

Recommendations:

The 34th SEC (Endocrinology & Metabolism) meeting held on 25.04.2017 at CDSCO HQ New Delhi and recommended the following:

Agenda no.	File no./Drug Name	Name of firm/Institute	Recommendations
Subsequent New Drugs Division			
1	12-146/2016-DC (Pt-Zim-Snd) Vitamin D3 (Cholecalciferol) orally disintegrating strips 60000 IU add. Strength	M/s.Zim	The firm presented the proposal before the committee. After detailed deliberation the committee opined that their application may be considered for BE –CT waiver as the same strength in different dosage form is already available in the market and vitamin D3 2000IU ODS is already approved by CDSCO based on BE study and recommendation of SECCommittee.
2	12-11/2016-DC (PT-Troikaa) Vitamin E hard gelatin capsule 400mg	M/s.Troikaa	The representative of the firm mentioned that they are going to submit evidence about the availability of such formulation in other country and also the pharmaceutical aspects of the product being developed by them. The proposal may be placed in the next meeting.
3	12-121/2016-DC (Pt-Olive healthcare-SND) Levothyroxine sodium 25, 50 and 100 mcg soft gelatin capsule	M/s. Olive Healthcare	The firm didn't turn up for the presentation.
Biological Division			
4	4-410/Wockhardt/17-BD Insulin Glargine suspension and insulin human injection 200IU/mL	M/s. Wockhardt Ltd.	Firm presented the animal data and CMC data of the drug product. RCGM has already granted the NOC for the proposed PK/PD study. After detail deliberation of the PK/PD study protocol of the Insulin Glargine suspension and insulin human injection 200IU/mL (70:30), committee recommended for granting permission for conduct of the study. However, the proposal for manufacture and marketing of the product shall be considered for requirement of further data on safety, efficacy and immunogenicity along with the data of PK/PD study generated.
Global Clinical Trial Division			

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5	CT/58/16 Dapagliflozin	M/s. AstraZeneca	Assessment of Risk versus benefit to the patients In light of the fact that the test drug is approved and marketed in India, the safety profile of the test drug justifies the conduct of the trial. Innovation Vis-à- Vis existing therapeutic option IMP mechanism of action results in a direct and insulin independent elimination of glucose by the kidneys, which results in reduced blood glucose levels in type 2 diabetes (T2D) patients. In addition, IMP has a mild diuretic and natriuretic effect. Moreover, IMP has also been shown to reduce BP and albuminuria, two essential prognostic risk factors for progression of CKD. Unmet medical need in the country The incidence of Chronic kidney disease is suggested to increase because increase in the prevalence of Diabetes, Hypertension and other related disorders. After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial subject to the condition that there must be a Nephrologist in the Investigator's team at all study centers.
6	CT/18/17 Exenatide	M/s. AstraZeneca	Risk versus benefit to the patients- In light of the fact that the test drug is approved and marketed in India, the safety profile of the test drug justify the conduct of the trial. Innovation vis-a-vis existing therapeutic option: The primary objective of this study is to test the hypothesis that glycemic control, as measured by change in hemoglobin A1c (HbA1c) from baseline to endpoint, with exenatide is superior (in at least 1 of the exenatide treatment arms), to that of placebo after 28 weeks of treatment in adolescent patients with type 2 diabetes who are naïve to antidiabetic agents, or patients who are being treated with metformin, an SU, or a combination of metformin and an SU. Unmet need in the country- The test drug may be better treatment option in Type 2 Diabetes Mellitus

