Recommendations of the SEC (Endocrinology & Metabolism) made in its 97th meeting held on 19.01.2023 & 20.01.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/CT/23/000001 ImegliminHCl 500mg/1000mg	M/s Synokem Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
2.	ND/MA/22/000169 Carglumic Acid 200mg	M/s Laurus Labs	The proposal was deferred for next meeting.
Biological Division			
3.	BIO/MA/21/000051 Insulin aspart IP100 U/ml solution for injection in 3ml cartridge and 10ml vial	M/s Biogenomics Limited	In light of earlier recommendation of SEC dated 21.09.2021, the firm presented results of completed Phase III clinical study before the committee. After detailed deliberation, the committee noted the results of the study.
4.	BIO/CT18/FF/2022/34430 Avalglucosidase Alfa Powder for concentrate for solution for infusion	M/s Sanofi Healthcare India Private Limited	The firm presented the proposal to import and market avalglucosidase alfa powder for concentrate for solution for infusion (10mg/ml) indicated for the treatment of long term enzyme replacement therapy for the treatment of patients with pompe disease with a request for waiver of Phase III & Phase IV clinical trial in the country. The committee noted that the drug falls under the orphan drug category and proposed indication is a rare disease. The committee also noted that the drug has been granted orphan drug status in US, Australia, Switzerland, Japan and Malaysia and approved in 13 countries including USA, EU, UK, Japan, Canada, Switzerland and Australia. After detailed deliberation, the committee recommended for grant of permission to import and market the drug with waiver of local Phase III & IV clinical trial in the country.
5.	4-78/Novonordisk Insulin degludec solution 100U/ml and 200U/ml.	M/s Novonordisk	In light of earlier recommendation dated 21.12.2022, the firm presented the proposal for update in the prescribing information of the drug. After detailed deliberation, the committee

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			recommended to include the following in the prescribing information of the drug in the section of use in special populations: "The treatment with Insulin degludec may be considered during pregnancy, if clinically needed".
6.	BIO/IMP/22/000090 Olipudasealfa Powder for concentrate for solution for infusion	M/s Sanofi Healthcare India Private Limited	The firm presented the proposal to import and market Olipudasealfa powder for concentrate for solution for infusion 20 mg vial indicated as enzyme replacement therapy for long-term treatment of non-central nervous system (CNS) manifestations of acid sphingomyelinase deficiency (ASMD) in paediatric and adult patients with a request for waiver of Phase III & Phase IV clinical trial in the country. The committee noted that the drug falls under the orphan drug category and proposed indication is a rare disease. The committee also noted that the drug has been granted 'orphan drug status' in US, EU, UK, Australia, Japan, Brazil & Malaysia and approved in 36 countries including USA, EU, UK, Japan, Brazil and UAE. After detailed deliberation, the committee recommended for grant of permission to import and market the drug with waiver of local Phase III & IV clinical trial in the country.
SND Division			
7.	SND/MA/18/000025 Cholecalciferol aqueous Injection 6,00,000 IU	M/s Cadila Pharmaceuticals	The firm presented the proposal of manufacture and marketing permission of Cholecalciferol aqueous injection 6,00,000 IU alongwith serum calcium level data of both the groups (Reference vs Test) after drug administration in PK/PD study before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacture and market of Cholecalciferol aqueous injection 6,00,000 IU for the proposed indication as "Indicated for the treatment of Vitamin D3 deficiency".

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FDC Division			
8.	FDC/MA/22/000079 Pioglitazone HCl IP eq. to Pioglitazone 7.5/15 mg + Vildagliptin50/50 mg tablets	M/s Mascot Health	In light of the earlier SEC recommendation dated 14.06.2022, the firm presented the BE study report. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC of Pioglitazone HCl IP eq. to Pioglitazone 15 mg + Vildagliptin 50 mg tablets. As regard to lower strength i.e. FDC of Pioglitazone HCl IP eq. to Pioglitazone 7.5 mg + Vildagliptin 50 mg tablets, firm should submit the Phase III CT Study protocol to CDSCO for review by the committee.
