

Recommendations of the SEC (Endocrinology & Metabolism) made in its 96th meeting held on 21.12.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/22/000068 Imeglimin HCl tablet 500 mg and 1000mg	M/s. Exemed	The firm presented its proposal for grant of permission to conduct Phase IV clinical trial study with Imeglimin HCl tablet 500 mg and 1000mg. After detailed deliberation, the committee recommended for the grant of permission to conduct the Phase IV clinical trial with Imeglimin HCl tablet 500 mg and 1000mg as per the protocol presented.
2.	ND/MA/22/000124 Imeglimin HCl SR tablets 500mg & 1000mg	M/s. Synokem Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 19.10.2022 & 20.10.2022, the firm presented the BE study results and Phase III CT protocol before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct Phase III CT as per the protocol presented.
Biological Division			
3.	4-78/Novonordisk Insulin degludec solution 100U/ml and 200U/ml.	M/s. Novonordisk	The firm presented the proposal for update in the prescribing information regarding use in pregnancy. After detailed deliberation, the committee recommended that the proposal should be deliberated in the presence of Gynaecologist & Obstetrician.
4.	BIO/CT/22/000036 Teriparatide 20 microgram/80 microlitre solution for injection in prefilled pen	M/s. Enzene Biosciences	The firm presented the proposal for amendment in PK/PD protocol titled "A randomized assessor-blind, balanced, pivotal, two period, two treatment, two sequence single-dose, 2 way crossover comparative bioavailability study of ENZ201 Teriparatide 20 microgram/80microlitre solution for injection in prefilled pen of Enzene Biosciences Ltd versus reference product Forsteo (Teriparatide) 20 microgram /80microlitre solution for injection in prefilled pen of Eli Lilly Nederland B.V in healthy adult male and female human subjects under fasting conditions" vide amendment to protocol version no 00 dated 26.09.2022.

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			After detailed deliberation, the committee recommended for the approval of the amended protocol.
SND Division			
5.	SND/MA/22/000149 Liraglutide 6mg/ml solution for injection in Prefilled Pen (18 mg/3ml pre-Filled Pen)	M/s. Biocon Pharma	The firm presented its proposal alongwith BE study report of Liraglutide 6mg/ml solution for injection in prefilled pen (18mg/3ml) (synthetic peptide) before the committee. After detailed deliberation, the committee recommended that the firm should conduct full phase BE study with adequate number of subjects as per the regulatory requirements.
6.	SND/MA/22/000235 Alpha Lipoic Acid Injection 25mg/ml (600 mg/24ml) (intravenous Infusion)	M/s. La Renon Healthcare	In light of earlier recommendation of SEC (endocrinology) dated 19.10.2022-20.10.2022, firm presented its proposal for grant of permission to manufacture and marketing of Alpha Lipoic Acid Injection 25mg/ml (600mg/24ml) (Intravenous Infusion) “For the treatment of symptoms of peripheral (Sensomotor) diabetic polyneuropathy” alongwith therapeutic rationale and some published clinical study reports in support of proposed additional dosage form before the committee. After detailed deliberation, the committee opined that no comparative systemic study report was presented by the firm in support of effect of Alpha Lipoic Acid for proposed indication. The committee recommended that the firm should conduct comparative clinical study of established superiority of the systemic Alpha Lipoic Acid injection over available oral dosage form of Alpha Lipoic Acid. Accordingly, firm should submit comparative clinical study protocol for further review by the committee.
FDC Division			
7.	FDC/MA/22/000079 Pioglitazone HCl IP eq. to Pioglitazone 7.5/15 mg +	M/s Mascot Health	The proposal was deferred for next meeting.

