

MINUTES OF 37th MEETING OF THE TECHNICAL COMMITTEE HELD ON 28.11.2016 UNDER THE CHAIRMANSHIP OF DGHS FOR SUPERVISING CLINICAL TRIALS ON NEW CHEMICAL ENTITIES IN THE LIGHT OF DIRECTIONS OF THE HON'BLE SUPREME COURT OF INDIA ON 03.01.2013.

Present:

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| 1. | Dr. Jagdish Prasad,
Director General of Health Services,
Nirman Bhawan, New Delhi | Chairman |
| 2. | Dr. Kamlakar Tripathi,
Prof. Department of Medicine,
Institute of Medical Sciences,
Banaras Hindu University, Varanasi. | Member |
| 3. | Dr. Yash Paul Sharma,
Prof. & Head, Department of Cardiology,
PGIMER, Chandigarh. | Member |
| 4. | Dr. Nandini Kumar,
Former Dy. Director General Sr. Grade,
Adjunct Professor, KMC, Manipal, Chennai | Member |

From CDSCO:

1. Dr. V. G. Somani,
Joint Drugs Controller (India)
2. Mr. R. Chandrashekar,
Deputy Drugs Controller (India)
3. Mrs. Annam Visala,
Deputy Drugs Controller (India)
4. Mrs. Rubina Bose
Deputy Drugs Controller (India)

The Chairman welcomed the members of the Committee for the 37th meeting. Thereafter, the Committee discussed the clinical trial proposals and other agenda one after another as under:

The Committee deliberated 17 cases related to approval of clinical trials. Out of these 17 cases, 03 cases was related to clinical trials of NCEs, 07 cases were related to Global Clinical Trials (GCT), remaining 07 cases were related to clinical trials for approval of New Drugs, Subsequent New Drugs, Fixed Dose Combinations and Biologicals.

1. Proposals of Clinical Trials of NCEs recommended by SECs.

The Committee evaluated three cases related to clinical trials of NCEs and made recommendations considering all aspects of safety, efficacy especially in terms of the three parameters viz. risk versus benefit to the patients, innovation vis-a-vis existing therapeutic option and unmet medical need in the country. After detailed deliberations, the Committee recommended approval for two proposals of Clinical Trial. The recommendations of the Committee are enclosed at **Annexure-I**.

2. Proposals of Clinical Trials of GCT recommended by SECs.

The Committee evaluated six cases related to global clinical trials. After detailed deliberations, the Committee recommended approval for six proposals of clinical trials. The recommendations of the Committee are enclosed at **Annexure-II**.

3. Proposals of Clinical Trials other than GCT/ NCEs recommended by SECs.

The Committee evaluated seven cases of other than GCT/clinical trial of NCEs. After detailed deliberations, the Committee recommended approval for seven proposals. The recommendation of the Committee is enclosed as **Annexure-III**.

4. Waiver of Clinical Trial in Indian population for approval of New Drugs and Biologicals which have already been approved outside India:

05 proposals were placed before the Committee for consideration of permission for manufacture/import for marketing in the country with waiver of local clinical trial. The details of recommendations of the Committee along with recommendations of the SEC are annexed as **Annexure-IV**.

Further, the committee opined that in cases of applications for approvals of new drugs for manufacturing/marketing in the country, onsite inspection of their facilities where such drugs has been developed may be conducted to ensure GMP compliance.

5. Others: Reconsideration for waiver of local clinical trial of the drug Secukinumab 150 mg/mL for two additional indications (Psoriatic Arthritis and Ankylosing) of M/s Sandoz

The committee noted that the firm has submitted application for approval of two additional indications (**Psoriatic Arthritis and Ankylosing**) of the drug Secukinumab 150mg/mL. The committee opined that the drug is already approved in India and the firm has submitted PSUR data for the first six months. Hence, after detailed deliberation the committee recommended waiver of local clinical trial.

Proposals of clinical trial of NCEs along with their evaluations and recommendations of the Technical Committee in its 37th Meeting held on 28.11.2016:

