Recommendations of the SEC (Endocrinology & Metabolism) made in its 101th meeting held on 18.05.2023 & 19.05.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biologics Division			
1.	BIO/CT04/FF/2023/35910 Insulin Injection IP 100 IU/mL	M/s. Regenix Biosciences Ltd.	The firm presented the Phase III clinical trial protocol titled "A prospective, multi-center, randomized, open-label, parallel-group, active-controlled, Phase III study to compare the efficacy, safety and immunogenicity of Regenix Biosciences Limited, India, Human Insulin Short acting (Investigational drug) - Regenix Insulin R with the Eli Lilly's bacteria based Human Insulin Short acting (Reference drug) – Humulin R® in Diabetes mellitus (Type 1 and Type 2)" vide Protocol No.: CT23-001 Version 01 Protocol dated 21 Jan 2023. After detailed deliberation, the committee recommended that the firm should revise the protocol as follows: 1) The trial should be double blinded. 2) The secondary efficacy endpoint with respect to proportion of patients with change in HbA1c from baseline to week 12 and week 24 needs to be clearly defined. 3) The number of evaluable patients in the test arm should not be less than 100. Accordingly, the firm should submit the revised protocol to CDSCO for further review by the committee.
SND Division			
2.	SND/MA/22/000363 Cholecalciferol aqueous Injection 60000 IU	M/s. Akums Drugs & Pharmaceuticals Limited	The firm did not turn up for the presentation.
3.	SND/MA/23/000070 Cholecalciferol mouth dissolving granules 60000 IU(additional dosage form)	M/s. Tirupati Medicate Ltd.	The firm presented the proposal for manufacture and marketing of Cholecalciferol mouth dissolving granules 60000 IU for already approved indication along with BE study and clinical trial waiver justification before the committee. The committee opined that the firm could not present proper justification, adequate supporting data and supportive literature

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			for BE study and clinical trial waiver. After detailed deliberation, the committee recommended that the firm should submit & present proper justification and adequate data alongwith published literature in support of the BE study and clinical trial waiver for further review by the committee.
FDC Division			
4.	FDC/MA/22/000402 Glimepiride IP 1mg+Lobeglitazone Sulfate 0.5 mg Film Coated Tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm presented the proposal before the committee along with justification for BE and Phase III clinical trial study waiver. The firm informed the committee that permission for Lobeglitazone Sulfate 0.5 mg tablet was issued on 23.03.2023 after conducting the BE study. After detailed deliberation, the committee recommended that the firm should submit the BE study protocol for further review by SEC.
5.	FDC/MA/23/000082 Combi Pack of Part A contains 20 tablets: Sitagliptin 50mg + Metformin 500mg and Part B 10tablets: Dapagliflozin 10mg tablet	M/s. Aeon	The firm presented the proposal before the committee. the committee noted: 1. The strength of the proposed combikit is not found in line with strengths approved in FDC. 2. Scientific peer reviewed journal for proposed Combikit is not presented. 3. The Firm should submit the justification w.r.t need of this Combikit. After detailed deliberation, the committee recommended that the firm should present the proposal for further review by the committee.
6.	FDC/MA/23/000085 Lobeglitazone sulfate 0.25mg/0.25mg+ Sitagliptin Phosphate monohydrate 50mg/100mg tablets	M/s. Akums	The firm did not turn up for the presentation.
7.	FDC/MA/23/000089 DapagliflozinPropanediol monohydrate eq. to Dapagliflozin5mg/5mg/10	M/s. Exemed	The firm presented the proposal before the committee along with BE study protocol. After detailed deliberation, the committee

