Recommendations of the SEC (Endocrinology & Metabolism) made in its 104th meeting held on 22.08.2023 & 23.08.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	4-66/Novonordisk /PAC-R Semaglutide/2020-BD Semaglutide Tablets 3mg,7mg and 14mg	M/s.Novo-Nordisk	The firm presented their proposal for amending approved indication of Semaglutide tablets (Rybelsus 3mg, 7 mg and 14 mg tablets) in line with supplement approval of USFDA. After detailed deliberation, the committee recommended to amend the indication as:- "RYBELSUS is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of use. •RYBELSUS has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis (see section 4.4 Special warnings and precautions for use) •RYBELSUS is not indicated for use in patients with type 1 diabetes mellitus" **instead of** Semglutide is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus • As monotherapy when metformin is considered inappropriate due to intolerance or contraindications • In combination with other medicinal products for the treatment of diabetes. (Dr. Sadish kumar Kamalnthan did not participate in deliberation.)
2.	BIO/CT04/FF/2021/27169 Insulin Lispro UR	M/s. Eli-Lilly	The firm presented their proposal to conduct Phase IV study of Insulin Lispro Ultra rapid (UR) injection 100 units/mL solution for injection titled as "a 26-week, multicenter, open-label, single-arm, Phase 4 study to assess the safety of Lyumjev in adult patients with type 2 diabetes mellitus in India" vide protocol No. I8B-MC-ITTA (b) dated 01.05.2023. After detailed deliberation, the committee recommended for approval of the

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			proposed protocol to conduct the Phase IV clinical trial as presented by the firm.
FDC Division			
3.	FDC/MA/22/000333 Metformin HCL IP as extended release 500mg/500mg/1000mg/1000mg + Glimepiride IP 1mg/2mg/1mg/2mg + Sitagliptin phosphate monohydrate eq. to Sitagliptin IP 50mg/50mg/50mg/50 mg Tablets	M/s. Innova Captab Limited	The firm didn't turn up for presentation.
4.	FDC/MA/23/000182 Linagliptin 2.5mg/2.5mg + Imeglimin HCL 500mg/1000mg film coated tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal along with BE study and Phase III clinical trial protocol before the committee. The firm informed that Phase IV clinical trial study of Imeglimin HCL is ongoing and clinical trial report is yet to be submitted. 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.	FDC/MA/22/000422 DapagliflozinPropanediol Monohydrate + Linagliptin(5mg/10mg/5mg/10mg +2.5mg/2.5mg/5mg/5mg) Tablets	M/s. Windlas	The firm didn't turn up for presentation.
6.	FDC/MA/21/000166 DapagliflozinPropanediol Monohydrate eq. to Dapagliflozin + Glimepiride IP + Metformin Hydrochloride IP (as extended release) (10mg/10mg+1mg/2mg+1000mg/1000mg) Tablets	M/s. Sun Pharma Laboratories Ltd.	In light of earlier SEC recommendation dated 24.08.2021 & 25.08.2021 the firm presented their proposal along with Phase III clinical trial report and BE study report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC, subject to condition that the firm should conduct Phase IV clinical trial. Accordingly, the firm should submit

