Recommendations of the SEC (Endocrinology & Metabolism) made in its 92nd meeting held on 09.09.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/21/000035 Etelcalcetide Injection 2.5mg/0.5ml, 5mg/ml	M/s. Amgen Technology Pvt. Ltd.	The firm didn't turn up for presentation.
2.	ND/MA/22/000106 Trelagliptin Succinate12.5, 25, 50, 100mg Tablets	M/s. Synokem pharmaceuticals Ltd.	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Trelagliptin 12.5, 25, 50 & 100 mg Tablets along with Phase III clinical trial protocol and BE study protocol before the committee. After detailed deliberation, the committee recommended that firm should conduct BE study and submit the BE study results before the committee for further consideration.
3.	ND/MA/22/000109 Lobeglitazone Sulfate 0.5/0.5mg + Metformin Hydrochloride 500/1000mg ER Tablets	M/s. Glenmark	The firm presented their proposal for manufacturing and marketing of Lobeglitazone Sulphate 0.5/0.5mg + Metformin HCL 500/1000mg ER tablets along with safety efficacy and safety data. After detailed deliberation, the committee recommended that the firm should submit the complete clinical trial & present the report before the committee for further consideration.
Biological Division			
4.	BIO/CT04/FF/2022/32087 Liraglutide Injection (r-DNA origin) 6mg/mL(18mg/3mL)	M/s. Virchow Biotech Limited	The firm presented the proposal to conduct "An open label, balanced, randomized, two-treatment, two-sequence, two-period, single-dose, cross-over, bioequivalence study of Liraglutide 0.6 mg Injection (6 mg/ml) (Test) (prefilled pen) of Virchow Biotech Private Limited, India and Victoza® (Liraglutide) Injection in pre-filled pen 0.6 mg (6 mg/mL) (Reference) of Novo Nordisk A/S Novo Allé DK-2880 Bagsværd, Denmark, in normal, healthy adult, human subjects under fasting conditions" vide protocol number AR005-22,version 01 dated 11.05.2022. After detailed deliberation, the committee recommended to grant permission to

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			conduct the study as presented.
SND Division			
5.	SND/MA/22/000235 Alpha Lipoic Acid Injection 25 mg/ml (600 mg/24ml) (intravenous Infusion)	M/s. La Renon	The firm didn't turn up for presentation.
FDC Division			
6.	FDC/MA/000009,10, 11,12 Gliclazide 80mg/80mg/40mg/40 mg + Metformin 500mg/500mg/500mg /500mg + Voglibose 0.3mg/0.2mg/0.3mg /0.2mg tablets	M/s. Eris Life Sciences	The firm didn't turn up for presentation
7.	FDC/MA/20/000131 Pioglitazone 30mg/100mg + Vildagliptin 15mg/100mg film coated bilayered tablet	M/s. Synokem Pharmaceuticals	Inlight of earlier SEC recommendation dated 14.06.2022, the firm presented the BE study results before the committee. After detailed deliberation, the committee recommended for initiation of the Phase III CT study for which clinical trial permission has already been issued.
8.	FDC/MA/22/000222 Metformin Hydrochloride (as sustained release) 1000mg/500mg/500mg/1000mg+ Teneligliptin Hydrobromide Hydrate Eq. to Teneligliptin 20mg/20mg/20mg/20 mg +Dapagliflozin Propanediol Monohydrate Eq. to Dapoagliflozin 10mg 5mg/10mg/5mg Film coated tablet	M/s. Pure & Cure Healthcare	The firm presented the proposal alongwith BE study protocol. After detailed deliberation, the committee recommended to present the Phase III CT study protocol in the next SEC meeting.

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9.	FDC/MA/22/000146 Teneligliptin IP 20mg/20mg+Metformin HCl IP 500mg/1000mg +Pioglitazone HCl IP 15mg/15mg	M/s. Synokem Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
10.	FDC/MA/22/000257 Metformin Hydrochloride IP (As extended Release) 1000mg/500mg/1000mg/1000mg/500mg/1000mg + Empagliflozin 5mg/10mg/10mg/12.5mg/25mg/25mg	M/s. Pure & Cure Healthcare Pvt. Ltd.	The proposal was deferred for next meeting.
11.	FDC/MA/21/000254 Gliclazide SR 30mg/60mg + Sitagliptin 100mg/100mg tablets	M/s. Eris Lifesciences Ltd.	The firm presented their proposal along with BE and Phase III Clinical trial study protocol. After detailed deliberation, the committee recommended for conducting the proposed Phase III CT study and BE study with the condition that BE study results should be presented before the SEC before initiation of the Phase III trial.
12.	FDC/MA/21/000284 Metformin hydrochloride IP (as an extended release form) 1000mg + Sitagliptin Phosphate monohydrate IP 100mg + Dapagliflozin Propanediol monohydrate 10mg tablets	M/s. Exemed	The proposal was deferred for next meeting.
13.	FDC/MA/22/000231 Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg/5mg +	M/s. Exemed	The proposal was deferred for next meeting.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg/15mg tablets		
GCT Division			
14.	CT/02/20 Online Submission (16791) Tirzepatide versus Dulaglutide	M/s. Eli Lilly	The firm presented the proposed amendment in Phase III protocol No: 18F-MC-GPGN(d) dated 14Oct2021, before the committee. After detailed deliberation, the committee recommended for the protocol amendment.
15.	CT/04/20 Online Submission (18063) Samopacitan	M/s. Novo-Nordisk	The firm presented the proposed protocol amendment version 8.0 dated 08MAR2022 under the REAL 5 protocol no. NN8640-4245, before the committee. After detailed deliberation, the committee recommended for grant of permission for the conduct of trial as per the proposed amended protocol.
16.	CT/58/17 Online Submission (18579) CV181375 (D1680C00019)	M/s. PRA India	The firm presented proposed protocol amendment Version 08 dated 23Feb2022 under the phase 3 protocol no. CV181375 (D1680C00019) before the Committee. After detailed deliberation, the committee recommended for grant of permission for the amended protocol.
17.	CT/07/22 Online Submission (18712) IcoSema and insulin icodec	M/s. Novo-Nordisk	The firm presented justification for the waiver of the condition no. (1) vide the permission dated 02-JUN-2022 for the COMBINE-1 trial protocol no. NN1535-4591, version 3.0 dated 10Aug2021, before the committee. After detailed deliberation, the committee recommended for removal of the 'interim analysis' from the said condition however the firm should submit the safety data of initial 30 subjects for review by committee and further continuation of the study in the country.
18.	CT/14/22 Online Submission (18676) Paltusotine	M/s. Pharma-Olam	The firm presented the India specific addendum version 1.0 to protocol version 2.0 dated 15/06/2022 in light of earlier SEC recommendation that the applicant should submit India Specific protocol addendum prior to inclusion of first

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			subject w.r.t to not collection and analysis of Acromegaly Quality of life questionnaires/scale at clinical trial site and accordingly ICD to be submitted. The committee noted that the applicant has submitted India specific addendum version 1.0 to protocol version 2.0 dated 15/06/2022 and revised ICD. After detailed deliberation, the committee agreed to waive off the earlier condition No. 1 and recommended for grant of permission to conduct the proposed trial as presented.
19.	CT/71/22 Online Submission (33251) Cagrilinitide + Semaglutide	M/s. Novo-Nordisk	The firm presented the proposed Phase IIIa trial protocol no. NN9838-4608, Version 03 dated 24Jun2022 (REDEFINE) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the trial with the condition that the firm should submit the trial safety and efficacy data to the committee for review and further initiation of the extension phase.