9.	FDC/MA/21/000043 Teneligliptin hydrobromide hydrate eq to Teneligliptin IP + Metformin hydrochloride (SR) IP + Dapagliflozinpropanediol monohydrate eq to Dapagliflozin (20mg/20mg/20mg/20mg+ 500mg/1000mg/500mg/1000mg+ 5mg/5mg/10mg/10mg) Film coated bilayered tablet	M/s. Synokem Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 18.03.2021 & 19.03.2021, the firm presented their proposal alongwith justification for BE and CT Study waiver. After detailed deliberation, the committee considered the request of the firm for BE study waiver. As regard to Phase III CT Study waiver, the committee noted that: 1. The FDC is not approved internationally. 2. Insufficient data presented by the firm. 3. There is no unmet need. In view of above, committee reiterated its recommendation dated 18.03.2021 & 19.03.2021 with respect to Phase III CT Study. Accordingly, firm should conduct the Phase III CT Study after taking NOC from CDSCO.
10.	FDC/MA/22/000325 DapagliflozinPropanediol monohydrate eq to Dapagliflozin + Linagliptin + Metformin HCleq to Metformin (as sustained release) (5mg/5mg/10mg/10mg/5mg/5mg/10mg/10mg +2.5mg/2.5mg/2.5mg/2.5m	M/s. Theon Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 24.11.2022. The firm presented the BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conducting the BE study. The result of the BE study shall be presented before the committee for further review of Phase III CT study protocol.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	g/5mg/5mg/5mg+500mg/1000mg/500mg/1000mg/500mg/1000mg/500mg/1000mg) tablets		
11.	FDC/MA/21/000235 Vildagliptin SR 50mg/50mg/100mg/100mg + Metformin (SR) 500mg/1000mg/500mg/1000mg tablets	M/s. Pure & Cure Healthcare Pvt. Ltd.	In light of the earlier SEC recommendation dated 14.06.2022, the firm presented the BE Study report alongwith justification for Phase III CT study waiver. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC.
12.	FDC/MA/21/000144 Sitagliptin Phosphate IP eq to Sitagliptin + Pioglitazone Hydrochloride IP eq. to Pioglitazone + Metformin Hydrochloride IP (as sustained released form) (100mg/100mg+15mg/15mg+500mg/1000mg) tablets	M/s. Alkem Laboratories Ltd.	In light of the earlier SEC recommendation dated 24.08.2021 & 25.08.2021, the firm presented the BE and CT study report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC.
13.	FDC/MA/21/000001 Vildagliptin 50mg + Dapagliflozin 5mg tablets	M/s. USV Private Limited	In light of the earlier SEC recommendation dated 18.03.2021 & 19.03.2021, the firm presented the BE and CT study report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC.
14.	FDC/MA/21/000017 Pyridoxal-5-Phosphate+Methylcobalamin +L-Methylfolate Calcium + Biotin (0.5mg+1500mcg+1mg+5mg) tablets	M/s. Pure and Cure Healthcare Pvt. Ltd.	In light of the earlier SEC recommendation dated 18.03.2021, the firm presented their proposal alongwith justification. After detailed deliberation, committee opined that firm should submit the justification/evidence/ peer reviewed literature for proposed indication alongwith Phase III CT protocol for further review by the committee.
15.	FDC/MA/21/000274 Dapagliflozin + Sitagliptin +Metformin HCL (ER) (10 mg + 50mg + 500mg, 10 mg + 50mg + 1000mg & 10mg + 100mg + 100mg)	M/s Zydus	In light of the earlier SEC recommendation dated 21.12.2021 & 22.12.2021, the firm presented BE study protocol alongwith justification for Phase III CT study waiver. After detailed deliberation, the committee recommended for grant of permission for conducting the BE study.

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	tablet		The result of the BE study shall be presented before the committee for further review on request for waiver of Phase III CT study.
