Recommendations of the SEC (Endocrinology & Metabolism) made in its 99th meeting held on 21.03.2022 & 22.03.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000054 FDC of Lobeglitazone 0.5 mg +Glimepiride 1 mg tablet	M/s. Glenmark	In light of earlier SEC recommendation dated 26.04.2022 & 29.04.2022, the firm presented the clinical trial report before the committee. The committee observed that the Lobeglitazone Tablets 0.5mg is approved in India. The clinical trial results demonstrate the efficacy and safety of combination treatment of Lobeglitazone and Glimepiride in Indian patient with Type 2 Diabetes Mellitus. After detailed deliberation, the committee recommended for grant of permission to manufacture and market of Lobeglitazole Sulphate 0.5mg + Glimepiride 1mg Tablet for the proposed indication subject to the condition that 1. The drug should be sold by retail only under the prescription of Endocrinologist or Internal Medicine Specialist. 2. The firm should conduct Phase IV clinical trial study. Accordingly, firm should submit Phase IV clinical trial protocol within 3 months of the approval of the drug.
2.	ND/CT/23/000001 Imeglimin HCl 500mg and 1000mg	M/s. Synokem Pharmaceuticals Ltd.	In light of SEC recommendation dated 16.02.2023 & 17.02.2023, the firm presented the amended protocol for conduct of Phase IV study. After detailed deliberation, the committee recommended for the grant of permission to conduct the Phase IV clinical trial with Imeglimin HCl tablet 500mg and 1000mg as per the amended protocol presented.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
3.	BIO/CT/22/000044 Insulin Aspart Mix 70/30 Injection	M/s. Mankind Pharma Ltd.	In light of earlier SEC recommendation dated 24.11.2022, the firm presented the proposal to conduct PK/PD study titled "A randomized, double blinded, balanced, two treatment, two period, two sequence, cross over, euglycemic clamp study to compare the pharmacokinetic and pharmacodynamics activity of RapilinTM 30 (30% Insulin aspart and 70% Insulin aspart protamine suspension) injection with NovoMix 30 after single dose subcutaneous injection in healthy human adult male subjects under fasting condition" vide protocol no 001-23, version No.1, final, dated 16 mar 2023. After detailed deliberation, the committee recommended for conduct of the PK/PD study of the drug as per the presented protocol and the results should be submitted to CDSCO for further review and approval of Phase III protocol which was discussed in the 95th SEC (Endocrinology & Metabolism) meeting dated 24-11-2022.
SND Division			
4.	SND/MA/23/000039 Semaglutide 14 mg Tablet	M/s. Torrent Pharmaceuticals Limited	The firm presented the proposal to conduct BA/BE study of Semaglutide 14 mg Tablet (using synthetic Semaglutide) before the committee as per protocol number Project No. 22-143, version No. 01 dated 23-11-2022. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per protocol presented.
5.	SND/MA/22/000363 Cholecalciferol aqueous injection 600000IU	M/s. Akums Drugs & Pharmaceuticals Limited	The firm did not turn up for presentation.
6.	SND/MA/23/000014 Semaglutide 14 mg Tablets	M/s. Torrent Pharmaceuticals Limited	The firm presented the proposal to conduct BA/BE study of Semaglutide 14 mg tablet (using synthetic Semaglutide) before the committee as per protocol number Project No. 22-144, version No.01 dated 07-12-2022.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per protocol presented.
7.	SND/MA/22/000365 Cholecalciferol Sachets 60000.000 IU	M/s. Zuventus Healthcare Limited	The firm presented the proposal for manufacture and marketing of Cholecalciferol granules in sachets 60,000 IU for already approved indication alongwith BE and CT waiver justification before the committee. The committee opined that the firm could not present proper justification, adequate supporting data and supportive literature for BE study and CT waiver. After detailed deliberation, the committee recommended that firm should submit & present proper justification and adequate data alongwith published literature in support of BE study and CT waiver for further review by the committee.
8.	SND/MA/23/000033 Cholecalciferol oral granules 60000IU	M/s. Stedman Pharmaceuticals Pvt. Ltd.	The firm presented the proposal for manufacture and marketing of Cholecalciferol granules in sachets 60,000 IU for already approved indication alongwith BE study and CT waiver justification before the committee. The committee opined that the firm could not present proper justification, adequate supporting data and supportive literature for BE study and CT waiver. After detailed deliberation, the committee recommended that firm should submit & present proper justification and adequate data alongwith published literature in support of BE study and CT waiver for further review by the committee.