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			Phase IV clinical trial protocol to CDSCO within 03 months of approval for review by the committee.
7.	FDC/MA/23/000141 Metformin HCl IP 500mg/500mg + Glimepiride IP 1mg/2mg + Sitagliptin phosphate monohydrate IP 50mg/50mg Tablets	M/s. Mascot Health Series Pvt. Ltd.	The firm didn't turn up for presentation.
8.	FDC/MA/23/000036 Metformin Hydrochloride IP (as extended release) 500mg/1000mg/500mg/1000mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin100mg/100mg/50mg/50mg + DapagliflozinPropanediol Monohydrate eq. to Dapagliflozin 5mg/5mg/10mg/10mg Tablets	M/s. Akums Drugs & Pharmaceuticals	The firm presented their proposal before the Committee. After detailed deliberation, the Committee opined that: 1. The firm did not present any published literature in support of significant clinical need for the proposed strengths of the FDC. 2. The product is not approved internationally. 3. Dosing frequency of the proposed strengths of the FDC is not matching. 4. There is no unmet need for the proposed strengths of the FDC. In view of above, the firm should submit above data for further review by the committee.
9.	FDC/MA/23/000013 Metformin HCL IP 500mg/1000mg + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg/10mg + Linagliptin 5mg/5mg Tablets	M/s. Mascot Health Series Pvt. Ltd.	The firm presented their proposal along with BE study report and requested for Phase III clinical trial wavier before the committee. After detailed deliberation, the committee considered the BE study report. Further, committee did not consider the request of clinical trial wavier and recommended to conduct Phase III clinical trial with the proposed FDC. Accordingly, Phase III clinical trial protocol should be submitted by the firm for further review by the committee.
10.	FDC/MA/20/000131 Pioglitazone + Vildagliptin (30mg/100mg +	M/s. Synokem Pharmaceuticals	In light of earlier SEC recommendation dated 14.06.2022 & 09.09.2022, the firm presented clinical trial report before the committee. The committee noted that firm has

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	15mg/100mg) film coated bilayered tablet		already presented BE study report in SEC meeting held on 09.09.2022. The committee also noted that clinical trial study was conducted in low risk individual and small sample size. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC, subject to condition that the firm should conduct Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 03 months of approval for review by the committee.
11.	FDC/MA/23/000015 Metformin Hydrochloride IP (As ER) + Lobeglitazone sulfate (500mg+ 0.25mg) tablets	M/s. Akums Drugs & Pharmaceuticals	In light of earlier SEC recommendation dated 18.05.2023 & 19.05.2023, the firm presented their proposal along with BE study protocol in higher strength before the committee. The firm informed that they have also submitted separate application for higher strength (0.5 mg +1000mg). After detailed deliberation, the committee recommended that the firm should submit BE protocol for the higher strength in the said application for further consideration.
12.	FDC/CT/23/000051 Gliclazide 40mg/80mg + Sitagliptin phosphate 50 mg/50mg + Metformin Hydrochloride 1000mg/1000mg Tablets	M/s. Dr. Reddy's Laboratories	The firm presented their proposal along with BE study and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended to conduct BE Study. As regard to Phase III clinical trial protocol, the committee recommended that the firm should either change the study population or comparator arm. Accordingly, firm should submit revised Phase III clinical trial protocol for further review by the committee.
13.	FDC/MA/23/000203 Sitagliptin Phosphate Monohydrate IP 100mg/100mg + Empagliflozin	M/s. Synokem Pharmaceuticals	The firm presented the proposal before the committee with request to the present Phase III clinical trial protocol in two strength i.e. Sitagliptin Phosphate Monohydrate IP 100mg/100mg + Empagliflozin 25mg/10mg tablets and