16.	FDC/MA/21/000034 Sitagliptin phosphate monohydrate + Metformin HCl + Voglibose (50mg/50mg+500mg/500mg+0.2mg/0.3mg) tablets	M/s. Hetero Labs Ltd.	The proposal was deferred for next meeting.
17.	FDC/MA/22/000289 Linagliptin5mg/5mg + Metformin HCl 500mg/1000mg tablets	M/s. Hetero Labs Ltd.	The firm presented their proposal before the committee along with BE protocol. After detailed deliberation, committee recommended for grant of permission for conducting the BE study with condition that 1. The firm should exclude the COVID-19 patients from the study. 2. Gender should be clearly mentioned. The result of the study shall be presented before the committee for further review.
18.	FDC/MA/22/000337 Metformin HCl IP (as extended release) 1000mg/500mg/1000mg + Linagliptin 5mg/5mg/5mg + Empagliflozin 10mg/25mg/25mg tablets	M/s. Pure & Cure	The firm presented their proposal before the committee along with BE protocol. The firm informed the committee that the product in strengths i.e 1000mg + 5mg + 25mg & 1000mg + 5mg + 10mg is already approved by USFDA. After detailed deliberation, committee recommended for conducting the BE study with condition that 1. The firm should exclude the COVID-19 patient from the study. 2. Gender should be clearly mentioned. The result of the study shall be presented along with Phase IV CT protocol before the committee for further review.
19.	FDC/MA/22/000338 Metformin HCl IP (as extended release) 500mg/1000mg/500mg/100	M/s. Pure & Cure	The firm presented their proposal before the committee along with BE and CT protocol. After detailed deliberation, committee recommended for grant of permission for

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	0mg+Linagliptin 5mg/5mg/5mg/5mg+ Dapagliflozin 5mg/5mg/10mg/10mg tablets		conducting the CT study and BE study with condition that 1. Firm should exclude the COVID-19 patient from the study. 2. Gender should be clearly mentioned. The result of the BE study shall be presented to the committee before initiation of the CT study.
20.	FDC/MA/22/000345 Metformin HCl (as sustained release) 500mg/1000mg+Vildagliptin (as sustained release) 100mg/100mg + Dapagliflozin 5mg/5mg tablets	M/s. Exemed Pharmaceuticals	The firm presented their proposal before the committee. The committee noted that product is already approved in higher strengths i.e 1000mg + 100mg + 10mg & 500mg + 100mg + 10mg by CDSCO. After detailed deliberation, committee recommended for grant of permission to manufacture & market the FDC.
21.	FDC/MA/22/000339 Glimepiride 1mg/2mg/1mg/2mg+Sitagliptin Phosphate Monohydrate IP eq to Sitagliptin50mg/50mg/100mg/100mg tablets	M/s. Exemed Pharmaceuticals	The firm presented their proposal before the committee along with BE and CT protocol. After detailed deliberation, committee recommended for conducting the CT study and BE study with condition that 1. The firm should exclude the COVID-19 patient from the study. 2. Gender should be clearly mentioned. The result of the BE study shall be presented to the committee before initiation of the CT study.
22.	FDC/MA/22/000306 Metformin HCl IP (as ER) + Dapagliflozin Propanediol Monohydrate Eq to Dapagliflozin + Sitagliptin (500mg+50mg+5mg, 1000mg+50mg+5mg &500mg+100mg+10mg) film coated tablets	M/s. Theon Pharmaceuticals Ltd.	The firm presented their proposal alongwith justification for CT and BE study waiver. The firm informed the committee that they wish to withdraw the two strengths of the FDC i.e. (500mg+50mg+5mg, & 1000mg +50mg +5mg). The committee noted that the FDC of Metformin HCl IP (as ER) 500mg + Dapagliflozin 500mg + Sitagliptin 10mg film coated tablets is already approved by CDSCO on 16.09.2022. In view of above, CDSCO may accordingly take decision.