Proposal No	Details of the proposal	Assessment of the Proposal <i>vis -a vis</i> specified Parameters	Recommendations 1. Subject Expert Committee 2. Technical Committee
1.	<p>Name of the Drug: Parenteral TK-112690 (METREXASSIST™)</p> <p>Date of Application: 17/2/2016</p> <p>Protocol No: CLP-2690-0002</p> <p>Phase of the trial: Ib</p> <p>Name of the Applicant: M/s R A Chem Pharma Ltd., India</p> <p>Name of the Sponsor: Tosk, Inc., 2672 Bayshore Parkway, Suite 507, Mountain View, CA 94043</p> <p>Name of the Manufacturer: M/s R A ChemPharma Ltd, India for Drug Substance and M/s TherDose Pharma Pvt. Ltd., Hyderabad, India</p> <p>Title: A Phase Ib, Multi-center, Study of METREXASSIST™ (Parenteral TK-112690)</p>	<p>Risk versus Benefit to the patients- The safety profile of the test drug from preclinical studies including single dose toxicity, repeat dose toxicity; genotoxicity and Clinical Phase I study justify the conduct of the study.</p> <p>Innovation vis a vis existing therapeutic option- The purpose of the study is to assess the efficacy Metrexassist administered weekly to subjects with locally advanced or recurrent or metastatic SCCHN scheduled to receive MTX as chemotherapy.</p> <p>Unmet need- The test drug may be alternative option in the treatment of patients locally advanced or recurrent or metastatic SCCHN</p>	<p>1. The Proposal was deliberated in SEC (Oncology) held on 3/5/2016.</p> <p>After detailed deliberation the committee noted the following</p> <ol style="list-style-type: none"> The rationale of using of the trial drugs for the mucoprotection of patients on Methotrexate is not clear and not substantiated by available published literature, specifically the role of Uridine in reducing mucositis and not interfering with the action of Methotrexate on cancer cells was not substantiated with evidences They have not presented in vitro pre clinical or animal studies showing that the trial drug does not interfere with the efficacy of Methotrexate The rationale for addition of Uridine supplement in the trial will confound the outcome of the trial. <p>The Proposal was Re-deliberated in SEC</p>

	<p>Administered in Combination with Methotrexate as a Weekly Infusion to Subjects with SCCHN Undergoing Treatment with Methotrexate. A Dose Escalation/Safety study with No Control.</p>		<p>(Oncology) held on 19/7/2016</p> <p>The firm presented protocol and the following clarifications still need to be addressed:</p> <ol style="list-style-type: none"> 1. Only the summary version of non clinical pharmacological and toxicological data of the study drug was presented. The same need to be presented in full detail including the data for the combination of Uridine with Metrexassist. 2. The committee was informed that the protocol was approved in US in 2011 ; however no patients were recruited ,the reason for non recruitment for a period of five years is unclear. Hence the committee did not recommend the approval to conduct the study <p>The Proposal was Re-deliberated in SEC (Oncology) held on 23/8/2016</p> <p>After detailed deliberation the committee has recommended the conduct of phase Ib trial in at least 25 patients. Accordingly modified protocol for phase Ib is submitted to DCGI office.</p> <p>List of SEC Experts:</p> <ol style="list-style-type: none"> 1. Dr. Sameer Bakshi, Professor, Dept. of Medical Oncology,
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37th Technical Committee Meeting -28.11.2016

			<p>AIIMS, New Delhi</p> <ol style="list-style-type: none"> 2. Dr. H.P Pati, Prof, Dept of Hematology, AIIMS, New Delhi. 3. Dr. Prantar Chakraborty, Dept. of Haematology, NKS Medical College, Kolkata. 4. Dr. C.K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata. 5. Dr. H.S Rehan , Prof & Head of Dept. of Pharmacology, Lady Harding Medical College, New Delhi 6. Dr. Renu Saxena, Prof & Head, Dept. of Hematology, AIIMS, New Delhi. <p>2. Recommendation of the Technical Committee:</p> <p>The committee opined that the clinical trial with the NCE is proposed to be India centric, with no other participating countries. After detailed deliberation, the committee has requested the applicant to make a detailed protocol presentation before it in the next meeting and an expert in Pharmacology and Toxicology also be invited.</p>
<p>2.</p>	<p>Name of the Drug: Etrolizumab Solution for Injection [105 mg/0.7mL Pre-filled Syringe] (rhuMAb Beta7)</p> <p>Date of Application: 24/06/2016</p>	<p>Assessment of Risk vs. Benefit to the patients: The safety profile of the study drugs from preclinical safety pharmacological toxicology studies and clinical studies justify the conduct of the trial.</p>	<p>1. The proposal was deliberated in SEC (Gastroenterology) held on 09/09/2016.</p> <p>After detailed deliberation, the committee found merit in the phase III study (Protocol GA29102). However, for protocol</p>

