

Recommendations of the SEC (Endocrinology & Metabolism) made in its 06th/24 SEC meeting held on 21.03.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2024/4 1564 Liraglutide injection 6mg/ml	M/s. Virchow Biotech Private Limited	<p>The firm presented the proposal to conduct Phase III clinical trial protocol titled “A Phase III, randomized, parallel, open label, non-inferiority, multicenter study to compare efficacy and safety of VBLG01 to Victoza in patients with Type 2 Diabetes” vide VBLG01/2024-CT1, version 1 dated 20.01.2024 along with results of Phase I clinical trial study conducted by the firm.</p> <p>After detailed deliberation, the committee recommended the firm to review the protocol completely considering the purpose and objective of the proposed clinical trial study. The following parameters are to be clearly defined & included in the revised protocol</p> <ol style="list-style-type: none"> 1. Study title including clear objective of the study 2. Rescue medication 3. Withdrawal criteria 4. Hypoglycemia management 5. BMI in inclusion criteria considering the objective. 6. Dose titration 7. Justification for conducting the study as open label instead of double blind 8. calcitonin monitoring shall be included 9. progression of severe non proliferative and diabetic retinopathy should be monitored <p>Accordingly, the firm should submit the revised protocol to CDSCO for further deliberation before the committee.</p>
2.	E-13974 Somatrogen 24mg/1.2ml and 60mg/1.2 ml	M/s. Pfizer	<p>The firm presented the proposal to conduct the active surveillance study protocol titled “A multicenter, non-interventional prospective active surveillance study among participants</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>receiving Somatrogen under routine clinical care in India” vide protocol number C0311026, version :V 1.0 dated 24 January 2024.</p> <p>After detailed deliberation, the committee recommended following changes in the presented protocol</p> <ol style="list-style-type: none"> 1. Sample size should be increased to minimum 100 subjects 2. The follow-up period should be minimum 3 years 3. Schedule of events should be clearly defined in the protocol visit/follow-up wise. <p>Accordingly, the firm should submit the revised protocol to CDSCO for further deliberation before the committee.</p>
BA/BEDivision			
3.	12-09/2024/BA-BE/MISC-20/DC BABE/CT05/FF/2023 /40641 Testosterone Undecanoate capsules 125 mg and 175 mg	M/s. Citus Research LLP, Gandhinagar – 382009, Gujarat.	<p>The firm presented bioavailability study protocol No. BE/23/365 version No. 0.0 dated 30.10.2023.</p> <p>After detailed deliberation, the committee recommended to conduct the comparative bioavailability study as presented by the firm.</p>
SND Division			
4.	SND/MA/23/000115 Metformin Hydrochloride SR Tablets 500mg/1000mg	M/s. USV Private Limited	<p>The proposal is for updation of prescribing information specially in fertility and pregnancy and lactation part. In light of earlier SEC recommendations dated 27.09.2023 & 29.09.2013, it has been decided that the proposal should be deliberated in presence of Gynecologist and Neonatologist experts. Due to non-availability of Gynecologist and Neonatologist experts during the meeting, the committee opined to deliberate proposal in next meeting in presence of above subject experts.</p>
New Drugs Division			
5.	ND/CT/24/000001	M/s. Glenmark Pharmaceuticals	In line with earlier SEC recommendations dated 19.10.23 & 20.10.23 firm presented

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	FDC of Lobeglitazone Sulfate 0.5 mg and Glimepiride 1mg Tablet	Limited	<p>their proposal for grant of permission to conduct Phase IV clinical trial for drug FDC of Lobeglitazone Sulfate 0.5 mg and Glimepiride 1mg tablet before committee.</p> <p>After detailed deliberation, the committee recommended for conducting of Phase IV clinical trial with drug FDC of Obeglitazone Sulfate 0.5 mg and Glimepiride 1mg tablet as per the protocol presented subject to the condition that firm should defined upper limit for the HbA1c i.e. NMT 9 % under the inclusion criteria.</p>
