Recommendations of the SEC (Endocrinology & Metabolism) made in its 91st meeting held on 25.08.2022 & 26.08.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/21/00031 Lobeglitazone sulfate Tablets 0.5 mg	M/s. Glenmark Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 16.12.2020 & 21.09.2021, the firm presented Phase III clinical trial results before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of Lobeglitazone 0.5mg Tablets for the proposed indication subject to condition that the drug should be sold by retail only under the prescription of Endocrinologists or Internal Medicine Specialists.
2.	ND/MA/22/000063 Sodium Phenylbutyrate oral Powder	M/s. Laurus	The firm presented their proposal of BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conducting the proposed BE study in its presented form.
3.	ND/MA/22/000113 Imeglimin HCL +Vildagliptin (1000 + 50 mg)	M/s. Exemed	The firm presented proposal for Phase III clinical trial and bioequivalence study protocol before the committee. After detailed deliberation, the committee recommended that the details of FDCs along with BE & CT Phase III Protocol may be presented after approval of single drug Imeglimin in the country.
4.	ND/IMP/21/000035 Etelcalcetide Injection 2.5mg/0.5ml, 5mg/ml	M/s. Amegen Technology Pvt.Ltd.	The firm didn't turn up for presentation.
5.	ND/MA/21/000169 Imeglimin 500/1000mg	M/s. Exemed	The firm presented their proposal for grant of permission to manufacture and market drug Imeglimin 500/1000mg along with the Phase III clinical trial data. After detailed deliberation, the committee opined that the firm should make detailed comprehensive presentation on all the clinical trial data generated in India and other countries along with specific justification for their claim as mono-therapy in treatment naïve patient.

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6.	ND/MA/22/000106 Trelagliptin 12.5, 25, 50,100mg tablets	M/s. Synokem	The proposal was deferred for next meeting.
7.	ND/MA/22/000112 Imeglimin HCL Sitagliptin tablets (1000mg+50mg)	M/s. Exemed Pharmaceuticals	The firm presented proposal for Phase III clinical trial and bioequivalence study protocol before the committee. After detailed deliberation, the committee recommended that the details of FDCs along with BE & CT Phase III Protocol may be presented after approval of single drug Imeglimin in the country.
8.	IND/IMP/22/0001 Finished product of Plectranthus amboinicus Extact & Centella Asiaca Cream	M/s. Genedrift Solution LLP	The firm presented proposal for import and marketing along with request for Phase III clinical trial waiver before the committee. After detailed deliberation, the committee recommended that the firm should submit Phase III clinical trial protocol along with the details of extraction & purification procedure and minimum four bio-active or phytochemical compounds of an extract of a medicinal plant or its part as per definition of Phyto Pharmaceutical of NDCT Rules, 2019 to CDSCO for further consideration.
Biological Division			
9.	4-81/Cadila/PAC-R-Teriparatide/17BD Teriparatide Injection 750ug/3ml	M/s Zydus Lifesciences Limited	In light of earlier SEC recommendations dated 21.12.2021 and 22.12.2021, the firm presented the comparison between the firm and innovator's package insert for update in Package insert. After detailed deliberation, the committee recommended that the firm should submit more safety data for the proposed PI update.
10.	BIO/CT18/FF/2022/30813 Semaglutide Solution for injection 0.25mg, 0.5 mg,1mg,1.7mg & 2.4 mg in multi-dose pen	M/s. NovoNordisk Pvt. Ltd	In continuation to earlier SEC meeting on 14.07.2022 and 15.07.2022, the firm again presented the proposal for import and marketing of the 0.25 mg, 0.5 mg, 1 mg, 1.7 mg & 2.4 mg as solution for injection in pre-filled pen in multi dose pen injector for subcutaneous use in India with the duration of 104 weeks and warning statement as "To be sold by retail on prescription of "Registered Endocrinologist or Internal Medicine Physicians (MD) or Obstetricians & Gynaecologists or Bariatric surgeons