37th Technical Committee Meeting -28.11.2016

	<p>Protocol No: GA28951</p> <p>Phase of the trial: Open Label Extension (OLE)</p> <p>Name of the Applicant: Roche Products (India) Pvt. Ltd. 1503, 15th Floor, The Capital, Plot No. C-70, Bandra Kurla Complex, Bandra East, Mumbai – 400051, India</p> <p>Name of the Sponsor: F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 CH-4070 Basel, Switzerland</p> <p>Name of the Manufacturer: F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 CH-4070 Basel, Switzerland.</p> <p>Title: An open-label extension and safety monitoring study of moderate to severe ulcerative colitis patients previously enrolled in Etrolizumab phase II/III Studies.</p>	<p>Innovation vis-à-vis Existing Therapeutic Option: Protocol No GA29102: To evaluate the efficacy of Etrolizumab (105mg) subcutaneous every 4 weeks (Q4W) compared with placebo for maintenance of remission at week 62 for randomized patients in remission at week 10, as determined by the mayo clinic score.</p> <p>Protocol No GA28951: To assess the long-term safety and efficacy of Etrolizumab in patients eligible for OLE. For progressive multifocal leukoencephalopathy (PML) safety monitoring.</p> <p>Unmet Medical Need in the country: The test drug may potentially provide alternative treatment of subjects with moderate to severe Active Ulcerative Colitis who are naive to TNF inhibitors.</p>	<p>GA28951, the committee recommended that inclusion criteria should be modified such that those who do NOT respond to the initial 10 weeks of induction therapy are not given the investigation product in an open label manner. This is because these patients are TNF alpha inhibitor naïve and hence it is ethically not correct to not offer them TNF-alpha inhibitors. A suitably modified form of these protocols for India should be submitted for further review. These should include long-term safety monitoring (including PML) for all patient exposed to the investigational product.</p> <p>The proposal was re-deliberated in SEC (Gastroenterology) held on 26/10/2016</p> <p>The firm now provided data showing that extension of Etrolizumab beyond 10 weeks results in a similar degree of response as compared to TNF-α inhibitor therapy. The firm has provided satisfactory explanation; therefore the committee recommended the conduct of the study in its presented form.</p> <p>SEC Expert List:</p> <p>1. Dr. A. Saraya, Professor, Dept. of Gastroenterology AIIMS, New delhi-110029.</p>
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37th Technical Committee Meeting -28.11.2016

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<p>3.</p>	<p>Name of the Drug: Etrolizumab Solution for Injection [105 mg/0.7mL Pre-filled Syringe] (rhuMAb Beta7)</p> <p>Date of Application: 24/06/2016</p>	<p>Assessment of Risk vs. Benefit to the patients: The safety profile of the study drugs from preclinical safety pharmacological toxicology studies and clinical studies justify the conduct of the trial.</p>	<p>1. The proposal was deliberated in SEC (Gastroenterology) held on 09/09/2016. After detailed deliberation, the committee found merit in the phase III study (Protocol GA29102).</p>

37th Technical Committee Meeting -28.11.2016

	<p>Protocol No: GA29102</p> <p>Phase of the trial: III</p> <p>Name of the Applicant: Roche Products (India) Pvt. Ltd. 1503, 15th Floor, The Capital, Plot No. C- 70, Bandra Kurla Complex, Bandra East, Mumbai – 400051, India</p> <p>Name of the Sponsor: F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 CH-4070 Basel, Switzerland</p> <p>Name of the Manufacturer: F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 CH-4070 Basel, Switzerland</p> <p>Title: Phase III, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy (maintenance of remission) and safety of Etrolizumab compared with placebo in patients with moderate to severe active ulcerative colitis who are naive to TNF inhibitors</p>	<p>Innovation vis-à-vis Existing Therapeutic Option: Protocol No GA29102: To evaluate the efficacy of Etrolizumab (105mg) subcutaneous every 4 weeks (Q4W) compared with placebo for maintenance of remission at week 62 for randomized patients in remission at week 10, as determined by the mayo clinic score.</p> <p>Protocol No GA28951: To assess the long-term safety and efficacy of Etrolizumab in patients eligible for OLE. For progressive multifocal leukoencephalopathy (PML) safety monitoring.</p> <p>Unmet Medical Need in the country: The test drug may potentially provide alternative treatment of subjects with moderate to severe Active Ulcerative Colitis who are naive to TNF inhibitors.</p>	<p>However, for protocol GA28951, the committee recommended that inclusion criteria should be modified such that those who do NOT respond to the initial 10 weeks of induction therapy are not given the investigation product in an open label manner. This is because these patients are TNF alpha inhibitor naïve and hence it is ethically not correct to not offer them TNF-alpha inhibitors. A suitably modified form of these protocols for India should be submitted for further review. These should include long-term safety monitoring (including PML) for all patient exposed to the investigational product.</p> <p>The proposal was re-deliberated in SEC (Gastroenterology) held on 26/10/2016</p> <p>The firm now provided data showing that extension of Etrolizumab beyond 10 weeks results in a similar degree of response as compared to TNFα inhibitor therapy. The firm has provided satisfactory explanation; therefore the committee recommended the conduct of the study in its presented form.</p> <p>SEC Expert List:</p>
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37th Technical Committee Meeting -28.11.2016

			<ol style="list-style-type: none">1. Dr. A. Saraya, Professor, Dept. of Gastroenterology AIIMS, New delhi-110029.2. Dr. P. Shravan Kumar, Professor, HOD of Gastroenterology, Gandhi Medical College and Hospital, Secunderabad, Telangana.3. Dr. Shalini Chawla, Professor, Dept. of Pharmacology, MAMC, New Delhi.4. Dr. Shobha Bhatia, Professor, Dept. of Gastroenterology and Hepatology Seth GS Medical College and KEM Hospital, Parel, Mumbai-400012.5. Dr. Sudhir Gupta, Prof. and Head, Government Medical College and Super speciality, Nagpur.6. Dr. Sandeep Nijhawan, Sr. Professor, SMS Medical College, Jaipur.7. Dr. Manoj Kumar Sharma, Associate Prof., Institute of Liver and Biliary Sciences, D-1 Vasant Kunj, New Delhi <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
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Proposals of clinical trial of GCTs along with their evaluations and recommendations of the Technical Committee in its 37th Meeting held on 28.11.2016:

Proposal No.	Details of the proposal	Assessment of the Proposal <i>vis –a vis</i> specified Parameters	Recommendations 1. Subject Expert Committee 2. Technical Committee
1.	<p>Name of the Drug: Faster Acting Insulin Aspart (FIAsp)</p> <p>Date of Application: 09/02/2016</p> <p>Protocol No: NN1218-4101</p> <p>Phase of the trial: III b</p> <p>Name of the Applicant: Novo Nordisk India Pvt. Ltd.</p> <p>Name of the Sponsor: Novo Nordisk</p> <p>Name of the Manufacturer: Novo Nordisk A/S, Denmark.</p> <p>Title Efficacy and Safety of Faster-acting Insulin Aspart compared to NovoRapid[®] both in Combination with Insulin Degludec in Children and Adolescents with Type 1 Diabetes.</p>	<p>Risk versus Benefit to the patients- the safety profile of the test drugs in pre-clinical and clinical studies justify the conduct of the study with faster acting insulin aspart.</p> <p>Innovation vis a vis existing therapeutic option- The purpose of the study is to confirm efficacy in terms of glycaemic control of treatment with mealtime faster-acting insulin aspart in combination with insulin degludec in children and adolescents with type 1 diabetes mellitus.</p> <p>Unmet need- The test drug may be an alternative treatment option in subjects with type 1 diabetes.</p>	<p>1. The Proposal was deliberated in SEC (Endocrinology) held on 28/4/2016</p> <p>After detailed deliberation the committee noted that Insulin Degludec which is used in the trial along with other IMP's is still not approved for use in population aged 1-17 years in India. Hence the committee did not recommend the conduct of the trial.</p> <p>The Proposal was Re-deliberated in SEC (Endocrinology) held on 11/8/2016</p> <p>After detailed deliberation, the committee noted that Insulin Degludec which is to be used in the trial along with other IMPs is still not approved for use in population aged 1 to 17 years in India. Hence the Committee did not recommend the conduct of the trial. Now the firm has requested for re-deliberation on the matter. The firm did not provide the justification for use of two IMPs unapproved</p>

		<p>in India for use in 1 to 17 years age group.</p> <p>Thus, the Committee did not approve the conduct of the trial in its present form.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Rajesh Khadgawat, Associate Professor, Dept. of endocrinology, AIIMS, New Delhi-110029. 2. Dr. Manoj Chadha, Dept. of Endocrinology P.D. Hinduja National Hospital Mahim, Mumbai, Maharashtra-400016. 3. Dr. Rajesh Rajput, Department of Medicine VI and Endocrinology, PGIMS, Medical Road, Rohtak-124001. 4. Dr. Richa Dewan, Department of Medicine, MAMC, New Delhi. 5. Dr. Shalini Chawla, Professor Dept. of Pharmacology, AIIMS, New Delhi. <p>2. Recommendation of the Technical Committee:</p> <p>After detailed deliberation, the committee opined Insulin Degludec is approved in many countries including India and Insulin Aspart is also approved in India for all age groups. The proposed study is with the drug Faster Acting Insulin Aspart in combination with Insulin Degludec and is a part of Global Clinical Trial in</p>
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37th Technical Committee Meeting -28.11.2016

			children aged 1-17 years. Hence, after detailed deliberations the committee recommended approval for the study.
2.	<p>Name of the Drug: Nintedanib</p> <p>Date of Application: 25/4/2016</p> <p>Protocol No: 1199.36</p> <p>Phase of the trial: III</p> <p>Name of the Applicant: Boehringer Ingelheim India Private Limited, East, Mumbai – 400 051, INDIA</p> <p>Name of the Sponsor: Boehringer Ingelheim India Private Limited on behalf of Boehringer Ingelheim International GmbH</p> <p>Name of the Manufacturer: Catalent Germany Eberbach GmbH Gammelsbacher Strasse 2 69412 Eberbach, Germany.</p> <p>Title: A 24-week, double-blind, randomized, parallel-group study evaluating the efficacy (health related quality of</p>	<p>Risk versus benefit to the patients: - In light of the fact that the study drugs are approved and marketed in India, the safety profile of these drugs justify the conduct of the study.</p> <p>Innovation vis-a-vis existing therapeutic option: -The primary objective of the study is to assess efficacy and safety of concomitant treatment with Nintedanib and sildenafil in IPF patients with advanced lung function impairment.</p> <p>Unmet need in the country- The test drugs may be an alternate treatment option in IPF (Idiopathic Pulmonary Fibrosis) patients with advanced lung function impairment.</p>	<p>1. The Proposal was deliberated in SEC (Pulmonary) on 16/06/2016</p> <p>After detailed deliberation the committee did not recommend the conduct of the study for the following reasons;</p> <ol style="list-style-type: none"> 1. There is no rationale/justification for use of sildenafil in patients with IPF without evidence of PAH. 2. Group 3 patients of PAH will usually experience worsening of gas exchange. 3. The current gold standard for diagnosis of PAH is right heart catheterization which is not being performed in this study. Doppler echocardiography is associated with high percentage of false negative and false positive results. <p>The Proposal was deliberated in SEC (Pulmonary) on 29/09/2016</p> <p>After detailed deliberation the committee recommended the conduct of the trial with following modification in</p>