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	mg/10mg + Linagliptin 5mg/5mg/5mg/5mg + Metformin HCl eq. to Metformin (as sustained release) 500mg/1000mg/500mg/1000mg tablets		recommended for grant of permission for conduct of the BE study. The firm should submit the result of the BE study along with Phase III clinical trial protocol to the CDSCO for further review by the committee.
8.	FDC/MA/23/000083 Vildagliptin (as sustained release)100mg/100mg/100mg/+Rosuvastatin calcium IP eq. to Rosuvastatin 5mg/10mg/20mg tablets	M/s. Exemed	The firm was not ready for the presentation.
9.	FDC/MA/22/000264 Sitagliptin Phosphate monohydrate 100mg + Pioglitazone HCl IP 15mg film coated tablets	M/s. Synokem	In light of the earlier SEC recommendation dated 19.10.2022 & 20.10.2022, the firm presented BE study report before the committee along with justification for Phase III clinical trial waiver. After detailed deliberation, the committee considered the BE report and recommended to present the Phase III clinical trial results for which clinical trial NOC was already issued to the firm on 18.11.2022.
10.	FDC/MA/22/000360 Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg/100mg+Glimepiride IP 1mg/2mg + Metformin HCl IP (as ER) 1000mg/1000mg tablets	M/s. Exemed	The committee reiterated its earlier SEC recommendation dated 16.02.2023 & 17.02.2023.
11.	FDC/MA/22/000168 Linagliptin5mg/5mg+ Dapagliflozin 10mg/5mg tablets	M/s. Alkem Health Science	In light of the earlier SEC recommendation dated 14.06.2022, the firm presented the Phase III clinical trial report in one strength i.e 5mg + 10mg tablet before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture & market the product in the said strength.
12.	FDC/MA/22/000145 Linagliptin2.5mg/5mg/5mg+ Metformin Hydrochloride	M/s. Alkem Laboratories Ltd.	In light of the earlier SEC recommendation dated 14.06.2022, the firm presented BE study report before the committee. The committee noted that the product is

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	(ER)1000mg/500mg/1000 mg film coated bilayered tablet		already approved in strengths i.e (2.5 mg + 1000mg + 5mg + 1000mg) by CDSCO on 08.04.2022. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product in the proposed strengths.
13.	FDC/MA/22/000333 Metformin HCl IP as extended release500mg/500mg/1000mg/1000mg+Glimepiride IP 1mg/2mg/1mg/2mg +Sitagliptin phosphate monohydrate eq. to Sitagliptin IP 50mg/50mg/50mg/50mg Tablets	M/s.Innova Captab Limited	The firm did not turn up for the presentation.
14.	FDC/MA/22/000325 DapagliflozinPropanediol monohydrate eq. to Dapagliflozin + Linagliptin + Metformin HCl eq. to Metformin (as sustained release) (5mg/5mg/10mg/10mg/5mg/5mg/10mg/10mg+2.5mg/2.5mg/2.5mg/2.5mg/5mg/5mg/5mg+500mg/1000mg/500mg/1000mg/500mg/1000mg/500mg/1000mg) tablets	M/s. Theon Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 21.03.2023 & 22.03.2023, the firm presented the revised clinical trial protocol with request to withdraw the following strengths i.e 2.5 mg + 5mg+ 500mg, 2.5 mg + 5mg+ 1000mg, 2.5 mg + 10mg+ 500mg & 2.5 mg + 10 mg+ 1000mg tablets. After detailed deliberation, the committee recommended for conducting the Phase III clinical trial. The clinical trial should only be initiated, after the BE study result is presented before the SEC for which NOC has already been granted.
15.	FDC/MA/23/000041 Rosuvastatin Calcium IP eq. to Rosuvastatin+Linagliptin (5mg/10mg/20mg+5mg/5mg/5mg) Tablets	M/s. Exemed Pharmaceuticals	The firm did not make the presentation.
16.	FDC/MA/23/000057 Rosuvastatin calcium IP eq. to Rosuvastatin 5mg/10mg/20mg + Sitagliptin phosphate monohydrate IP eq. to sitagliptin 100mg/100mg/100mg	M/s. Exemed	The firm did not make the presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
17.	FDC/MA/23/000015 Metformin Hydrochloride IP (As ER) + Lobeglitazone sulfate (500mg+ 0.25mg) tablets	M/s. Akums Drugs	The firm presented the proposal along with BE study protocol and justification for Phase III clinical trial waiver. The product in strengths i.e 500mg + 0.5mg & 1000mg + 0.5mg is already approved by CDSCO on 31.12.2022. After detailed deliberation, the committee considered the request for Phase III clinical trial waiver and recommended for conducting the BE study. The result of the BE study should be presented for review by SEC.
18.	FDC/MA/23/000117 Dapagliflozin10mg/10mg/5mg/5mg + Linagliptin5mg2.5mg/5mg/2.5mg tablets	M/s. Eris	The firm presented the proposal before the committee with request to present its protocol in one strength i.e 10mg + 5mg. The committee opined that clinical trial reports have been submitted by other firms. After detailed deliberation, the committee recommended that firm should submit the Phase III clinical trial protocol in all proposed strengths.
19.	FDC/MA/23/000105 Glimepiride1mg/1mg/2mg/2mg+Linagliptin2.5mg/2.5mg/2.5mg/2.5mg+Metformin Hydrochloride (Extended Release)500mg/1000mg/500mg/1000mg Film coated Bilayered Tablets	M/s. Synokem	The firm presented the proposal before the committee along with BE study & Phase III clinical trial protocol in two strengths only i.e 1mg+ 2.5mg +1000mg & 2 mg +2.5mg +1000mg. After detailed deliberation, the committee recommended for conduct of the BE study and Phase III clinical trial. The result of the studies should be presented for review by the SEC.
20.	FDC/MA/23/000104 Lobeglitazone Sulfate 0.5mg/0.5mg + Metformin HCl SR 500mg/1000mg tablets	M/s. Mascot Health Series Pvt. Ltd	The firm presented the proposal before the committee along with BE study protocol. After detailed deliberation, the committee recommended for conduct of the BE study with the condition that reference product should be innovator`s product. The result of the BE study should be presented before SEC for further review.
21.	FDC/MA/23/000113	M/s. Mascot Health Series	The firm presented the proposal before the committee along with BE study