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	Vildagliptin50/50 mg Tablets		
8.	FDC/MA/22/000289 Linagliptin5mg/5mg+ Metformin HCl 500mg/1000mgtablets	M/s. Hetero Labs Ltd.	The proposal was deferred for next meeting.
9.	FDC/MA/22/000337 Metformin HCl IP (as extended release) 1000mg/500mg/ 1000mg+Linagliptin 5mg/5mg/5mg+ Empagliflozin 10mg/25mg/25mg tablets	M/s. Pure & Cure	The proposal was deferred for next meeting.
10.	FDC/MA/22/000338 Metformin HCl IP (as extended release) 500mg/1000mg/ 500mg/1000mg+ Linagliptin 5mg/5mg/5mg/5mg+ Dapagliflozin 5mg/5mg/10mg/10mg tablets	M/s. Pure & Cure	The proposal was deferred for next meeting.
11.	FDC/MA/22/000345 Metformin HCl (as sustained release) 500mg/1000mg+ Vildagliptin (as sustained release) 100mg/100mg + Dapagliflozin 5mg/5mg tablets	M/s. Exemed Pharmaceuticals	The proposal was deferred for next meeting.
12.	FDC/MA/22/000339 Glimepiride 1mg/2mg/1mg/2mg+ Sitagliptin Phosphate Monohydrate IP eq to Sitagliptin50mg/50mg /100mg/100mg tablets	M/s. Exemed Pharmaceuticals	The proposal was deferred for next meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
13.	FDC/MA/21/000235 Vildagliptin SR 50mg/50mg/100mg/ 100mg + Metformin (SR) 500mg/1000mg/ 500mg/1000mg tablets	M/s. Pure & Cure Healthcare Pvt. Ltd.	The proposal was deferred for next meeting.
14.	FDC/MA/21/000144 Sitagliptin Phosphate IP eq to Sitagliptin + Pioglitazone Hydrochloride IP eq. to Pioglitazone + Metformin Hydrochloride IP (AS sustained released form)(100mg/100mg+ 15mg/15mg+500mg/ 1000mg) tablets	M/s. Alkem Laboratories Ltd.	The proposal was deferred for next meeting.
15.	FDC/MA/21/000043 Teneligliptin hydrobromide hydrate eq to Teneligliptin IP + Metformin hydrochloride (SR) IP + Dapagliflozinpropane diol monohydrate eq to Dapagliflozin (20mg/20mg/20mg/ 20mg+500mg/ 1000mg/ 500mg/ 1000mg+5mg/5mg/ 10mg/10mg) Film coated bilayered tablet	M/s. Synokem Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
16.	FDC/MA/22/000325 DapagliflozinPropane diol monohydrate eq to Dapagliflozin + Linagliptin +	M/s. Theon Pharmaceuticals Ltd.	The proposal was deferred for next meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Metformin HCl eq to Metformin (as sustained release) (5mg/5mg/10mg/10mg/5mg/5mg/10mg/10mg+2.5mg/2.5mg/2.5mg/2.5mg/5mg/5mg/5mg+500mg/1000mg/500mg/1000mg/500mg/1000mg) tablets		
17.	FDC/MA/22/000306 Metformin HCl IP (as ER) + Dapagliflozin Propanediol Monohydrate Eq to Sitagliptin (500mg+50mg+5mg, 1000mg+50mg+5mg & 500mg+100mg+10mg) film coated tablets	M/s. Theon Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
GCT Division			
18.	CT/73/22 Online Submission (33271) LY3209590	M/s. Eli Lilly	The proposal was deferred for next meeting.
19.	CT/74/22 Online Submission (33286) LY3209590	M/s. Eli Lilly	The proposal was deferred for next meeting.
20.	CT/112/22 Online Submission (34060) LY3298176	M/s. Eli Lilly	The proposal was deferred for next meeting.
21.	CT/07/22 Online Submission (21675) Insulin icodec	M/s. Novo-Nordisk	The proposal was deferred for next meeting.

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22.	CT/136/20 Online Submission (20694) Liraglutide	M/s. Novo- Nordisk	The proposal was deferred for next meeting.