	<p>life assessment) and safety of oral Nintedanib co-administered with oral sildenafil, compared to treatment with Nintedanib alone, in patients with idiopathic pulmonary fibrosis (IPF) and advanced lung function impairment.</p>		<p>protocol;</p> <ol style="list-style-type: none"> 1. Title of the study needs modification to put emphasis on quality of life assessment. 2. Quality of the assessment questionnaires should be annexed in protocol. <p>In line with the above recommendations the firm needs to submit the revised protocol to the DCGI office for further review.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Subodh Kumar, Assistant Professor, Dehradun. 2. Dr. Sushant H. Meshram, Professor, Government Medical College and Hospital, Nagpur. 3. Dr. J.C. Suri, Professor, VMMC and Safdurjung Hospital, New Delhi. 4. Dr. C.D Tripathi, Professor and Head, Department of Pharmacology, VMMC, New Delhi. <p>2. Recommendation of the Technical Committee:</p> <p>Title of the study is now modified and quality of life assessment questionnaire is annexed to the protocol.</p> <p>After detailed deliberation the committee recommended the conduct of the study in-line with SEC recommendations subject to the condition that PFT test must be conducted</p>
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			that base-line and subsequently at the end of the study
3.	<p>Name of the Drug: Sofosbuvir 400mg and Velpatasvir 100 mg Fixed Dose Combination.</p> <p>Date of Application: 08/06/2016</p> <p>Protocol No: GS-US-342-1521 Original: 12 February 2016</p> <p>Phase of the trial: III</p> <p>Name of the Applicant: Klinera Corporation India, 401 Hill view Industrial Estate, LBS Marg, Ghatkopar (West), Mumbai 400086.</p> <p>Name of the Sponsor: Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404, USA</p> <p>Name of the Manufacturer: Sofosbuvir was manufactured at Cambrex Charles City, 1205 11th. Street Charles City, IA 50616 USA</p> <p>Velpatasvir was manufactured at Fabbrica Italiana Sintetici S.p.A. (FIS), Viale Milano 26, 36075 Montecchio Maggiore, Vincenza, Italy</p>	<p>Assessment of Risk vs. Benefit to the patients: The safety profile of the study drugs from single dose, repeat dose toxicity studies, reproductive toxicity studies, local tolerance studies, genotoxicity studies, phototoxicity studies of Velpatasvir and repeat dose toxicity studies for Sofosbuvir and clinical studies justify the conduct of the trial.</p> <p>Innovation vis-à-vis Existing Therapeutic Option: To evaluate the efficacy of treatment with SOF/VEL FDC for 12 weeks in subjects with chronic HCV infection as measured by the proportion of subjects with sustained viral response 12 weeks after cessation of treatment (SVR12). To evaluate the safety and tolerability of treatment with SOF/VEL FDC for 12 weeks</p> <p>Unmet Medical Need in the country: The test drug may potentially provide alternative treatment of subjects with Chronic Hepatitis C Virus (HCV) infection.</p>	<p>1. The proposal was deliberated in SEC (Gastroenterology) held on 04/07/2016.</p> <p>The proposal is to conduct Phase III, open label, safety and efficacy clinical trial; the firm presented the proposed protocol. After detailed deliberation the committee observed that there is no comparator arm in the protocol and therefore recommended that the firm should revise the protocol to add a comparator arm with standard care and submit the revised protocol to the office of the DCGI for further consideration.</p> <p>The proposal was Re-deliberation in SEC (Gastroenterology) held on 26/10/16.</p> <p>The firm now informed that similar phase III single arm studies with Sofosbuvir + Velpatasvir are ongoing in other countries. Since there is no other drug approved for pangenotypic Hepatitis C infection, the committee has recommended the single arm study with this combination.</p> <p>SEC Expert List:</p> <p>1. Dr. A. Saraya, Professor,</p>