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			only". The firm presented the outcome of various clinical studies including the studies conducted in Indian patients before the committee. The committee noted (1) The clinical data submitted for the treatment up to 104 weeks. (2) That the single dose formulation of the same drug is already approved by CDSCO. (3)The applied formulation is approved by UK, EU and Canada for weight management. After detailed deliberation, the committee recommended for grant of import and marketing of the drug in line with EU approved indication with following conditions: (1) Prescription of the drug should be restricted to Endocrinologist and Internal medicine only. (2) The duration of treatment should not exceed 104 weeks based on available study data.
11.	BIO/IMP/19/000078 Semaglutide Tablets 3mg,7mg, & 14mg	M/s. Novo Nordisk Pvt. Ltd	The firm was issued importing and marketing permission for Semaglutide 3 mg Tablets, 7 mg Tablets and 14 mg Tablets (Rybelsus) in India with the Warning: To be sold by retail on prescription of "Registered Endocrinologist only". Further in line with the recommendation of SEC dated 16.12.2020, as per the firm's application the amendment in warning statement was issued as "To be sold by retail on prescription of "Registered Endocrinologist or Physician with Post Graduate Qualification in Medicine Only". Now the firm presented their proposal for amendment in warning statement as "To be sold by retail on prescription of Registered Medical Practitioner". After detailed deliberation, the committee recommended that the firm should submit additional safety data in Indian

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			population for further review by the committee.
FDC Division			
12.	FDC/MA/22/000099 Dapagliflozin 10mg+Pioglitazone HCl IP eq to Pioglitazone 15mg tablets	M/s. USV Pvt. Ltd.	This proposal was already deliberated before SEC and placed inadvertently.
13.	FDC/MA/21/000123 Metformin hydrochloride IP (as an extended release form) +Sitagliptin Phosphate IP eq. to Sitagliptin + Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin(500mg/ 1000mg+100mg/100 mg+10mg/10mg) tablets	M/s. Alkem Laboratories Ltd.	In light of earlier SEC recommendation dated 14.07.2021 & 15.07.2021, firm presented the BE and Phase III CT Report for higher strength of FDC i.e. FDC of Metformin hydrochloride IP (as an extended release form) 1000mg +Sitagliptin Phosphate IP eq. to Sitagliptin 100mg +Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg tablets. After detailed deliberation, the committee recommended for grant of permission for manufacture and marketing of the proposed both strengths of FDC.
14.	FDC/MA/21/000115 Dapagliflozin + Metformin Hydrochloride (Extended Release) + Sitagliptin (10mg+1000mg+100 mg) Tablets	M/s. Sun Pharma Laboratories Limited	In light of earlier SEC recommendation dated 15.06.2021 & 16.06.2021, the firm presented the BE and Phase III CT report for proposed FDC. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.
15.	FDC/MA/22/000143 Vildagliptin (as sustained release) + Pioglitazone Hydrochloride eq. to Pioglitazone IP (100mg/100mg+15mg /30mg) tablets	M/s. Exemed Pharmaceuticals	The firm made a detailed presentation before the committee requesting for amendment in the approved CT protocol w.r.t. comparator. Committee noted that the firm was issued CT NOC and BE NOC by this office on 04.07.2022. After detailed deliberation, the committee recommended for the proposed amendment in the CT Phase III protocol.
16.	FDC/MA/21/000187 Dapagliflozinpropane diol 5mg+ Vildagliptin 50mg	M/s. Mascot	The firm presented the BE study report along with request for Phase III clinical trial study waiver before the committee. After detailed deliberation, the committee recommended that firm should conduct

