA/22/000268 Linagliptin 5mg/2.5 mg/5mg/2.5mg + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin (10 mg/10mg/5mg/5mg tablets	M/s.Exemed	The firm presented their proposal with Phase III CT protocol along with justification for BE study waiver. After detailed deliberation, the committee recommended for grant of permission for conducting the Phase III CT study on the highest strength.
GCT Division			
22.	CT/60/22 Online Submission (32869) Somapacitan with Norditropin®	M/s. Novo-Nordisk	The firm presented their proposal for Phase IIIa clinical trial before the committee. After detailed deliberation, the committee recommended for grant permission for conducting the Phase IIIa clinical trial. However, the committee opined that the method of testing of GH is to be fixed in the protocol. Accordingly, the firm needs to submit revised protocol to CDSCO for further consideration.
New Drug Division			
23.	ND/MA/21/000081 Liothyronine sodium	M/s. Acme Generics	The firm presented the proposal for conduct of Phase IV clinical trial with Liothyronine Sodium Tablets 5 mcg & 20

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	5 mcg & 20mcg		mcg before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trialas per the protocol presented with condition.