37th Technical Committee Meeting -28.11.2016

	<p>Title: A Phase 3, Open-label Study to Investigate the Efficacy and Safety of Sofosbuvir/Velpatasvir Fixed Dose Combination for 12 weeks in Subjects with Chronic Hepatitis C Virus (HCV) infection.</p>		<p>Dept. of Gastroenterology AIIMS, New Delhi-110029.</p> <ol style="list-style-type: none"> 2. Dr. P. Shravan Kumar, Professor, HOD of Gastroenterology, Gandhi Medical College and Hospital, Secunderabad, Telangana. 3. Dr. Shalini Chawla, Professor, Dept. of Pharmacology, MAMC, New Delhi. 4. Dr. Shobha Bhatia, Professor, Dept. of Gastroenterology and Hepatology Seth GS Medical College and KEM Hospital, Parel, Mumbai-400012. 5. Dr. Sudhir Gupta, Prof. and Head, Goernment Medical College and Super Speciality, Nagpur. 6. Dr. Sandeep Nijhawan, Sr. Prof. SMS Medical College, Jaipur. 7. Dr. Manoj Kumar Sharma, Associate Professor, Insitute of Liver and Biliary Sciences, D-1, Vasantkunj, New Delhi. <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
<p>4.</p>	<p>Name of the Drug: Palbociclib (PD-0332991)</p> <p>Date of Application: 21/12/2015</p> <p>Protocol No: A5481037</p>	<p>Assessment of Risk vs. Benefit to the patients: The safety profile of the study drugs from preclinical safety pharmacology and toxicology studies including Single dose toxicity, repeat dose toxicity,</p>	<p>1. The proposal was deliberated in SEC (Oncology) held on 15/03/2016.</p> <p>After detailed deliberation, the committee opined that the</p>

	<p>Phase of the trial: IIIb/IV</p> <p>Name of the Applicant: Pfizer Limited, The Capital, 1802/1901, Plot No. C - 70, Bandra (East), Mumbai 400051, Maharashtra, India</p> <p>Name of the Sponsor: Pfizer Inc., 235 East 42nd Street, New York, NY 10017, USA.</p> <p>Name of the Manufacturer: Pfizer Inc., 235 East 42nd Street, New York, NY 10017, USA.</p> <p>Title: A Study of Palbociclib in Combination With Letrozole as Treatment of Post-Menopausal Women With Hormone Receptor-Positive, HER2-Negative Advanced Breast Cancer for Whom Letrozole Therapy is Deemed Appropriate</p>	<p>reproductive and developmental toxicity, genotoxicity and clinical studies justify the conduct of the trial.</p> <p>Innovation vis-à-vis Existing Therapeutic Option: To provide access to Palbociclib to post-menopausal patients with hormone receptor-positive [HR(+)], HER2-negative [HER2(-)] ABC who are deemed appropriate for letrozole therapy.</p> <p>Unmet Medical Need in the country: The test drug may potentially provide alternative treatment of post-menopausal women with hormone receptor-positive, HER2-Negative Advanced Breast Cancer for whom Letrozole therapy is deemed appropriate.</p>	<p>primary objective of the study to provide access to Palbociclib should be changed to assessment of safety parameters (the first point under the section of secondary objective). The other two points under the section of secondary objective should stay as it is. The applicant is required to recruit atleast 100 subjects from India for the study. The revised protocol should be submitted to CDSCO for further review by the committee.</p> <p>The proposal was re-deliberated in SEC (Oncology) held on 18/10/2016.</p> <p>The firm presented the revised protocol as per the recommendations of SEC held on 15/03/2016. After detailed deliberation the committee recommended the conduct of the phase IIIb/IV clinical trial as per the revised protocol submitted.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Subodh Kumar, Assistant Professor, Dehradun. 2. Dr. Sushant H. Meshram, Professor, Government Medical College and Hospital, Nagpur. 3. Dr. J.C. Suri, Professor, VMMC and Safdurjung Hospital, New Delhi. 4. Dr. C.D Tripathi, Professor and Head, Department of
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37th Technical Committee Meeting -28.11.2016

			<p>Pharmacology, VMMC, New Delhi.</p> <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
5.	<p>Name of the Drug: Aclidinium Bromide /Formoterol fumarate FDC and Aclidinium bromide.</p> <p>Date of Application: 30/11/2015</p> <p>Protocol No: M-AS464-30 (AZ code: D6570C00002)</p> <p>Phase of the trial: III</p> <p>Name of the Applicant: PAREXEL International Clinical Research Private Limited Kadubisanahalli, Varthur Hobli Bengaluru – 560087, Karnataka.</p> <p>Name of the Sponsor: AstraZeneca AB Karlebyhus, Astraallén Södertälje SE-151 85 Sweden.</p> <p>Name of the Manufacturer: Ranke Química, S.A. Ctra. Granollers-Girona (C-35), Km 58.85,08470 Sant Celoni, Barcelona,Spain.</p>	<p>Risk versus benefit to the patients- The safety profile of test drug from preclinical 4- and 13-week inhalation toxicity studies in dogs and clinical phase I, II studies justify the conduct of the study.</p> <p>Innovation I existing therapeutic option The purpose of study is to assess the Efficacy and Safety of Aclidinium bromide/Formoterol fumarate compared with Individual Components and Placebo and Aclidinium bromide compared with Placebo when administered to Patients with Stable Chronic Obstructive Pulmonary.</p> <p>Unmet need in the country- The test drug may be an alternative treatment option in Patients with Stable Chronic Obstructive Pulmonary.</p>	<p>1. The proposal was deliberated in SEC (Pulmonary) held on 29/03/2016.</p> <p>After detailed deliberation the committee recommended the conduct of the study with following conditions</p> <ol style="list-style-type: none"> 1. Monitoring for glaucoma and urinary retention must be performed at base line, 3 months and end of the study visit. 2. X rays and sputum examination to rule out active TB must be done. <p>The proposal was deliberated in SEC (Pulmonary) held on 29/09/2016.</p> <p>The firm has presented their justification for the queries raised during last meeting dated 29/03/16.</p> <p>After detailed deliberation the committee has recommended the conduct of the study.</p>

