Recommendations of the SEC (Endocrinology & Metabolism) made in its 90th meeting held on 14.07.2022 & 15.07.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/IMP/21/000035 Etelcalcetide Injection 2.5mg/0.5ml, 5mg/ml	M/s. Amgen Technology Pvt. Ltd.	The firm didn't turn up for presentation.
Biological Division			
2.	BIO/CT18/FF/2022/31365 Somatrogon solution for injection in prefilled pen(24mg/1.2ml and 60mg/1.2 ml solution for injection in prefilled pen)	M/s. Pfizer products India Private Limited	The firm presented their proposal for import and marketing of the drug based on the Global clinical trial conducted in India and waiver of Phase IV trial. The committee noted that the drug is approved in EU, Switzerland and other countries such as Canada, Australia, Japan, UK etc. and was granted orphan drug designation in EU and Switzerland. After detailed deliberation, the committee recommended for grant of permission to import and market the drug for the proposed indication subject to the conduct of Phase IV clinical study. Accordingly, the firm should submit Phase IV clinical study protocol within 3 months of the approval.
3.	BIO/CT18/FF/2022/30813 Semaglutide 0.25 mg, 0.5 mg, 1 mg, 1.7 mg & 2.4 mg (Pre-filled multi-dose pen)	M/s. Novo Nordisk Pvt ltd	To be further deliberated in the SEC meeting.
4.	BIO/CT/20/000021 Insulin Glargine 100U/ml solution for injection	M/s. Biogenomics	The firm presented the amendment in Phase I clinical trial protocol. After detailed deliberation, the committee recommended for approval of the amendment of protocol version 20-VIN0108 version 02 dated 20 Apr 2022.
SND Division			
5.	SND/MA/22/000171 Liraglutide 6mg/ml solution for Injection in Prefilled Pen (18mg/3ml Pre-filled Pen) (Synthetic)	M/s.Biocon Pharma	The firm presented their proposal of BE study of Liraglutide 6mg/ml solution for Injection in Prefilled Pen (18mg/3ml Pre-filled Pen) (Synthetic) and two separate BE protocol (1). SYNCD-034-22, Version: 1.0, Date 30.05.2022 and (2). SYNCD-035-22, Version: 1.0, Date 02.06.2022, before the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			After detailed deliberation, the committee recommended for grant of permission to conduct the respective BE studies as per the protocols presented.
FDC Division			
6.	FDC/MA/000009,10, 11,12 Gliclazide 80mg/80mg/40mg/40 mg + Metformin 500mg/500mg/500mg /500mg + Voglibose 0.3mg/0.2mg/0.3mg/0 .2mg tablets	M/s. Eris Life Sciences	The firm didn't turn up for presentation.
7.	FDC/MA/21/000056 DapagliflozinPropane diol Monohydrate eq. to Dapagliflozin+Sitagli ptin Phosphate Monohydrate IP eq. to Sitagliptin (5mg/10mg+100mg/1 00mg)film coated tablet	M/s. Sun Pharma Laboratories Ltd.	The proposal is deferred for next meeting as requested by the firm.
8.	FDC/MA/22/000131 DapagliflozinPropane diol Monohydrate eq. to Dapagliflozin 5mg/10mg+ Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg/50mg tablets	M/s. Sun Pharma Laboratories Ltd.	The proposal is deferred for next meeting as requested by the firm.
9.	FDC/MA/22/000150 Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg/50mg + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/10mg tablets	M/s. Theon Pharmaceuticals Ltd.	The firm didn't turn up for presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
10.	FDC/MA/22/000092 Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg/50mg+Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/10mg tablets	M/s. Synokem	The firm presented their proposal before the committee alongwith request for BE and Phase III clinical Study waiver. The committee noted that the proposed FDC in higher strength i.e FDC of Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin (50mg + 5mg & 100mg + 10mg) tablets was approved by CDSCO on 30.06.2022. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC of Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg tablets for approved indication with condition that contraindications of individual drugs should be mentioned in the revised package insert.
11.	FDC/MA/22/000169 Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg/100mg+Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg/5mg tablets	M/s. Exemed Pharmaceuticals	The firm presented their proposal before the committee alongwith request for BE and Phase III CT Study waiver. The committee noted that the proposed FDC in higher strength i.e FDC of Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin +Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin(50mg + 5mg & 100mg + 10mg) tablets was approved by CDSCO on 30.06.2022 after conduct of Phase III CT study on higher strength. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC of Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin (50mg + 10mg & 100mg + 5mg) tablets for approved indication with condition that contraindications of individual drugs should be mentioned in the revised package insert.
12.	FDC/MA/22/000139 Sitagliptin Phosphate Monohydrate eq. to Sitagliptin	M/s. Logos Pharma	The firm didn't turn up for presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	50mg/50mg+ Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/10mg tablets		
13.	FDC/MA/22/000155 Metformin Hydrochloride (as extended release) 500mg/1000mg/500mg/1000mg /500mg/1000mg/500mg/1000mg+ Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg/50mg/50mg/50mg100mg/100mg/100mg/100mg+ Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/5mg/10mg/10mg /5mg/5mg/10mg/10mg tablets	M/s. Logos Pharma	The firm presented their proposal along with BE and Phase III CT study protocol only in higher strength of proposed FDC i.e FDC of Metformin Hydrochloride (as extended release) 1000mg + Sitagliptin Phosphate Monohydrate eq to Sitagliptin 100mg + Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin 10mg tablets. After detailed deliberation, the committee opined that the firm should submit the justification for those strengths which are not yet deliberated earlier by SEC. In view of above, the committee recommended that the firm should present the said justification along with the revised Phase III CT protocol before SEC for further consideration.