9.	SND/MA/23/000034 Cholecalciferol oral Drops 800IU/ml	M/s. Stedman Pharmaceuticals Pvt. Ltd.	The firm presented the proposal for manufacture and marketing of Cholecalciferol granules in sachets 60,000 IU for already approved indication alongwith BE and CT waiver justification, before the committee. The committee opined that the firm could

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			not present proper justification, adequate supporting data and supportive literature for BE study and CT waiver. After detailed deliberation, the committee recommended that firm should submit & present proper justification and adequate data alongwith published literature in support of BE study and CT waiver for further review by the committee.
10.	SND/MA/23/000032 Cholecalciferol oral suspension 800IU/5ml	M/s. Stedman Pharmaceuticals Pvt. Ltd.	The firm presented the proposal for manufacture and marketing of Cholecalciferol granules in sachets 60,000 IU for already approved indication alongwith BE and CT waiver justification, before the committee. The committee opined that the firm could not present proper justification, adequate supporting data and supportive literature for BE study and CT waiver. After detailed deliberation, the committee recommended that firm should submit & present proper justification and adequate data alongwith published literature in support of BE study and CT waiver for further review by the committee.
11.	SND/MA/23/000030 Cholecalciferol oral suspension 400IU/5ml	M/s. Stedman Pharmaceuticals Pvt. Ltd.	The firm presented the proposal for manufacture and marketing of Cholecalciferol granules in sachets 60,000 IU for already approved indication alongwith BE and CT waiver justification, before the committee. The committee opined that the firm could not present proper justification, adequate supporting data and supportive literature for BE study and CT waiver. After detailed deliberation, the committee recommended that firm should submit & present proper justification and adequate data alongwith published literature in support of BE study and CT waiver for further review by the committee.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
12.	SND/MA/23/000031 Cholecalciferol Tablets 2000IU	M/s. Stedman Pharmaceuticals Pvt. Ltd.	The firm presented the proposal for manufacture and marketing of Cholecalciferol granules in sachets 60,000 IU for already approved indication alongwith BE and CT waiver justification, before the committee. The committee opined that the firm could not present proper justification, adequate supporting data and supportive literature for BE study and CT waiver. After detailed deliberation, the committee recommended that firm should submit & present proper justification and adequate data alongwith published literature in support of BE study and CT waiver for further review by the committee.
FDC Division			
13.	FDC/MA/22/000216 Teneligliptin HBr Hydrate IP eq. to Teneligliptin + Metformin HCl IP (As Extended release form) + Pioglitazone HCl IP eq. to Pioglitazone (20mg+500mg+15mg &20mg+1000mg+15 mg) Film Coated bilayered tablets	M/s. Akums Drugs & Pharmaceuticals Ltd.	As per the condition mentioned in Form CT-23 dated 06.02.2023, firm presented the Phase-IV CT Protocol before the committee. After detailed deliberation, the committee recommended for conducting the Phase IV clinical trial study. The result of the study should be presented before the committee for review.
14.	FDC/MA/22/000146 Teneligliptin IP +Metformin HCl IP +Pioglitazone HCl IP (20mg/20mg+500mg/ 1000mg+15mg/15mg) film coated bilayered Tablets	M/s. Synokem Pharmaceuticals Ltd.	As per the condition mentioned in Form CT-23 dated 04.11.2022, the firm presented the Phase-IV CT Protocol before the committee. After detailed deliberation, the committee recommended for conducting the Phase IV clinical trial study. The result of the study should be presented before the committee for review.
15.	FDC/MA/23/000025 Sitagliptin Phosphate	M/s. Akums Drugs & Pharmaceuticals Ltd.	The proposal was deferred for next meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	monohydrate IP Eq. to Sitagliptin 50mg/100mg + Lobeglitazone sulfate 0.5mg/0.5mg tablets		
16.	FDC/MA/23/000026 Sitagliptin Phosphate monohydrate IP 100mg + Lobeglitazone sulfate 0.5mg Film Coated tablets	M/s. Synokem Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
17.	FDC/MA/23/000033 Lobeglitazone sulfate 0.5mg/0.5mg + Dapagliflozinpropane diol monohydrate eq. to Dapagliflozin 5mg/10mg tablets	M/s. Glenmark Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
18.	FDC/MA/23/000041 Rosuvastatin Calcium IP eq. to Rosuvastatin5mg/10mg+Linagliptin 5mg/5mg Tablets	M/s. Exemed Pharmaceuticals	The proposal was deferred for next meeting.