	<p>Title: A 24-week Treatment, Randomised, Parallel-group, Double blinded, Double-Dummy, Multicenter Study to Assess the Efficacy and Safety of Acridiniumbromide / Formoterol fumarate compared with Individual Components and Placebo and Acridinium bromide compared with Placebo when administered to Patients with Stable Chronic Obstructive Pulmonary Disease.</p>		<p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. C.K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata. 2. Dr. Sanjay Kumar Singh, Dept. of Medical Oncology, Gajara Raja Medical College, Veer Savarkar Marg, Gwalior-474009 Gwalior. 3. Dr. Prantar Chakroborthy, dept. of Hematology, NRS Medical College, Kolkata-700014. 4. Dr. Renu Saxena, Professor and Head, Dept. of Hematology, AIIMS, New Delhi. 5. Dr. H.P. Pati, AIIMS, New Delhi. 6. Dr. D.S. Arya, Dept. of Pharmacology, AIIMS, New Delhi. <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
<p>6.</p>	<p>Name of the Drug: Insulin Degludec/insulin Aspart (IdegAsp).</p> <p>Date of Application: 27/06/2016</p> <p>Protocol No: NN5401-4266</p> <p>Phase of the trial: IIIb</p> <p>Name of the Applicant</p>	<p>Risk versus benefit to the patients- In light of the fact that the test drug is marketed in India and the safety profile justify the conduct of the trial.</p> <p>Innovation vis-à-vis existing therapeutic option The purpose of study is to investigate the effect and safety of insulin</p>	<p>1. The proposal was deliberated in SEC (Endocrinology) held on 22/08/2016.</p> <p>After detailed deliberation the committee recommended the conduct of the trial subject to the following :</p> <ol style="list-style-type: none"> 1. The time interval between two consecutive injections of Degludec/Aspart co-

37th Technical Committee Meeting -28.11.2016

	<p>Novo Nordisk India Private Ltd, Plot No. 32, 47 – 50, EPIP Area, Whitefield, Bangalore - 560 066, Karnataka, India</p> <p>Name of the Sponsor: Novo Nordisk India Private Ltd, Plot No. 32, 47 – 50, EPIP Area, Whitefield, Bangalore - 560 066, Karnataka, India</p> <p>Name of the Manufacturer: Novo Nordisk A/S, Novo AlléDK-2880, Bagsværd, Denmark</p> <p>Title: A 38 week trial comparing effect and safety of insulin Degludec/Insulin Aspart vs. Insulin Glargine plus Insulin Aspart in subjects with Type II Diabetes treated with basal insulin with or without oral anti-diabetic treatment in need of treatment intensification.</p>	<p>Degludec/Insulin Aspart vs. Insulin Glargine plus Insulin Aspart in subjects with type II Diabetes treated with basal insulin with or without oral anti-diabetic treatment in need of treatment intensification.</p> <p>Unmet need in the country- The test drug/regimen may be an alternative treatment option for subjects with type 2 diabetes who require intensification.</p>	<p>formulation should be minimum 8 hours.</p> <p>2. Degludec/Aspart co-formulation escalation of doses should be monitored not only by fasting plasma glucose but also by concomitant measurement of post-meal glucose.</p> <p>The proposal was Re-deliberated in SEC (Endocrinology) held on 08/11/2016.</p> <p>After detailed deliberation in the SEC meeting held on 22.08.2016. The committee recommended the conduct of the study with the following conditions:</p> <p>1. The time interval between two consecutive injections of degludec/aspart co-formulation should be minimum 8 hrs.</p> <p>2. Degludec/Aspart co-formulation escalation of doses should be monitored not only for FPG but also by concomitant measurement of post meal glucose.</p> <p>The applicant now presented the justification. The committee after detailed deliberation opined that the rationale/data now submitted is adequate. The trial may be conducted in its presented form.</p>
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			<p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Richa Dewan, Director and Professor, Dept. of Medicine, MAMC, New Delhi. 2. Dr. Bikash Medhi, Dept. of Pharmacology, PGIMER, Chandigarh 3. Dr. Md. Ashraf Ganie, Dept. of Endocrinology, AIIMS, J&K 4. Dr. Manoj Chadha, Dept. of Endocrinology, P.D, Hinduja National Hospital Mahim, Mumbai, Maharashtra <p>2. Recommendation of the Technical Committee:</p> <p>After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
7.	<p>Name of the Drug: CBT124 [Biosimilar candidate Bevacizumab concentrate for solution for infusion, 100 mg as 25 mg/mL solution]</p> <p>Date of Application: 05/08/2016</p> <p>Protocol No: CBT124/CT/002</p> <p>Phase of the trial: III</p> <p>Name of the Applicant: Cipla BioTec Pvt. Ltd., L-147/B, Verna Industrial</p>	<p>Assessment of Risk vs. Benefit to the patients: The safety profile of the study drugs from preclinical safety pharmacology and toxicology studies including Single dose toxicity, repeat dose toxicity, reproductive and developmental toxicity and clinical studies justify the conduct of the trial.</p> <p>Innovation vis-à-vis Existing Therapeutic Option: To evaluate the efficacy of CBT124 in comparison with</p>	<p>1. The proposal was deliberated in SEC (Oncology) held on 18/10/2016.</p> <p>After detailed deliberation the committee recommended the conduct of the study as per the protocol submitted.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. C.K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata. 2. Dr. Sanjay Kumar Singh, Dept. of Medical Oncology,