6.	ND/MA/22/000075 Nitisinone Capsules 2mg/5mg/10mg	M/s. Laurus	<p>The firm presented their proposal of grant of permission for inclusion of additional indication i.e. "To be used for the treatment of adult patients with Alkaptonuria (AKU)" to already approved indication for drug Nitisinone Capsules 2mg/5mg/10mg.</p> <p>After detailed deliberation, the committee noted that firm has granted manufacture and market permission on 09th June 2022 for the treatment of hereditary tyrosinemia type 1 (HT 1) in combination with dietary restriction of tyrosine and phenylalanine.</p> <p>After detailed deliberation, the committee opined that Alkaptonuria is a very rare disease and there is unmet medical need in the country.</p> <p>Accordingly, the committee recommended permission for inclusion of additional indication i.e. "To be used for the treatment of adult patients with Alkaptonuria (AKU)" to already approved indication for drug Nitisinone capsules 2mg/5mg/10mg subject to the condition that firm should conduct Phase IV clinical trial and firm should submit Phase IV CT protocol within three months of approval.</p> <p>The committee also recommended that opinion may be sought from expert from rare disease cell before the grant of permission.</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
7.	FDC/MA/24/000050 Alogliptin Benzoate eq. to Alogliptin 25mg/25mg + Pioglitazone Hydrochloride USP eq. to Pioglitazone 15mg/30mg film coated tablet	M/s. Torrent Pharmaceuticals Ltd.	<p>The firm presented their proposal along with justification for CT and BE waiver based on the BE study conducted on higher strength i.e. Fixed Dose Combination of Alogliptin 25 mg and Pioglitazone 45 mg Tablet for export purpose in 2016 before the committee.</p> <p>The firm informed that the said FDC is already approved in other countries i.e USA, Australia, Japan etc.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product after submission of data including dissolution data and justification for BE waiver as per the BE Study guideline with the condition that the firm should conduct Phase IV clinical trial.</p> <p>Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 03 months of approval for review by the committee.</p>
8.	FDC/MA/24/000051 Empagliflozin 10mg/10mg/10mg/10 mg+Glimepiride 1mg/1mg/2mg/2mg + Metformin HCl (ER) 500mg/1000mg/500mg/1000mg film coated bilayered tablet	M/s. Mascot Health Series Pvt. Ltd.	<p>The firm presented its proposal before the committee along with BE study protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. The result of the BE study should be presented before the committee for review along with Phase III clinical trial protocol.</p>
9.	FDC/MA/24/000052 Metformin Hydrochloride IP (ER) + Glimepiride IP + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 500mg/500mg/1000mg/1000mg + 1mg/2mg/1mg/2mg +	M/s. Logos Pharma	<p>The firm presented its proposal along with BE study protocol and Phase III clinical trial protocol before the committee.</p> <p>The committee noted that the firm presented Phase III clinical trial protocol for the strengths i.e Metformin Hydrochloride IP (ER) + Glimepiride IP + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 1000mg/1000mg + 1mg/2mg + 100mg/100mg film coated</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	100mg/100mg/100mg /100mg film coated bilayered tablet		bilayered tablet. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study and Phase III CT study. The report of the BE study and CT study should be presented for review before SEC.
10.	FDC/MA/24/000027 Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 5mg/10mg + Lobeglitazone sulfate 0.25mg/0.25mg film coated tablet	M/s. Akums Drugs and Pharmaceuticals Ltd.	Firm presented its proposal along with justification for waiver for BE study as well as Phase III CT study. The firm informed that they have already been granted Phase III CT NOC for the FDC Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg + Lobeglitazone sulfate 0.5mg film coated tablet. After detailed deliberation, the committee opined, that firm should present Phase III CT report for higher strength for further consideration of the BE study as well as Phase III CT waiver
11.	FDC/MA/24/000058 Empagliflozin + Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin + Metformin Hydrochloride IP (SR) (10mg+100mg+500mg / 10mg+100mg+1000mg / 25mg+100mg+500mg / 25mg+100mg+1000mg) film coated bilayered tablet	M/s. Mascot Health Series Pvt. Ltd.	The firm presented their proposal along with BE study protocol & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Further the firm should submit revised Phase III CT protocol after including rescue medication for hyperglycemia. Accordingly, firm should submit BE study report along with revised phase-III CT protocol to CDSCO for review by the committee.
12.	FDC/MA/23/000134 Ferrous Fumarate IP 30mg + Niacinamide IP 10mg + Pyridoxine Hydrochloride (Vit B6) IP 1mg + Folic	M/s. Hindustan Laboratories Limited	The firm did not turn up for presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Acid IP 250mcg + Riboflavin IP 1.2mg + Zinc Sulphate Monohydrate eq. to elemental Zinc 20mg + Thiamine Mononitrate IP 1.2mg + Cyanocobalamin (Vit B12) 2.5mcg + Ascorbic Acid (Coated) (Vit.C) 40mcg Capsules		