

Recommendations of the SEC (Endocrinology & Metabolism) made in its 72nd meeting held on 16.12.2020 at CDSCO HQ New Delhi.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/20/000148 Trelagliptin Succinate 50/100 mg tablet	M/s Hetero	Firm presented the proposal along with the BE protocol before the committee. The committee noted that the protocol was not scientifically designed and safety of the study subjects was not taken care of and therefore protocol presented by the firm was not acceptable in the present form. After detailed deliberation the committee recommended that the firm should submit well designed protocol to CDSCO for further review by the committee.
2.	ND/MA/20/000079 Tetracosactide Injection	M/s. Sun Pharmaceutical Industries	In light of earlier SEC recommendation dated 04.08.2020, the firm presented the protocol for PD study before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the PD study subject to the following conditions: 1. Study team should include M.D. Medicine/Anesthesiologist as PI/CO-PI. 2. Exclusion criteria needs to be redefined. 3. Since the firm conducting PD study only through IV route, the results of the study may not be applicable for approval of the product for IM route.
Biological Division			
3.	BIO/CT/20/000156 Isophane Insulin Human Injection (Wosulin N)	M/s. Wockhardt Limited	Firm presented the proposal for conduct of Phase-I (PK-PD) study for export purpose. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study as per the protocol presented
4.	05/Phase IV/Shire/19-BD Velagluclerage Alfa	M/s. Shire Biotech India Pvt Ltd	In light of earlier SEC recommendation dated 17.07.2018, firm presented their proposal for conduct of non-interventional PMS study. After detailed deliberation the committee recommended for grant of permission to conduct PMS study subject to the condition that the protocol should be revised to collect the prospective safety data for a period of one year along with the retrospective data already

			available and the data should be presented before the committee.
5.	BIO/IMP/19/00007 8 Semaglutide	M/s. Novo Nordisk India Pvt. Ltd.	Firm presented their proposal for amendment in warning statement mentioned in import and market permission issued to the firm. After detailed deliberation, the committee recommended for approval of amendment of warning to mention the statement as “To be sold by retail on the prescription of a “Registered Endocrinologist or Physician with Post Graduate qualification in Medicine only”.
6.	04-84/Elililly/PAC-R- Dulaglutide/2020-BD Dulaglutide	M/s Eli Lilly and Company (India) Pvt. Ltd	Firm presented their proposal for approval of new indication. The Committee noted that the indication is already approved by US FDA. After detailed deliberation, the committee recommended for grant of approval of proposed indication. The text of the indication should be same as approved by USFDA.
7.	BIO/CT18/FF/2020 /22202 Insulin Lispro	M/s Eli Lilly and Company (India) Pvt. Ltd	Firm presented their proposal for grant of marketing authorization along with clinical data generated in the country. After detailed deliberation, the committee recommended for grant of marketing authorization subject to following conditions: 1. The name of the drug should be appropriate to distinguish it from the existing formulation of Insulin Lispro and it should also clearly claim that it is for use in adults only. 2. Firm should conduct structured Phase IV clinical trial in Indian patients. Accordingly, firm should submit Phase IV protocol to CDSCO within three months from the date of approval for marketing of the drug.
FDC Division			
8.	FDC/MA/20/00005 9 Metaformin Hydrochloride (As sustained Release 1000mg + Gliclazide 80 mg tablet)	M/s Pure & Cure Healthcare Pvt Ltd	Firm present the BE Study data and requested for Phase III clinical trial waiver. After detailed deliberation, committee recommended that the complete BE study report should be forwarded for further review by the committee to take decision accordingly.
9.	4-12/2018-DC Saroglitazar+Metfo rmin Hydrochloride	M/s. Zydus Healthcare	Firm presented their proposal alongwith BE study report and CT data conducted on Saroglitazar 2mg/4mg tablets.

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	IP (In ER form) (4mg+1000mg) Uncoated bilayered tablet		After detailed deliberation, committee recommended that firm should conduct Phase III Clinical Trial with the proposed FDC and accordingly protocol should be submitted. Firm should also present PSUR data of Saroglitazar 2mg/4mg tablets.
10.	FDC/MA/20/00015 8 Saroglitazar +Metformin Hydrochloride IP (In extended release form) (2 mg + 1000 mg) Uncoated bilayer tablet	M/s Zydus Healthcare Limited	Firm presented their proposal alongwith BE study report and CT data conducted on Saroglitazar 2mg/4mg tablets. After detailed deliberation, committee recommended that firm should conduct Phase III Clinical Trial with the proposed FDC and accordingly protocol should be submitted. Firm should also present PSUR data of Saroglitazar 2mg/4mg tablets.
11.	FDC/MA//20/0015 5 Voglibose 0.2mg/0.3mg + Vildagliptin 50 mg/50 mg tablets	M/s. Emcure	Firm presented their proposal before the committee. Committee noted that that there is dosage schedule incompatibility between the ingredients (i.e. Vildagliptin- Twice Daily & Voglibose-Thrice Daily) and hence there is no rationality for the FDC. After detailed deliberation, the committee did not recommended for the approval of the FDC.