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Lobeglitazone Sulfate 0.5mg/0.5mg + Glimepiride 1mg/2mg tablets	Pvt. Ltd	protocol. After detailed deliberation, the committee recommended for conducting the BE study with condition that reference product should be innovator`s product. The result of the BE study should be presented before the SEC for further review.
22.	FDC/MA/22/000061 Linagliptin5mg/2.5mg/2.5 mg+Dapagliflozin 10mg/10mg/5mg tablets	M/s. Micro Labs Ltd.	In light of the earlier SEC recommendation dated 26.04.2022 & 29.04.2022, the firm presented Phase III clinical trial report in one strength i.e 5mg + 10mg. After detailed deliberation, the committee recommended for grant of permission to manufacture & market the product in said strength.
23.	04-2321/2015-DC(PSC-Inventia) Metformin HCl SR 500mg/500mg+Voglibose 0.2mg/0.2mg+Glimepiride 1/2mg tablets	M/s. Inventia	The firm presented the Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted the result of the clinical trial report.
24.	FDC/MA/22/000268 Linagliptin5mg/2.5mg/5mg/2.5mg + DapagliflozinPropanediol Monohydrate eq. to Dapagliflozin 10mg/10mg/5mg/5mg tablets	M/s. Exemed Pharmaceuticals	In light of the earlier SEC recommendation dated 19.10.2022 & 20.10.2022, the firm presented Phase III clinical trial report in one strength i.e 5mg + 10mg. After detailed deliberation, the committee recommended for grant of permission to manufacture & market the product in said strength.
25.	FDC/MA/23/000103 Metformin Hydrochloride (As sustained Release)+Vildagliptin (as immediate release) +Glimepiride (as immediate release) (500mg/1000mg+50mg/50mg+1mg/1mg) Oral/Tablet	M/s. Alkem	The firm presented the proposal before the committee along with BE study & Phase III clinical trial protocol. After detailed deliberation, the committee recommended for conduct of the BE study & Phase III clinical trial. The result of the BE study should be presented for review by SEC before initiation of the clinical trial.
GCT Division			
26.	CT/174/22 Online Submission	M/s. Novo-Nordisk	The firm presented Phase IIIa clinical trial protocol –NN9838-4942 before the

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	(35319) Cagrilintide 2.4 mg s.c.		committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study subject to conditions that each subject should be provided glucometer and also calcitonin level at baseline assay should be performed at a periodic interval.
27.	CT/14/22 Online Submission (23788) Paltusotine	M/s. Pharm-Olam	The firm presented the proposal/ justification to increase number of subjects in clinical trial protocol – CRN00808-08 before the committee. After detailed deliberation, the committee recommended for grant of permission to increase the subjects in the proposed study.
28.	CT/16/19 Online Submission (24567) Somapacitan	M/s. Novo-Nordisk	The firm presented the clinical trial protocol amendment –NN8640-4263(Real 4), version-9.0, dated 19 Dec 2022 before the committee. After detailed deliberation, the committee recommended for grant of approval for the protocol amendment as presented by the firm.