

Recommendations:-

The 33rd SEC (Endocrinology and Metabolism) meeting deliberated the proposals on 10.02.2017 and recommended the following:-

Agenda No	File Name & Drug name, Strength and Purpose	Firm Name	Recommendations
New Drugs Division Proposal			
1	12-47/14-DC(Pt-C), Analglipitin 100mg tablet Revised Clinical Trial protocol.	M/s MSN Laboratories Pvt. Ltd.	The firm has presented the revised clinical trial protocol wherein all the recommendations have been incorporated as suggested by the Committee in its earlier meetings. After detailed deliberation, the Committee recommended the grant of permission for conduct of phase III clinical trial and BE study as per the presented protocol. <i>(Dr. Deepak khandelwal did not participate in the deliberation.)</i>
Subsequent New Drugs Division Proposals			
2	12-127/2016-DC(Pt-IPCA-SND), Hydroxychloroquine Sulfate Tablets 300mg, Phase III CT permission (Dyslipidemia, Pre and Post diabetes)	M/s IPCA	The firm presented the draft protocol for grant of permission for conduct of phase III clinical trial. The committee observed following 1. The clinical trial title should clearly indicate the combination of HCQ and Atorvastatin will be compared with Atorvastatin alone. 2. The term pre-diabetic dyslipidemia should be corrected. 3. The sample size should be re-assessed. 4. Patients with pre-existing cardiovascular disease should be excluded. Accordingly the firm should submit the revised protocol to O/o DCGI for further review.
3	12-111/2015-DC(Pt-Astra-SND), Saxagliptin as first add-on after metformin in Indian type 2 diabetes patients, Non interventional observational study	M/s Astrazeneca	The Firm has withdrawn the application.
4	12-128/2016-DC(Pt-Vovantis-SND), Ascorbic Acid Effervescent Tablets 500mg, Manufacturing and Marketing Permission (Additional Dosage Form)	M/s Vovantis Laboratories Private Limited	After detailed deliberation, the committee opined that firm should Conduct a Bioequivalence study comparing their product with conventional tablet. Accordingly they should submit the protocol to office of DCGI for approval.

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Global Clinical Trials Division Proposals			
5	CT/45/16, Oral Semaglutide, Permission for conducting Phase IIIa Clinical trial. (Re-deliberation)	M/s.Novo Nordisk	Assessment of Risk vs. Benefit to the patients: The safety profile of the study drugs from preclinical toxicology studies including repeat dose toxicity, reproductive and developmental toxicity, carcinogenicity, genotoxicity and clinical studies justify the conduct of the trial. Innovation vis-à-vis Existing Therapeutic Option: To compare the effect of once-daily dosing of three dose levels of oral semaglutide (3, 7 and 14 mg) versus placebo on glycaemic control in subjects with type 2 diabetes mellitus treated with insulin. Unmet Medical Need in the country: The test drug may potentially provide alternative treatment in subjects with type 2 diabetes treated with insulin. After detailed re-deliberation the committee opined that the risk management plan/revised protocol is acceptable. Hence the committee recommended the conduct of the study(protocol amendment no: 2, version 3.0)
6	CT/46/16, Lixisenatide, Permission for conducting Phase IV Clinical trial. (Re-deliberation)	M/s.Sanofi	Assessment of Risk vs. Benefit to the patients: In light of the fact the study drug is approved in India since 15/Jan/2015. The safety profile of the study drug from preclinical and clinical trials justify the conduct of this study Innovation vis-à-vis Existing Therapeutic Option: To compare the safety, in terms of percentage of patients with symptomatic documented hypoglycemia during Ramadan fast, of lixisenatide versus sulfonylurea both on top of basal insulin, in type 2 diabetes mellitus patients fasting Ramadan. Unmet Medical Need in the country: The test drug may potentially provide alternative treatment in Type 2 Diabetes Mellitus subjects who elect to fast during Ramadan. After detailed re-deliberation the committee recommended the conduct of the study subject to the condition that the following is to be included in the protocol. 1. Blood glucose level should be monitored 8-12 hours after the last meal atleast thrice a week

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Biological Division Proposals			
7	4-398/WOCKHARDT /16-BD, Consegna N and Wosulin N, Consegna 30/70 And Wosulin 30/70, Consegna 30/70 And Mixtard 30/70 Permission to conduct PK/PD study 4-399/WOCKHARDT /16-BD& 4-400/WOCKHARDT /16-BD	M/s Wockhardt	The firm application for NOC to conduct comparative PK/PD study of an already approved drug of biphasic isophane insulin 30/70 injection 200IU (Wockhardt Consegna) and Mixtard 30/70 (NovoNordisk) was deliberated. The committee opined that there is no clarity in the application on the purpose and objective of this study. Therefore firm should submit purpose and objective of the study for further deliberation. Both the applications have been withdrawn (4-399/WOCKHARDT/16-BD& 4-400/WOCKHARDT /16-BD) by the firm.
8	4-369/ NovoNordisk /16-BD, Liraglutide, Request for waiver of conducting a separate clinical trial.	M/s NovoNordisk	In the previous SEC, the committee opined that the firm should carry out the study as detailed in the previous SEC minutes dated 8-11-2016. The firm has not submitted any protocol for Liraglutide (Saxenda) 3mg proposed in the indication of weight management in adult patients. Instead the firm again requested for waiver of clinical trial data requirement without submitting any new clinical data since last SEC meeting. It is to mention that marketing authorization for Liraglutide (Victoza) 1.8mg was issued on 8-2-2010 based on global clinical trial data having Indian participants, with the condition to conduct PMS study and submit the data. Now firm has presented subgroup analysis of global clinical trial data(active arm 59 patients ,placebo arm 27 patients , 2:1 randomization) of same global clinical trial data which is inadequate to consider the firm's request of market authorization of Liraglutide (Saxenda) 3mg. in weight management in adult Indian patients.
9	4-121/Wockhardt/PAC-R-Insulin Glargine/16BD, Insulin Glargine, Additional strength of Insulin Glargine 200IU/ml	M/s Wockhardt Ltd	After deliberation of the proposal for additional strength of recombinant insulin Glargine 200IU/ml. The committee opined that the PK/PD study data should be submitted for further consideration of the application.