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	25mg/10mg Tablets		requested for BE study wavier. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial study and considered for BE study wavier. The result of the study should be presented before the committee for review.
14.	FDC/MA/22/000402 Glimepiride IP 1mg + Lobeglitazone Sulfate 0.5 mg Film Coated Tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm didn't turn up for presentation.
15.	FDC/MA/23/000082 Combi Pack of Part A contains 20 tablets: Sitagliptin 50mg + Metformin 500mg and Part B 10 tablets: Dapagliflozin 10mg tablet	M/s. Aeon	In the light of earlier SEC recommendation dated 18.05.2023 & 19.05.2023, the firm presented their proposal along with justification. After detailed deliberation the committee noted that:- 1) The Firm has not presented any scientific peer reviewed journal data for proposed Combikit. 2) The firm has not presented justification with respect to need of this Combikit. 3) There is no unmet need. Accordingly, the committee didn't recommend for approval of the proposed Combikit.
16.	FDC/MA/22/000256 Metformin HCL + Glimepiride + DapagliflozinPropanediol Monohydrate eq. to Dapagliflozin (500mg/1000mg/500mg/1000mg+1mg/1mg/2mg/2mg+10mg/10mg/10mg/10mg) tablets	M/s. Macleods Pharmaceuticals Ltd.	In the light of earlier SEC recommendation dated 21.09.2022, the firm presented their proposal along with revised Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended that the firm should revise the clinical trial protocol by including third arm where three drugs are given separately and not as FDC of three drugs, for further review by the committee.
17.	FDC/MA/21/000067 Dapagliflozin 5mg + Vildagliptin 50mg + Metformin HCl IP	M/s. USV Pvt. Ltd.	The firm didn't turn up for presentation.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	500mg tablets		
18.	FDC/MA/21/000099 Sitagliptin Phosphate Monohydrate IP eq. to sitagliptin 50mg/50mg + Metformin Hydrochloride IP 1000mg/1000mg + Glimepiride IP 1mg/2mg film coated tablet	M/s. Sun Pharma Laboratories Ltd.	The firm presented their proposal along with Phase III clinical trial report and BE study report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.
19.	FDC/MA/22/000399 Sitagliptin Phosphate Monohydrate IP Eq. to Sitagliptin + Glimepiride IP + Metformin Hydrochloride IP (As Sustained Release form) (50mg/50mg + 1mg/2mg + 500mg/500mg) Tablets	M/s. Akums Drugs & Pharmaceuticals	The firm didn't turn up for presentation.
20.	FDC/MA/23/000199 Dapagliflozin + Glimepiride + Extended Release Metformin Hydrochloride (10 mg + 1 mg + 500 mg) / (10 mg + 2 mg + 500 mg)Tablets	M/s. Sun Pharma Laboratories Limited	The firm presented their proposal along with Phase III clinical trial and BE study report in higher strength i.e Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Glimepiride IP + Metformin Hydrochloride IP (as extended release) (10mg/10mg+1mg/2mg+1000mg/1000mg) tablets and requested for Phase III clinical trial and BE study wavier for lower strengths i.e. Dapagliflozin + Glimepiride + extended release Metformin Hydrochloride (10 mg + 1 mg + 500 mg) / (10 mg + 2 mg + 500 mg) tablets. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed lower strengths of the FDC.
GCT Division			
21.	CT/73/22 Online Submission (25991)	M/s. Eli-Lilly	The firm presented their proposal for amendment the protocol vide number: I8H-MC-BDCV, amendment number (b)

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	LY3209590		before the committee. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by firm.
22.	CT/22/23 Online Submission (36574) TP-102	M/s. JSS	The firm presented their proposal for grant of permission to conduct a Phase II b clinical trial vide protocol number: TP-102_102 version 4.1 dated 10 Jul 2023 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial.
23.	CT/53/23 Online Submission (37599) LY3437943	M/s. Eli-Lilly	The firm presented their proposal for grant of permission to conduct a Phase III clinical trial vide protocol number: J11-MC-GZBJ, amendment number (b) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.
24.	CT/71/22 Online Submission (26126) Cagrilintide S.C. 2.4mg + Semaglutide S.C. 2.4mg (CagriSema S.C. 2.4 mg/2.4mg)	M/s.Novo-Nordisk	The firm presented their proposal vide clinical trial NOC vide file no CT/22/000071 and protocol number: NN9838-4608, protocol version 4.0 dated 19-Aug-2022 before the committee for wavier of clinical trial NOC condition no. (1) i.e. "The firm should submit the trial safety and efficacy data to the committee for review and further intimation of the extension phase". After detailed deliberation, the committee recommended to waive off condition no. (1).
25.	CT/50/23 Online Submission (37549) LY3437943	M/s. Eli-Lilly	The firm presented their proposal for grant of permission to conduct a Phase III clinical trial vide protocol number: J11-MC-GZBK, amendment number (a) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial.
SND Division			
26.	SND/MA/23/000070 Cholecalciferol Granules 60000IU	M/s Tirupati Medicare	The firm didn`t turn up for presentation.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	(mouth dissolving Granules)		