14.	FDC/MA/21/000294 Metformin HCl IP eq. to Metformin (as extended release form) 1000mg+Dapagliflozin 10mg + Sitagliptin Phosphate monohydrate IP eq, to Sitagliptin 100mgfilm coated Tablets	M/s. Theon Pharmaceuticals Ltd.	The firm presented their proposal along with BE and Phase III CT study protocol for the proposed FDC. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE and Phase III CT Study subject to condition that the study sites should be distributed geographically & Government sites should also be included as well as the firm should submit the PI's undertaking before initiation of the CT study.
15.	FDC/MA/22/000001 Metformin Hydrochloride (as sustained release) + Vildagliptin (as sustained release) + Dapagliflozin Propanediol	M/s. Ravenbhel Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 20.01.2022, the firm presented revised Phase III CT Protocol along with BE study report before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the phase III CT study with condition that study sites should be

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	monohydrate eq. to Dapagliflozin(500mg/ 1000mg/500mg/1000 mg+100mg/100mg/10 0mg/100mg+5mg/5m g/10mg/10mg) tablet		distributed geographically and endocrinologist should be included in the study.
16.	FDC/MA/22/000173 Metformin HCl IP 1000mg/1000mg+Gli mepiride IP 1gm/2mg+Dapagliflo zin Propanediol Monohydrate eq. to Dapagliflozin 10mg/10mg tablets	M/s. Akums Drugs & Pharmaceutical 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 to conduct the proposed BE and Phase III CT study with condition that study sites should be distributed geographically and endocrinologist should be included in the study.
17.	FDC/MA/22/000189 Glimepiride 2mg/2mg/1mg/1mg+ Metformin HCl IP 500mg/1000mg/1000 mg/500mg+Vildaglipt in (in sustained release form) 100mg/100mg/100mg tablets	M/s. Macleods	The firm presented their proposal along with BE and Phase III CT study protocol before the committee. After detailed deliberation, the committee noted that the FDC of Glimepiride 2mg+ Metformin HCl IP 850mg+Vildagliptin 50mg had already been deliberated before SEC as well as in Technical Committee meeting dated 18.01.2022 wherein Technical committee didn't recommend for approval of the FDC with given justification due to possibility of hypoglycemia and difficulties for dose titration for such patients. In view of above, committee opined that the firm should submit the justification in light of said recommendation of the Technical Committee.
18.	FDC/MA/22/000190 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/ 5mg / 10mg/ 10mg+ Sitagliptin Phosphate Monohydrate eq. to Sitagliptin IP 50mg/ 50mg/ 100mg/ 100mg +Metformin HCl IP	M/s. Akums Drugs and Pharmaceuticals Ltd.	The firm presented their proposal along with BE and Phase III CT study protocol only in higher strength of the proposed FDC i.e FDC of Metformin Hydrochloride (as extended release) 1000mg + Sitagliptin Phosphate Monohydrate eq to Sitagliptin 100mg + Dapagliflozin Propanediol Monohydrate eq to Dapagliflozin 10mg tablets. After detailed deliberation, the committee noted that all proposed strengths were

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	(as extended release form) 500mg / 1000mg / 500mg/ 1000mg tablets		already deliberated before the SEC. In view of above, the committee recommended for grant of permission to conduct the BE & CT study with the higher strength. As regards to remaining strengths, the committee recommended that the decision will be taken based on results of the CT study of other firms.
19.	FDC/MA/22/000199 Sitagliptin Phosphate Monoihydrate IP Eq. to Sitagliptin IP 100mg/100mg+Metformin HCl IP (As sustained release form) 500mg/1000mg +Pioglitazone HCl IP eq. to Pioglitazone 15mg/15mg tablets	M/s. Akums Drugs and Pharmaceuticals Ltd.	The firm presented their proposal along with BE and Phase III CT study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE and Phase III CT study. The results of studies should be presented before the SEC.
20.	FDC/MA/21/000026 Dapagliflozin 5mg/10mg + Teneligliptin 20mg/20mgFilm Coated Tablet.	M/s. Synokem Pharmaceuticals Pvt. Ltd.	The firm presented their request for amendment in the approved Phase III CT protocol for which NOC was already granted on 10.08.2021. On the basis of 12 weeks clinical data, the firm requested for permission to manufacture & market the proposed FDC and firm would continue the study upto 24 weeks as per approved protocol. After detailed deliberation, the committee recommended that firm should present the study data upto 16 weeks before the committee for further consideration.
BA/BE Division			
21.	12-09/2022/BA-BE/Misc-15/DC Teneligliptin 10 mg Metformin Hydrochloride 500 mg (Extended Release) and Pioglitazone 15 mg Tablets	M/s. Ajanta Pharma Limited	The firm presented their proposal for BABE Study of the FDC of Teneligliptin 10 mg Metformin Hydrochloride 500 mg (Extended Release) and Pioglitazone 15 mg Tablets for Export Purpose along with the study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BABE Study for Export purpose.