

Recommendations of the SEC (Endocrinology & Metabolism) made in its 79th meeting held on 21.09.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/21/000031 Lobeglitazone Sulfate Tablets 0.5 mg	M/s. Glenmark	<p>In light of earlier SEC recommendation dated 16.12.2020, firm presented BE study report and revised clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct study with the following condition:</p> <ol style="list-style-type: none"> 1. The study should be 2-arm double blind 16 weeks study of Lobeglitazone vs. Pioglitazone followed by 3-arms 12 weeks study of Pioglitazone vs. Lobeglitazone vs. the FDC 2. The results of the 16 weeks double blind study should be submitted to CDSCO for further review by the committee. Based on the results of the said study, continuation of the study to the 3rd arm part of the study will be considered.
Biological Division			
2.	BIO/CT21/FF/2020/0 222 Insulin Glargine	M/s. Sanofi Healthcare India Pvt. Ltd.	<p>The firm presented the proposal for marketing authorization for Insulin Glargine 100 IU/mL cartridge (manufacturing the drug product at an additional site in the country using drug substance imported from Frankfurt, Germany) with request for waiver for additional requirement for local clinical trial.</p> <p>After detailed deliberation, the Committee recommended for grant of marketing authorization with waiver of additional requirement for local clinical trial in the country.</p>
3.	BIO/CT21/BO/2021/2 5312 Insulin Aspart	M/s BioGenomics Limited	<p>The firm presented the proposal for marketing authorization for Recombinant Insulin Aspart Injection (100 U/mL solution for injection) in 3 mL cartridge and 10 mL vial presentation based on the interim analysis results of Phase III clinical trial in the country.</p>

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			<p>After detailed deliberation, the committee recommended for the grant of marketing authorization for the drug subject to the condition that the firm should conduct Phase IV clinical trial and submit the protocol within 3 months from the date of obtaining the marketing authorization</p> <p>Further, the firm should submit complete clinical study report to CDSCO.</p>
SND Division			
4.	12-11/2016-DC-DC (Pt.Troikaa-SND) Vitamin E Tocopheryl Acetate IP) hard gelatin capsule 400 mg (water miscible)	M/s. Troikka Pharmaceuticals	<p>The firm presented the results of Bioequivalence study. Committee noted that there is significant difference in results of pharmacokinetic parameters for test and reference formulations.</p> <p>After detailed deliberation the committee recommended that firm should submit detailed justification/ documented evidence/ literature with respect to the desired therapeutic level of the drug in support of their claim vis-à-vis the PK parameters observed in the BE Study for further review by the committee.</p>
5.	SND/MA/21/00083 Gliclazide Extended release Tablet 90/120 mg	M/s Reddy's Laboratories	<p>In light of earlier SEC recommendation dated 14-05-2021, the firm presented justification and therapeutic rationality based on published literature of scientific data on efficacy and safety of Gliclazide Extended release Tablet 90 and 120 mg along with justification for biowaiver for Gliclazide Extended release Tablet 90 mg tablet.</p> <p>After detailed deliberation the committee recommended for grant of permission to manufacture and market Gliclazide Extended Release Tablet 90/120 mg with already approved indication, subject to the condition that the firm should submit protocol for active post marketing surveillance for Gliclazide Extended release Tablet 90/120 mg within 3 months of granting approval to manufacture and market Gliclazide Extended release Tablet 90/120 mg</p>

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FDC Division			
6.	FDC/MA/21/0000083 Glimepiride IP + Voglibose IP +Metformin Hydrochloride (as sustained release) IP (1 mg+ 0.2mg + 1000 mg & 2 mg + 0.2 mg + 1000 mg) tablets	M/s. Swiss Garnier	<p>The firm presented their proposal before the committee along with BE Study protocol with request of Phase III clinical trial waiver.</p> <p>Committee noted that the FDC of Glimepiride IP + Voglibose IP +Metformin Hydrochloride (as sustained release) IP (1 mg+ 0.2mg + 500 mg & 2 mg + 0.2 mg + 500 mg) tablets was approved.</p> <p>After detailed deliberation the committee recommended for grant of permission to conduct the proposed BE Study with the condition that glucose should be administered to the study subjects as per the guidelines to avoid hypoglycemia. The BE study report should be presented for further consideration by the committee.</p>
7.	FDC/MA/20/000059 Metformin Hydrochloride (As sustained Release) +Gliclazide	Pure & Cure Healthcare	<p>In light of earlier SEC recommendation dated 16.12.2020, the firm presented detailed BE study data before the committee.</p> <p>After detailed deliberation the committee recommended for grant of permission for manufacturing and marketing the proposed FDC.</p>
8.	FDC/MA/20/000039 FDC Naltrexone Hydrochloride + Zonisamide (32mg +91 mg, 32mg + 182 mg, 32 mg + 273 mg & 32 mg + 364 mg)	Dr. Reddy's Laboratories Ltd.	<p>In light of earlier SEC recommendation dated 18.02.2021, firm submitted their justification w.r.t the primary pharmacokinetic parameters of the PK/PD Study report and firm also presented the Phase II Protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed dose ranging Phase II Clinical trial with the following conditions.</p> <ol style="list-style-type: none"> 1. Pulse monitoring to be done during the study. 2. Duration of the study should be 24 weeks. 3. Sleep Study should be included in the trial.
9.	FDC/MA/21/00006 Dapagliflozin 5mg + vildagliptin 50 mg + Metformin HCl IP	M/s USV Pvt. Ltd.	<p>The firm presented their revised Phase III Clinical Trial Protocol before the committee.</p> <p>After detailed deliberation committee</p>

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	500mg tablet		recommended for grant of permission to conduct the proposed Phase-III clinical trial.
GCT Division			
10.	CT/102/20 Online Submission (11937) Semaglutide	M/s. Novo-Nordisk	The firm presented their protocol amendment version 3 dated 04 March 2021 before the committee. After detailed deliberation, the committee recommended for grant of permission for approval of the protocol amendment of version 3 dated 04 March 2021 Dr. Satinath Mukopadhyay did not participate in the deliberation.
BA/BE Division			
11.	12-09/2021/BA-BE/Misc-19/DC Eliglustat	M/s. Synnchron Research Service Pvt Ltd. Ahmedabad	The firm presented the proposal along with the BA/BE study protocol before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the BA/BE Study of Drug Eligustat Sublingual tablets 4mg and 8mg.