Recommendations of the SEC (Endocrinology & Metabolism) made in its 93rd meeting held on 21.09.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/MA/20/000074 Denosumab 60mg/ml	M/s. Enzene Bioscience Limited	The firm presented their proposal for amendment in warning statement of drug from "To be sold by retail on the prescription of a Rheumatologist and Orthopedicians only" to "To be sold by retail on the prescription of an Endrocrinologist, Rheumatologist and Orthopedicians only". After detailed deliberation, the committee recommended for grant of approval for warning statement as proposed.
FDC Division			
2.	FDC/MA/22/000146 Teneligliptin IP 20mg/20mg+ Metformin HCl (ER) IP 500mg/1000mg +Pioglitazone HCl IP 15mg/15mg	M/s. Synokem Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 14.06.2022, the firm presented the BE study results before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with the condition that Phase IV clinical trial should be conducted as per New drugs and clinical trial rules, 2019. Accordingly, the firm should submit the Phase IV clinical trial protocol within 03 months from date of approval for review by the committee.
3.	FDC/MA/22/000257 Metformin Hydrochloride IP (As extended Release) 1000mg/500mg/1000 mg/1000mg/500mg/ 1000mg + Empagliflozin 5mg/10mg/10mg/12.5 mg/25mg/25mg	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm presented their proposal along with BE study protocol before the committee. The committee noted that the proposed FDC was already approved in various strengths. However, the proposed additional strengths i.e Metformin Hydrochloride IP (As extended Release) 500mg/500mg + Empagliflozin 10mg/25mg do not add any therapeutic value for dose titration beyond the strengths already approved and hence the committee did not consider these additional strengths. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study with the

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			higher strength which is already approved by CDSCO.
4.	FDC/MA/21/000284 Metformin hydrochloride IP (as an extended release form) 1000mg + Sitagliptin Phosphate monohydrate IP 100mg + Dapagliflozin Propanediol monohydrate 10mg tablets	M/s. Exemed	In light of earlier SEC recommendations dated 14.07.2021 & 15.07.2021, the firm presented the BE study and Phase III study reports before the committee. The committee noted that the FDC was already approved by CDSCO recently. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing the proposed FDC which is already approved.
5.	FDC/MA/22/000231 Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg/5mg + Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg/15mg tablets	M/s. Exemed	The firm presented their proposal along with Phase III CT and BE study protocol before the committee on the higher strength. After detailed deliberation, the committee recommended for grant of permission to conduct proposed BE/CT study with condition that BE results should be presented to the committee before initiation of clinical trial. As regard to the lower strength, committee did not consider for approval as it may not have any additional therapeutic benefit.
6.	FDC/MA/21/000026 Dapagliflozin 5mg/10mg + Teneligliptin 20mg/20mg Film Coated Tablet	M/s. Synokem Pharmaceuticals Pvt. Ltd.	In light of earlier SEC recommendations dated 14.07.2022 & 15.07.2022, the firm presented the BE study report and 18 weeks Phase III study report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing the proposed FDC with the condition that the firm should continue the study upto 24 weeks and submit the report to CDSCO.
7.	FDC/MA/22/000249 Metformin HCl ER 500mg/500mg/ 1000mg/1000mg/ 1000mg/1000mg + Glimepiride 1mg/2mg/1mg/2mg/ 1mg/2mg +	M/s. Innova Captab Ltd.	The firm did not turn up for presentation.

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	Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/5mg/5mg/5mg/ 10mg/10mg tablets		
8.	FDC/MA/22/000256 Metformin HCl 500mg/1000mg/ 500mg/1000mg + Glimepiride 1mg/1mg/2mg/2mg + Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg/10mg/10mg/10 mg tablets	M/s. Macleods Pharmaceuticals Ltd.	The firm presented their proposal along with CT and BE study protocol only on the higher strength before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct BE study. As regard to Phase III clinical trial, committee recommended that the firm should revise the CT study protocol by including all the applied strengths for further review by the committee.
New Drug Division			
9.	ND/MA/21/000169 Imeglimin 500 mg/ 1000 mg tablets	M/s. Exemed Pharmaceuticals	In light of earlier SEC recommendations dated 25.08.2022 and 26.08.2022, the firm presented the Phase III clinical trial data generated in India and other countries along with specific justification for their claim as monotherapy in treatment naïve patients before the committee. After detailed deliberation, the committee noted that Imeglemin 500 mg tablet is approved in Japan for the treatment of type 2 diabetes mellitus. The committee recommended for grant of permission to manufacture and market the Imeglimin 500 mg tablet for the proposed indication subject to the condition that: 1. The drug should be sold by retail only under the prescription of Endocrinologists or Internal Medicine Specialists. 2. The firm should conduct Phase IV clinical trial as per New Drugs and Clinical Trial rules 2019. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within three months of approval for further consideration.