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			After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial. Dr. Rajesh Khadgawat did not participate in the deliberation.
7	CT/59/16 Liraglutide	M/s. Novo Nordisk	Assessment of Risk versus benefit to the patients In light of the fact that the test drug is approved and marketed in India, the safety profile of the test drug justifies the conduct of the trial. Innovation Vis-à- Vis existing therapeutic option In patients with T2DM who have not achieved glycaemic control on an SGLT2 inhibitor (with or without metformin), adding liraglutide to their treatment may achieve a better glycaemic control reflected in HbA1c reduction with associated decrease in body weight and no increase of hypoglycaemic events. Unmet medical need in the country T2DM is increasing in incidence and prevalence. Despite compliance with their treatment regimens, a large proportion of patients do not reach treatment targets, indicating that the current available treatment modalities are not satisfactory and more treatment options need to be explored. After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial.
8	CT/60/16 Semaglutide	M/s. Novo Nordisk	Assessment of Risk versus benefit to the patients The safety profile of the test drug from various preclinical pharmacology and toxicity studies including single dose toxicity, repeat dose toxicity studies and phase I, phase II, phase III clinical study justifies the conduction of the trial. Innovation Vis-à- Vis existing therapeutic option The aim for the present trial is to compare the effect of IMP versus canagliflozin, in subjects with T2D inadequately controlled with metformin, in terms of glycaemic control, weight

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			management and other efficacy parameters. Unmet medical need in the country Type 2 diabetes is a progressive disease and continuous treatment intensification is required in order to provide optimum glycaemic control. The currently available treatment modalities for T2D are still not satisfactory and there is a significant proportion of patients not reaching the treatment targets. After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial.
9	CT/52/16 MOD-4023	M/s. JSS Medical Research India Pvt.Ltd.	Risk vs Benefit to the patients: The safety profile of the test drug from various preclinical pharmacology and toxicity studies including single dose toxicity, repeat dose toxicity, Male fertility studies, female reproduction and developmental toxicity Studies, Carcinogenicity, Genotoxicity studies and phase I, phase II, phase III clinical study justifies the conduction of the trial. Innovation vis a vis against existing therapy: The purpose of the study is to demonstrate that weekly MOD-4023 administration is non-inferior to daily Genotropin administration in terms of safety and efficacy outcomes Unmet need- The test drugs may provide treatment option in pre-pubertal children with growth hormone deficiency. After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial. Dr. Rajesh Khadgawat did not participate in the deliberation.
10	CT/51/16 Dulaglutide	M/s. Eli Lilly	Risk versus benefit to the patients- In light of the fact that the test drug is old drug and marketed in India, the safety profile of the test drug justify the conduct of the trial. Innovation vis-a-vis existing therapeutic option The primary objective of this study is to test the hypothesis that Dulaglutide (0.75

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			mg and 1.5mg, pooled) given subcutaneously (SC) once a week for 26 weeks to children and adolescents with T2DM who have inadequate glycemic control, despite diet and exercise, with or without metformin and/or basal insulin is superior to placebo in the treatment of T2DM, as measured by baseline to Week 26 change in HbA1c. Unmet need in the country- The test drug may be treatment option in Pediatric Patients with Type 2 Diabetes Mellitus After detailed deliberation the committee recommended for grant of permission to conduct the clinical trial.

S.No	SEC –Experts Name & Designation	Signature
1.	Dr.B.Gupta, Prof & Head Dept of Medicine, NDMC Medical college & Hindu Rao Hospital, New Delhi.	
2.	Dr.Mohd Ashraf Ganie, MD (Internal Medicine), Teaching block, AIIMS, Ansari nagar, New Delhi.	
3.	Dr. Deepak Khandelwal, All India Institute of Medical Sciences, Delhi.	
4.	Dr.Vinod Kumar, UCMS, GTB Hospital, Dilshad Garden, Shahdara, New Delhi.	
5.	Dr. Rama Walia, PGIMER, Chadigarh.	
6.	Dr. K. H. Reeta, Dept. of Pharmacology, AIIMS, New Delhi.	
7.	Dr. Rajesh Khadgawat, Assoc. Prof., AIIMS, New Delhi	
8.	Dr Manoj Chadha, P.D. Hinduja National Hospital & Research Center, Mumbai.	