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	tablets		the Phase III CT study for which NOC was already issued on 25.11.2021. The results of Phase III CT study should be presented before the committee for review.
17.	FDC/MA/22/000152 Metformin HCl (sustained release) 1000mg/1000mg +Glimepiride 1mg/2mg+Sitagliptin Phosphate monohydrate eq. to sitagliptin 50mg/50mg tablets	M/s. Akums Drugs and Pharmaceuticals Ltd.	The firm presented the BE and CT protocol before the committee. After detailed deliberation, the committee recommended for conducting the BE study and Phase III CT study with condition that "Pregnant, lactating women or women of childbearing age who are not willing to use an acceptable method of birth control during the study period should also be mentioned in exclusion criteria".
18.	FDC/MA/22/000178 Pioglitazone Hydrochloride IP 15mg + Vildagliptin 50mg uncoated tablet	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal alongwith BE and Phase III CT Protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conducting proposed BE and CT Study.
19.	FDC/MA/22/000217 Imeglimin 500mg/1000mg + Sitagliptin 50mg/50mg tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal before the committee. During the presentation, firm has informed that the drug Imeglimin is not yet approved by this office. Therefore, the proposal was deferred.
20.	FDC/MA/22/000215 Imeglimin 500mg/1000mg + Vildagliptin50mg/50 mg Film Coated Tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal before the committee. During the presentation, firm has informed that the drug Imeglimin is not yet approved by this office. Therefore, the proposal was deferred.
21.	FDC/MA/20/000180 Vildagliptin 50mg + Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg tablets	M/s. USV Pvt. Ltd.	In light of earlier SEC recommendation dated 19.01.2021 & 20.01.2021, the firm presented the BE Report and Phase III CT Report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC.
22.	FDC/MA/22/000079 Pioglitazone HCl IP	M/s Mascot Health	In light of earlier SEC recommendation dated 14.06.2022, the firm presented their proposal along with BE Study Protocol

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	eq. to Pioglitazone 7.5/15 mg + Vildagliptin 50/50 mg Tablets		and requested CT waiver. Committee noted that some other firm had conducted CT on the Pioglitazone 15 mg + Vildagliptin 50 mg tablets. After detailed deliberation, as regard to the Pioglitazone 15 mg + Vildagliptin 50 mg tablets, the committee recommended for grant of permission for conduct of BE Study. Further committee recommended that Phase III CT Waiver should be considered depending on the outcome of the approval of the same FDC. As regard to lower strength i.e FDC of Pioglitazone 7.5 mg + Vildagliptin 50 mg tablets, committee recommended that firm should conduct a Phase III clinical study and protocol should be submitted for review by the committee.
23.	FDC/MA/22/000095 DapagliflozinPropanediol Monohydrate eq. to Dapagliflozin 10mg/10mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg/100mg + Metformin Hydrochloride IP (as extended release form) 500mg/1000mg film coated bilayered tablet	M/s. Windlas Biotech Ltd.	The firm presented their proposal alongwith BE and Phase III CT Protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conducting proposed BE and CT Study.
24.	FDC/MA/22/000208 Sitagliptin 100mg/100mg + Metformin 500mg/1000mg ER + Dapagliflozin 10mg/10mg	M/s. Synokem Pharmaceuticals Ltd.	The firm presented their proposal alongwith BE and Phase III CT Protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conducting proposed BE and CT Study.
25.	FDC/MA/22/000158 Dapagliflozin Propanediol Monohydrate Eq. to Dapagliflozin 5mg/5mg + Sitagliptin phosphate	M/s. Glenmark Pharmaceuticals	The firm presented their proposal along with request for waiver of Phase III clinical trial. After detailed deliberation, the committee reiterated its earlier recommendation.

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	monohydrate IP eq. to Sitagliptin 50mg/50mg+Metformin HCl IP 500mg/1000mg tablets for oral administration		
26.	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 with their interim data of phase III clinical study on 120 patients with respect to safety and efficacy. After detailed deliberation, the committee recommended to continue the CT study on remaining subjects. The final report should be submitted before the committee for further review.
GCT Division			
27.	CT/02/20 Online Submission (16791) Tirzepatide versus Dulaglutide	M/s. Eli Lilly	The proposal was deferred for next meeting.
28.	CT/04/20 Online Submission (18063) Samopacitan	M/s. Novo-Nordisk	The proposal was deferred for next meeting.
29.	CT/58/17 Online Submission (18579) CV181375 (D1680C00019)	M/s. PRA	The proposal was deferred for next meeting.
30.	CT/07/22 Online Submission (18712) IcoSema and insulin icodec	M/s. Novo-Nordisk	The proposal was deferred for next meeting.