19.	FDC/MA/23/000043 Metformin HCl IP (As extended release form) 500mg / 1000mg / 500mg /1000mg + Glimepiride IP 1mg1mg/2mg/2mg + Lobeglitazone sulfate 0.5mg/0.5mg/0.5mg/0.5mg tablets	M/s. Akums Drugs & Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
20.	FDC/MA/22/000317 Metformin HCL IP 500mg/1000mg + DapagliflozinPropane diol monohydrate eq to Dapagliflozin	M/s Exemed Pharmaceuticals	In light of the earlier SEC recommendation dated 16.02.2023 & 17.02.2023, firm presented their proposal before the committee. The committee noted that -

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	5mg/5mg +Sitagliptin phosphate monohytdrateeq to sitagliptin 50mg/50mg tablets		1. Permission has already been granted to M/s. Sun Pharma on 13.03.2023 for FDC of Metformin HCL IP 500mg/1000mg + Dapagliflozin Propanediol monohydrate eq to Dapagliflozin 5mg/5mg +Sitagliptin phosphate monohytdrate eq to Sitagliptin 50mg/50mg tablets. 2. The proposed FDC has already been approved to M/s. Akums in higher strengths i.e FDC of Metformin HCl IP (as ER) 500mg/1000mg+Dapagliflozin Propanediol monohydrate eq to Dapagliflozin 10mg/10mg+Sitagliptin phosphate monohytdrate eq to Sitagliptin 100mg/100mg tablets on 18.11.2022. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.
21.	FDC/MA/22/000358 Metformin HCl IP (as ER) 500mg/1000mg+Dapagliflozin Propanediol monohydrate eq to Dapagliflozin 5mg/5mg+Sitagliptin phosphate monohytdrate eq to sitagliptin 50mg/50mg tablets	M/s. Akums	In light of the earlier SEC recommendation dated 16.02.2023 & 17.02.2023, firm presented their proposal before the committee. The committee noted that - 1. The permission has already been granted to M/s. Sun Pharma on 13.03.2023 for FDC of Metformin HCL IP 500mg/1000mg + Dapagliflozin Propanediol monohydrate eq to Dapagliflozin 5mg/5mg +Sitagliptin phosphate monohytdrate eq to Sitagliptin 50mg/50mg tablets. 2. The proposed FDC has already been approved to the applicant in higher strengths i.e FDC of Metformin HCl IP (as ER) 500mg/1000mg+Dapagliflozin Propanediol monohydrate eq to Dapagliflozin 10mg/10mg+Sitagliptin phosphate monohytdrate eq to

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			Sitagliptin 100mg/100mg tablets on 18.11.2022. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with the condition to conduct the Phase IV clinical trial study. Accordingly, Phase IV clinical trial study protocol should be submitted to CDSCO for further review by the committee.
22.	FDC/MA/21/000043 Teneligliptin hydrobromide hydrate eq to Teneligliptin IP + Metformin hydrochloride (SR) IP + Dapagliflozin propanediol 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.	The proposal was deferred for next meeting.
GCT Division			
23.	CT/71/22 Online Submission (22901) Semaglutide	M/s. Novo Nordisk	The firm presented the proposal for protocol amendment version 4.0 dated 19 August 2022, Protocol No: NN9838-4608 before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment version 4.0 dated 19 August 2022.
24.	CT/152/21 Online Submission (23002) Semaglutide	M/s. Novo Nordisk	The firm presented the proposal for increase of number of subjects from 30 to 50 for ongoing clinical study protocol no: NN9535-4533, Protocol version 6.0 (06-June-2022). After detailed deliberation, the committee recommended for approval of 20 additional subjects from India.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
25.	FDC/MA/22/000325 Linagliptin + Dapagliflozin +Metformin(ER) 2.5mg+5mg+500mg, 2.5mg+5mg+1000mg, 5mg+5mg+500mg, 5mg+5mg+1000mg, 2.5mg+10mg+500mg, 2.5mg+10mg+ 1000mg, 5mg+10mg+500mg, 5mg+10mg+1000mg Tablets.	M/s. Theon Pharmaceuticals Ltd	In light of the earlier recommendation dated 19.01.2023 & 20.01.2023, the firm presented the Phase III clinical trial study protocol for one strength only i.e FDC of Linagliptin 5mg+ Dapagliflozin 10mg+Metformin(ER) 1000mg tablets. After detailed deliberation, the committee recommended that firm should present the rationality, dosing schedule, therapeutic justification etc. of lower strengths i.e 2.5mg+5mg+500mg, 2.5mg+5mg+1000mg, 5mg+5mg+500mg, 5mg+5mg+1000mg, 2.5mg+10mg+500mg, 2.5mg+10mg+1000mg. Accordingly, the firm should present its proposal along with revised Phase III clinical trial protocol by incorporating all proposed strengths for further review by the SEC.