23.	FDC/MA/22/000367	M/s. Akums	The proposal was deferred for next meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	DapagliflozinPropanediol Monohydrate eq. to Dapagliflozin 10mg + Pioglitazone HCl IP eq. to Pioglitazone 15mg tablets		
24.	FDC/MA/22/000225 Dapagliflozinpropanediol to monohydrate eq to Dapagliflozin 5mg/5mg +Sitagliptin +50mg/50mg + Metformin	M/s. Sun Pharma Laboratories Ltd.	The proposal was deferred for next meeting.
25.	FDC/MA/22/0000411 Metformin HCl IP (As extended release 500 mg/1000mg/500mg/1000m g +Glimepride IP 1mg/1mg/2mg/2mg + Empagliflozin 10mg 10mg/10mg/10mg Tablets	M/s. Pure & Cure Healthcare Pvt. Ltd.	The proposal was deferred for next meeting.
26.	FDC/MA/22/000205 DapagliflozinPropanediol Monohydrate eq. to Dapagliflozin + Linagliptin (5mg + 5mg & 10mg + 5mg) tablets	M/s. Hetero	The proposal was deferred for next meeting.
27.	FDC/MA/22/000305 Dapagliflozin 5mg + Vildagliptin 50mg + Metformin 500mg tablets	M/s. Windlas	The proposal was deferred for next meeting.
28.	FDC/MA/22/000358 Metformin HCl IP (as ER) 500mg/1000mg + Dapagliflozin Propanediol monohydrate eq to Dapagliflozin 5mg/5mg+Sitagliptin phosphate monohytdrateeq to Sitagliptin 50mg/50mg tablets	M/s. Akums	The proposal was deferred for next meeting.
29.	FDC/MA/22/000317	M/s Exemed Pharmaceuticals	The proposal was deferred for next meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Metformin HCL IP (as ER) 500mg/1000mg+Dapagliflozin Propanediol monohydrate eq to Dapagliflozin 5mg/5mg+Sitagliptin phosphate monohytdrateeq to Sitagliptin 50mg/50mg tablets		
GCT Division			
30.	CT/73/22 Online Submission (33271) LY3209590	M/s. Eli Lilly	The firm presented Phase III clinical trial study Protocol no. I8H-MC-BDCV before the committee. After detailed deliberation, committee recommended for grant permission to conduct the trial.
31.	CT/74/22 Online Submission (33286) LY3209590	M/s. Eli Lilly	The firm has withdrawn the application.
32.	CT/112/22 Online Submission (34060) LY3298176	M/s. Eli Lilly	The firm presented phase III clinical trial study Protocol no. I8F-MC-GPIJ version 1.0 dated 14/JUNE/2022 before the committee. After detailed deliberation, committee recommended for grant of permission to conduct the trial
33.	CT/136/20 Online Submission (20694) Liraglutide	M/s. Novo-Nordisk	The firm presented clinical trial protocol NN8022-4392 amendment version4.0, dated 19-May-2022 before the committee. After detailed deliberation, committee recommended for grant approval to the amended protocol.
34.	CT/07/22 Online Submission (21675) Insulin icodec	M/s. Novo-Nordisk	The firm presented clinical trial protocol NN1535-4591 amendment version 3.0, dated 10-Aug-2021 before the committee. After detailed deliberation, committee recommended for grant approval to the amended protocol.
35.	CT/128/22 Online Submission (34468)	M/s. Novo-Nordisk	The firm presented clinical trial protocol NN9838-4609 before the committee. After detailed deliberation, committee

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Cagrilintide S.C. 2.4 mg		recommended for grant permission to conduct the study.
36.	CT/64/15 Offline Submission (10190) NNC0195-0092	M/s. Novo-Nordisk	The firm presented clinical trial protocol NN8640-4172 amendment version 7.0, dated 12-Sep-2022 before the committee. After detailed deliberation, committee recommended for grant approval to the amended protocol.
New Drugs Division			
37.	ND/MA/22/000124 Imeglimin Hydrochloride Sustained release tablets 500mg& 1000mg	M/s. Synokem Pharmaceuticals Ltd	The proposal was deferred for next meeting.