Recommendations of the SEC (Endocrinology & Metabolism) made in its 98th meeting held on 16.02.2023 & 17.02.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/23/000001 Imeglimin HCL 500mg and 1000mg tablet	M/s. Synokem Pharmaceutical Ltd.	In line with the Imeglimin HCL 500mg and 1000 mg manufacturing and marketing permission condition, the firm presented Phase IV clinical trial protocol for drug Imeglimin HCL 500mg and 1000mg. After detailed deliberation, the committee recommended that the firm should increase the study duration and sample size of the proposed Phase IV clinical trial. Accordingly, the firm should submit the amended protocol before the committee for further consideration.
2.	ND/MA/22/000106 Trelagliptin 12.5, 25, 50 & 100mg tablets	M/s. Synokem Pharmaceutical Ltd.	The firm presented the proposed protocol amendment to the already approved BE study with drugs Trelagliptin 100 mg tablet. After detailed deliberation, the committee noted that the proposed amendment in selection and withdrawal criteria, exclusion criteria and sample size procedures are minor in nature including other administrative changes. Accordingly, the committee recommended for the grant of permission to the proposed protocol amendment.
3.	ND/MA/22/000169 Carglumic Acid Dispersible Tablets 200mg	M/s. Laurus Labs Ltd.	The firm presented its proposal for grant of permission to manufacture and market Carglumic acid 200mg dispersible tablets with clinical trial waiver in the country and presented BE study protocol to conduct the BE study before the committee. The committee reviewed firm's proposal along with BE study protocol. After detailed deliberation, the committee recommended that the firm should submit revised BE study protocol by capturing complete details as objective of the study, detailed clinical safety measure, protocol no., version etc. Accordingly, the firm should submit revised BE study protocol to CDSCO for further review by the committee.

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4.	ND/MA/22/000197 Trelagliptin 50/100 mg tablets	M/s. Pure and Cure	The firm presented its proposal along with Phase III clinical trial and BE study protocol before the committee. The committee reviewed Phase III and BE study protocols. After detailed deliberation, the committee recommended for grant of permission to conduct BE and clinical trial study subject to condition that the no. of subjects in Phase III clinical trial study should not be less than 400. The result of BE study should be presented before the committee for further review before initiation of Phase III clinical trial study.
FDC Division			
5.	4-27/2012-DC (Pt. Sun) Voglibose IP 0.2mg/0.2mg +Glimipiride IP 1mg/2mg+Metformin Hydrochloride (SR) 500mg/500mg uncoated bilayered tablets	M/s. Sun Pharma Laboratories	In light of earlier SEC recommendation dated 19.12.2019, the firm presented the Phase IV clinical trial report before the committee. The permission was already granted on 14.01.2020 with condition to conduct the Phase IV clinical trial for which NOC was already issued to the firm on 14.01.2020. After detailed deliberation, the committee considered the result of Phase IV clinical trial report.
6.	FDC/MA/22/000254 Gliclazide SR 30mg/60mg + Sitagliptin 100mg/100mg tablets	M/s. Eris Lifesciences Ltd.	In light of earlier SEC recommendation dated 09.09.2022, the firm presented the BE report before the committee. After detailed deliberation, the committee recommended to consider the BE report and to initiate the Phase III clinical trial study.
7.	FDC/MA/21/000225 Dapagliflozin Propanediol to monohydrate eq to Dapagliflozin 5mg/5mg + Sitagliptin 50mg/50mg + Metformin Hydrochloride 500mg/1000mg tablets	M/s. Sun Pharma Laboratories Ltd.	In light of earlier SEC recommendation dated 26.10.2021, the firm presented the CT report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC.

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8.	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 firm presented its proposal before the committee along with BE protocol and Phase III CT protocol. The committee noted that Voglibose 0.3mg is not approved. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study for FDC of Sitagliptin phosphate monohydrate 50mg + Metformin HCl 500mg + Voglibose 0.2mg tablet. Accordingly, the firm should present the revised Phase III CT protocol before the committee.
9.	FDC/MA/22/000346 Sitagliptin phosphate monohydrate IP eq. to Sitagliptin 50mg/100mg + Lobeglitazone sulfate 0.5mg/0.5mg tablets for oral administration	M/s. Glenmark Pharmaceuticals	The firm did not turn up for presentation.
10.	FDC/MA/22/000367 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Pioglitazone HCl IP eq. to Pioglitazone 15mg tablets	M/s. Akums	The firm presented its proposal before the committee along with BE study and Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the BE and Phase III clinical trial study with condition that study sites should be geographically distributed. The result of the study should be presented before the committee for review.
11.	FDC/MA/23/000015 Metformin Hydrochloride IP (As ER) 500mg + Lobeglitazone sulfate 0.25mg tablets	M/s. Akums Drugs	The firm presented its proposal before the committee along with justification for waiver of BE study and Phase III clinical trial. The firm informed the committee that the product is approved in South Korea. After detailed deliberation, the committee recommended that firm should present the BE study protocol before the committee.
12.	FDC/MA/22/000422 Dapagliflozin Propanediol Monohydrate	M/s. Windlas	The firm presented its proposal before the committee along with Phase III clinical trial protocol as well as justification for BE study waiver. After detailed deliberation, the committee

