Recommendations of the SEC (Endocrinology & Metabolism) made in its 87th meeting held on 18.05.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT/20/000062 (Pt-I) Densoumab	M/s. Intas	The firm did not turn up for presentation.
2.	BIO/CT04/FF/2022/31197 Teriparatide solution for injection in prefilled pen	M/s. Alkem Laboratories Ltd	The firm presented the proposal to conduct PK/PD study of Teriparatide 20microgram/80 micro liter solution for injection in prefilled pen. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial as per protocol CL-141-2, version: 00, Date: 15.03.2022.
3.	BIO/CT/20/000027 Biphasic Insulin Aspart	M/s. Bio Genomics	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-VIN-0109 version 02 dated 10 Feb 2022.
4.	BIO/CT18/FF/2022/29555 BIO/CT18/FF/2022/31694 BIO/CT18/FF/2022/31691 BIO/CT18/FF/2022/31689 Insulin Aspart Injection	M/s Biocon Biologics Limited	The firm presented proposal for import and marketing of the drug with waiver of Phase III clinical trial in the country. The firm presented detailed proposal alongwith CMC, pre-clinical and clinical trial data. The committee noted that the firm has conducted Phase I and Phase III trial with the drug in Germany and USA respectively and based on the results of the trial, the drug has been granted marketing authorization by EMA and Health Canada. After detailed deliberation, the committee recommended for grant of permission to import and market the drug with waiver of Phase III clinical trial in the country with the condition that firm should conduct Phase IV clinical trial in India (which also includes a sub-set population to generate PK/PD and immunogenicity and submit the protocol to CDSCO before placing the drug in the market) as per existing guidelines in the country.
FDC Division			

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
5.	FDC/MA/21/000235 Vildagliptin SR + Metformin (SR) (50mg/50mg/100mg/100mg+500mg/1000mg/500mg/1000mg) Tablets	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm did not turn up for presentation
6.	FDC/MA/21/000083 Glimepiride IP + Voglibose IP + Metformin Hydrochloride (as sustained release) IP (1mg + 0.2mg + 1000mg & 2mg + 0.2mg + 1000mg) tablets	M/s. Swiss Garnier	As per condition of permission dated 05.08.2021, the firm presented Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee opined that: 1. Details of lab investigations to be done at screening and various visits are not mentioned in the protocol. 2. The study sites should be geographically distributed and more Governments sites should be included. Accordingly, the firm should submit revised Phase IV clinical trial protocol for further review by the committee.
7.	FDC/MA/20/000142 Metformin HCL IP(SR)500mg/1000mg/500mg/1000mg + Vildagliptin SR 50mg/50mg/ 100mg/100mg Tablets	M/s Mascot	The firm did not turn up for presentation.
8.	FDC/MA/22/000099 Dapagliflozin 10mg + Pioglitazone HCl IP eq to Pioglitazone 15mg tablets	M/s. USV Pvt. Ltd.	The firm presented their proposal along with Phase III clinical trial and BE study protocols before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE/CT study with condition that BE study results should be presented to the committee before initiation of the clinical trial.
9.	FDC/MA/22/000079 Pioglitazone HCl IP eq. to Pioglitazone 7.5/15 mg+ Vildagliptin 50/50 mg Tablets	M/s Mascot Health	The firm did not turn up for presentation.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
10.	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 firm did not turn up for presentation.
11.	FDC/MA/22/000135 Metformin Hydrochloride (as sustained release) 1000mg+Vildagliptin (as sustained release) 100mg + Dapagliflozin 10mg tablets	M/s. Exemed Pharmaceuticals	The firm presented their proposal for Phase III clinical trial waiver and BE protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study. As regard to the Phase III CT waiver, the committee noted that the firm is yet to complete the Phase III CT study on FDC of Vildagliptin + Dapagliflozin for the remaining study duration of 8 weeks. The committee recommended that the firm should present the BE study report as well as complete report of the above Phase III CT including the stratified data on the patients administered Metformin concomitantly with the FDC for further consideration by the committee.
GCT Division			
12.	CT/07/22 Online Submission (30127) IcoSema& Insulin Icodec + Semaglutide	M/s. Novo-Nordisk	The firm presented Phase IIIa clinical trial protocol before the committee. After detailed deliberation, the committee noted that the firm has not conducted Phase II study. The committee recommended that the firm should conduct the study with initial 30 subjects and their interim analysis data should be submitted for review by the committee for further continuation of the study.
13.	CT/92/19 Online submission (16056) Tirzepatide	M/s. Eli-Lilly	The firm presented protocol amendment I8F-MC-GPHK version (b) dated 04/10/2021 before the committee.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
			After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
14.	CT/24/22 Online submission (30822) Tirzepatide	M/s. Eli-Lilly	The firm presented Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed clinical trial with condition that male/female subjects aged between 12-18 years should not be allowed to donate their sperm/eggs during participation in the trial.