Recommendations of the SEC (Endocrinology & Metabolism) made in its 108th meeting held on 23.11.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	4-34/ Sanofi / PAC-R-SoliquaSolostar/2023-BD Insulin Glargine + Lixenatide	M/s. Sanofi	The firm presented their proposal for revision in the approved indication of the drug Fixed Ratio Combination of Insulin Glargine 100U/mL + Lixisenatide 50 mcg/mL/33mcg/mL indicated for the treatment of adults patients with Obesity with insufficiently controlled type 2 diabetes mellitus to improve glycemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT2 inhibitors, when this has not been provided by metformin alone or metformin combined with another oral glucose lowering medicinal product (sulfonylurea, glinide, DPP-4 inhibitors or gliptins, and Sodium-glucose cotransporter 2 (SGLT2) inhibitors or gliflozins) or with basal insulin or with glucagon-like peptide-1 (GLP-1) receptor agonist. The firm has now proposed to remove restriction of Obesity in the approved indication to align it with indication approved by other global regulatory authorities such as USFDA, EMA and Japan. The committee noted that approved indication was as per the recommendation of the Technical Committee in meetings dated 29.06.2022 and 21.12.2022. Therefore, the firm may approach Technical Committee for proposed revision in approved indication.
2.	Dy. No, 5670 Insulin Glargine + Lixenatide	M/s. Sanofi	The firm presented their proposal for revision in the warning statement of the approved drug Fixed Ratio Combination of Insulin Glargine 100U/mL + Lixisenatide 50 mcg/mL/33mcg/mL from "To be sold by retail on the prescription of an Endocrinologist only" to "To be sold by retail on the prescription of a Registered Endocrinologist or Physician with Post Graduate qualification in Medicine only" or to remove condition for warning statement.

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			After detailed deliberation, the committee recommended for revision in the warning statement as “To be sold by retail on the prescription of a Registered Endocrinologist or specialist in Internal Medicine only" subject to the condition that firm should submit evidence for similar approvals from other global regulatory authorities to CDSCO.
SND Division			
3.	SND/MA/23/000030 Cholecalciferol Oral Suspension 400 IU/5ml (Additional Indication & Additional Dosage Form)	M/s. Stedman Pharma Private Limited	The firm presented their proposal for grant of permission to manufacture and marketing of Cholecalciferol Oral Suspension 400 IU/5ml (Additional Dosage Form) & Cholecalciferol Oral Suspension 800 IU/5ml (Additional Dosage Form) along with justification for waiver of Bioequivalence study & CT before the committee. It has been informed by the firm the proposed formulation is for the paediatric use and submitted paediatric treatment guideline as 400–1000 IU per day may be needed for children aged less than 1 year and 600–1000 IU per day for children aged 1 year or more. After detailed deliberation, the committee opined that, as the formulation meant is for paediatric population, therefore the proposal will be again deliberated in presence of paediatrician. Accordingly, the proposals are deferred for next SEC meeting.
4.	SND/MA/23/000032 Cholecalciferol Oral Suspension 800 IU/5ml (Additional Indication & Additional Dosage Form)	M/s. Stedman Pharma Private Limited	
FDC Division			
5.	FDC/MA/22/000356 Linagliptin + Metformin Hydrochloride IP (ER) 2.5mg+1000mg, 5mg+1000mg film coated bilayered tablet	M/s. Synokem Pharmaceuticals Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 24.04.2023, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct of the Phase IV clinical trialwith the condition to include more government sites, which should be geographically distributed. The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.

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6.	FDC/MA/23/000234 Linagliptin + DapagliflozinPropanediol Monohydrate eq. to Dapagliflozin (2.5mg+10mg/ 5mg+5mg/ 2.5mg+5mg) Tablets	M/s. Exemed Pharmaceutical Ltd.	In light of the earlier SEC recommendation dated 27.09.2023 & 29.09.2023, the firm presented their proposal along with more evidence and supporting literature for the proposed FDC in lower strength (Linagliptin 5mg + Dapagliflozin 5mg) based on their Clinical Trial report of higher strength (Linagliptin 5mg + Dapagliflozin 10mg). Firm informed that they have withdrawn other two strengths i.e. Linagliptin + Dapagliflozin (2.5mg+10mg/ 2.5mg+5mg). After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC in lower strength (Linagliptin 5mg + Dapagliflozin 5mg).
7.	FDC/MA/21/000034 Sitagliptin phosphate monohydrate IP eq. to Sitagliptin + Metformin HCl IP + Voglibose IP 50mg/50mg+500mg/500mg+0.2mg/0.3mg film coated tablet	M/s. Hetero Labs Ltd.	In the light of earlier SEC recommendation dated 16.02.2023 & 17.02.2023, the firm presented their proposal along with revised Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended that in the exclusion criteria eGFR value should be modified as per the standard guidelines. Accordingly, the revised Phase III clinical trial protocol along with BE study report should be presented before the SEC.
8.	FDC/MA/23/000310 Repaglinide IP + Voglibose IP + Metformin Hydrochloride IP (SR) 0.5mg+0.2mg+500mg, 1mg+0.2mg+500mg uncoated bilayered tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm presented its proposal along with BE study and Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study. The committee opined that the Phase III CT protocol should be adequately modified w.r.t. inclusion criteria, exclusion criteria, withdrawal criteria, provision of rescue therapy, sample size calculation etc. Accordingly, BE study report should be presented before the SEC along with revised Phase III clinical trial protocol.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
9.	FDC/MA/22/000152 Metformin Hydrochloride IP (SR)+ Glimepride IP + Sitagliptin Phosphate Monohydrate IP eq. To Sitagliptin 1000mg/1000mg + 1mg/2mg + 50mg/50mg film coated bilayered tablet	M/s. Akums Drugs and Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 25.08.2022 & 26.08.2022, the firm presented their proposal along with BE study report and justification for CT waiver before the committee. After detailed deliberation, the committee considered the BE study report. However, the committee did not agreed to the justification for CT waiver and recommended to conduct Phase III CT study for which CT NOC has already been issued on 16.09.2022.
GCT Division			
10.	CT/02/20 Online Submission (27572) Tirzepatide	M/s. Eli Lilly	The firm has presented Protocol addendum (7.1), dated 22-May-2023, Protocol number 18F-MC-GPG After detailed deliberation, the committee recommended for approval of protocol addendum as presented by firm.
11.	CT/67/20 Online Submission (27245) Semaglutide	M/s. Novo-Nordisk	The firm has presented protocol amendment version 4.0 dated 22 May 2023, Protocol no. NN9924-4437 After detailed deliberation, the committee recommended for approval of protocol amendment as presented by firm. (Dr. Abhishek Agrawal did not participate in deliberation.)
BA/BE Division			
12.	File No. 12-09/2023/BA-BE/MISC-26/DC (BABE/CT05/FF/2023/37493) Capsaicin + Duloxetine Ointment 0.075% +0.25% (T1) & 0.075% +0.75% (T2)	M/s. Dr. Reddy's Laboratories Limited, Telangana.	The firm presented the protocol No.BE 010-2023Version 01 Dt 07-03-2023 before the committee. After detailed deliberation, the committee recommended for the grant of BE –NOC for export purpose only.