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	5mg/10mg/5mg/ 10mg + Linagliptin 2.5mg/2.5mg/5mg/ 5mg tablets		recommended that: 1. The firm should modify the value of e-GFR. 2, Third arm should be included. 3. Urine Culture test should be done as and when required. Accordingly, revised Phase III clinical trial protocol should be submitted to CDSCO for review by committee.
13.	FDC/MA/23/000017 Glimepiride 1mg/2mg + Linagliptin 5mg/5mg tablets	M/s. Exemed	The firm presented its proposal before the committee along with BE study protocol and Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the BE and Phase III clinical trial study. The result of the study should be presented before the committee for review.
14.	FDC/MA/22/000317 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 Exemed Pharmaceuticals	The firm presented its proposal before the committee along with justification for waiver of BE study and Phase III clinical trial study. The firm informed the committee that the product is already approved in higher strength i.e FDC of Dapagliflozin 10mg/10mg + Sitagliptin 100mg/10mg + Metformin HCl (ER) 500mg/1000mg tablets on 16.09.2022 after conducting the clinical trial. After detailed deliberation, the committee recommended that firm should present the PK study protocol for review by committee.
15.	FDC/MA/22/000205 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Linagliptin (5mg + 5mg & 10mg + 5mg) tablets	M/s. Hetero	The firm presented its proposal before the committee along with BE study protocol and Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study and Phase III clinical trial study. The result of the study should be presented before the committee for review.
16.	FDC/MA/22/000305 Dapagliflozin 5mg + Vildagliptin 50mg +	M/s. Windlas	The firm presented its proposal before the committee along with Phase III clinical trial protocol as well as justification for BE study waiver.

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	Metformin 500mg tablets		After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial study. The result of the study should be presented before the committee for further review.
17.	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	The firm presented its proposal before the committee along with justification for BE and clinical trial study waiver. After detailed deliberation, the committee recommended that CDSCO should take decision as the applied FDC has been recommended for manufacturing and marketing to other firm.
18.	FDC/MA/22/000411 Metformin HCl IP (As extended release) 500mg/1000mg/ 500mg/1000mg + Glimepiride IP 1mg/1mg/2mg/2mg + Empagliflozin10mg/ 10mg/10mg/10mg tablets	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm presented its proposal before the committee along with BE study protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. The result of the study should be presented before the committee for review along with Phase III clinical trial protocol.
19.	FDC/MA/23/000004 Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg/20mg + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg/10mg Tablets	M/s. Exemed	The firm presented their proposal before the committee along with BE study protocol and Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission for conducting the BE and Phase III clinical trial study. The result of the study shall be presented before committee for review.
20.	FDC/MA/22/000360 Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg + Glimepiride IP 2mg + Metformin HCl IP (as ER)	M/s. Exemed	The firm presented its proposal before the committee along with BE study protocol and Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the BE and Phase III clinical trial study.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	1000mg tablets		The result of the study should be presented before committee for review.
21.	FDC/MA/22/000043 Teneligliptin Hydrobromide hydrate eq to Teneglitin IP 20mg/20 mg /20 mg /20 mg + Metformin hydrochloride (SR) IP 500mg/1000mg/500 mg/1000mg + Dapagliflozin propanediol propanediol monohydrate eq to Dapagliflozin 5mg/5mg/10mg/ 10mg film coated tablet	M/s. Synokem Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 19.01.2023 & 20.01.2023, the firm presented clinical data on FDC of Dapagliflozin 5mg/10mg + Teneligliptin 20mg tablet. After detailed deliberation, the committee recommended to reiterate its earlier recommendation dated 19.01.2023 & 20.01.2023. Accordingly, the firm should present the Phase III clinical trial study data before the committee for which permission was already granted to the firm.
GCT Division			
22.	CT/07/22 Online Submission (21675) Insulin Icodec	M/s. Novo-Nordisk	In light of earlier SEC held on 20.01.2023, the applicant presented safety data of 30 Indian subjects in compliance with CT NOC condition no. 1. – "The firm should submit safety data of initial 30 subjects from India for review by CDSCO for further continuation of the trial." The applicant informed that global enrollment is over, therefore further no more subjects will be enrolled from India in the study. After detailed deliberation, the committee recommended for continuation of trial with already 30 ongoing Indian subjects.
BA/BE Division			
23.	12-09/2023/BA-BE/Misc-02/DC Levothyroxine Sodium 100 mcg Tablets + Liothyronine Sodium 25 mcg Tablets	M/s Veeda Clinical Research Limited, Ahmedabad – 380015	The firm presented its proposal before the committee for grant of permission to conduct BA/BE study for export with Levothyroxine Sodium 100 mcg Tablets + Liothyronine Sodium 25 mcg Tablets After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that the firm should conduct the study first with dose level one i.e T3 100mcg + T4

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			400mcg and submit the safety data before the committee for evaluation for further approval for conduct of the study for Dose Level 2 i.e T3 150mcg + T4 600mcg.