Recommendations of the SEC (Endocrinology & Metabolism) made in its 8th/24 meeting held on 23.04.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	E-16122 Insulin degludec/Insulin Aspart (rDNA origin)	M/s. Novo Nordisk	The firm presented the proposal for amendment in the warning statement for already approved drug product Insulin degludec/Insulin Aspart (rDNA origin) from current warning statement "To be sold by retail on the prescription of registered Endocrinologist and/or MD (Internal Medicine) treating diabetic patients only" to "To be sold by retail on the prescription of a Registered Medical Practitioner" or "To be sold by retail on the prescription of a Registered MBBS Practitioner only". After detailed deliberation, the committee recommended for the proposed amendment in the warning statement as "To be sold by retail on the prescription of a Registered Medical Practitioner only".
2.	E-16132 Insulin degludec (rDNA origin)	M/s. Novo Nordisk	The firm presented the proposal for amendment in the warning statement for already approved drug product Insulin degludec (rDNA origin) from current warning statement "To be sold by retail on the prescription of registered Endocrinologist and/or MD (Internal Medicine) treating diabetic patients only" to "To be sold by retail on the prescription of a Registered Medical Practitioner only" or "To be sold by retail on the prescription of a Registered MBBS Practitioner only". After detailed deliberation, the committee recommended for the proposed amendment in the warning statement as "To be sold by retail on the prescription of a Registered Medical Practitioner".
FDC Division			
3.	FDC/MA/24/000084 Empagliflozin 10mg/10mg/25mg/25	M/s. Logos Pharma	The firm presented their proposal along with request for BE study waiver and the proposal of another firm was placed before SEC on 19.10.2023 & 20.10.2023

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	mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg/100mg/50mg/100mg film coated Tablet		for FDC Empagliflozin 10mg/10mg/25mg/25mg + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg/100mg/50mg/100mg film coated Tablet. The recommendation is that "The firm presented their proposal along with Phase III CT Protocol for two strengths i.e., Empagliflozin + Sitagliptin (10 mg+100 mg, 25 mg+100 mg) tablets and requested for BE study waiver. After detailed deliberation, the committee considered the request for BE study waiver and recommended for grant of permission to conduct Phase III CT. The results of the study should be presented before the committee for further review.
4.	FDC/CT/24/000030 Linagliptin + Metformin Hydrochloride IP (ER) 2.5mg+1000mg, 5mg+500mg, 5mg+1000mg film coated bilayered tablet	M/s. Mascot Health Series Pvt. Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 15.11.2023, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for conduct of the Phase IV clinical trial. The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
5.	FDC/CT/24/000032 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Glimepiride IP + Metformin Hydrochloride IP (ER) (10 mg + 1 mg + 1000 mg), (10 mg + 2 mg + 1000 mg) film coated Tablet	M/s. Mascot Health Series Pvt. Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 07.12.2023, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for conduct of the Phase IV clinical trial. The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
6.	FDC/MA/23/000089 Dapagliflozin Propanediol monohydrate eq to Dapagliflozin 5mg/5mg/10mg/10mg + Linagliptin	M/s. Exemed Pharmaceuticals	In light of earlier SEC recommendation dated 04.12.2023, wherein the committee considered BE report for the proposed FDC in higher strength. Now, firm presented the proposal along with justification for Phase III clinical trial waiver before the committee. The committee noted that the FDC of

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	5mg/5mg/5mg/5mg + Metformin HCl eq. to Metformin (as extended release) 500mg/1000mg/500mg/ 1000mg tablets		Dapagliflozin 10mg/10mg + Linagliptin 5mg/5mg + Metformin HCl eq. to Metformin (ER) 500mg/1000mg tablets is already been approved on 08.03.2024. Further, the firm informed that they have withdrawn two strengths i.e. Dapagliflozin 5mg/5mg+ Linagliptin 5mg/5mg+ Metformin HCl eq. to Metformin (ER) 500mg/1000mg tablets. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product after submission of data including dissolution data and justification for BE waiverfor lower strength (FDC of Dapagliflozin 10mg + Linagliptin 5mg + Metformin HCl eq. to Metformin (ER) 500mg tablets) as per the BE Study guideline, to CDSCO.
SND Division			
7.	SND/MA/24/000005 Semaglutide Injection 2mg/1.5ml (1.34mg/ml) & 4mg/3ml (1.34mg/ml) (Synthetic Origin)	M/s Alkem Laboratories Limited	The firm has presented their proposal for grant of permission to manufacture and marketing of Semaglutide Injection 2mg/1.5ml (1.34mg/ml) & 4mg/3ml (1.34mg/ml) (Synthetic Origin) along with Bioequivalence study protocol and Phase-III clinical trial before the Committee. The firm has informed that Semaglutide solution for injection (rDNA origin) 0.25mg/0.5ml, 0.5mg/0.5ml, 1mg/0.5ml, 1.7mg/0.75ml and 2.4mg/0.75ml already approved by the CDSCO on 20.04.2022. After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study as per protocol presented by the firm and committee opined that the firm should revise their Phase-III clinical trial protocol in for following 1. the study duration shall be 24 weeks instead of 16 weeks 2. Inclusion of test parameter like Serum calcitonin, antigenicity & immunogenicity in inclusion criteria.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			Accordingly, the firm should submit revised Phase-III clinical trial protocol along with BE study report to CDSCO for further review by the Committee.
8.	SND/MA/24/000062 Semaglutide solution for injection (Synthetic origin) 0.25mg/0.5ml,0.5mg/ 0.5ml,1mg/0.5ml,1.7 mg/0.75ml and 2.4mg/0.75ml	M/s Sun Pharma Laboratories Limited	The firm has presented their proposal for grant of permission to manufacture and marketing of Semaglutide solution for injection (Synthetic origin) 0.25mg/0.5ml, 0.5mg/0.5ml, 1mg/0.5ml, 1.7mg/0.75ml and 2.4mg/0.75ml along with Phase-III clinical trial and Bioequivalence study protocol before the Committee. The firm has informed that Semaglutide solution for injection (rDNA origin) 0.25mg/0.5ml, 0.5mg/0.5ml, 1mg/0.5ml, 1.7mg/0.75ml and 2.4mg/0.75ml already approved by the CDSCO on 20.04.2022. After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study and Phase-III clinical trial subject to condition that firm should include serum calcitonin test parameter in inclusion criteria. Further, the firm should submit Bioequivalence report and get evaluated by the SEC committee before initiating the Phase III clinical trial.