37th Technical Committee Meeting -28.11.2016

	<p>Estate, Verna, Salcette, Goa, India 403722.</p> <p>Name of the Sponsor: Cipla BioTec Pvt. Ltd., L-147/B, Verna Industrial Estate, Verna, Salcette, Goa, India 403722.</p> <p>Name of the Manufacturer: Cipla BioTec Pvt. Ltd., L-147/B, Verna Industrial Estate, Verna, Salcette, Goa, India 403722.</p> <p>Title: A Randomized, Double-blind, Multicentric, Parallel-group Study Comparing Efficacy, Safety and Immunogenicity of CBT124, a Candidate Biosimilar Bevacizumab in Combination with Carboplatin and Paclitaxel with EU sourced Avastin[®] in Combination with Carboplatin and Paclitaxel in First-line Treatment for Subjects with Stage IV (Unresectable Recurrent Disease or Metastatic) Non-squamous Non-Small Cell Lung Cancer (NSCLC).</p>	<p>EU-sourced Avastin (at cycle 6) and to evaluate pharmacokinetics (PK) of CBT124 in comparison with outsourced Avastin.</p> <p>Unmet Medical Need in the country: The test drug may potentially provide alternative treatment of Subjects with Stage IV (Unresectable Recurrent Disease or Metastatic) Non-squamous Non-Small Cell Lung Cancer (NSCLC).</p>	<p>Gajara Raja Medical College, Veer Savarkar Marg, Gwalior-474009 Gwalior.</p> <ol style="list-style-type: none"> 3. Dr. Prantar Chakraborty, dept. of Hematology, NRS Medical College, Kolkata-700014. 4. Dr. Renu Saxena, Professor and Head, Dept. of Hematology, AIIMS, New Delhi. 5. Dr. H.P. Pati, AIIMS, New Delhi. 6. Dr. D.S. Arya, Dept. of Pharmacology, AIIMS, New Delhi. <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
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37th Technical Committee Meeting -28.11.2016

Annexure III

Proposals of clinical trial of other than NCE/GCT along with their evaluations and recommendations of the Technical Committee in its 37th Meeting held on 25.11.2016:

S.No.	Name of the Drug	Firm Name	Recommendations:
1	<p>Quadrivalent Human Papilloma Virus</p> <p>Date of Application: 02.06.2016</p> <p>Phase - I</p>	<p>M/s Serum Institute of India Private Limited</p> <p>Indication – Indicated in girls or women aged 9 through 45 years and boys or men, aged 9 through 26 years for the prevention of HPV 6, 11 infections that are responsible for genital warts and HPV 26, 18 infections that are responsible for cervical, vulvar and vaginal cancer or CIN1, CIN2, CIN3 lesions and AIS, VIN2, VIN3 and VaIN2 and VaIN3.</p>	<p>1. Subject Expert Committee</p> <p>2. Technical Committee</p> <p>1. Recommendation of the SEC Committee: The Phase I study protocol submitted by the firm has been deliberated in detail and the committee recommended for approval of protocol</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi 110029. 2. Dr. A. P. Dubey, Prof & Head, Dept. of Pediatric, Maulana Azad Medical College & LNJP Hospital, Delhi. 3. Dr. Savita Verma, Pharmacology, PGIMS 4. Dr. Veena Verma, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. 5. Dr. P.P. Gupta, Department of Pharmacology, B.R.D Medical College & Nehru Hospital, Patna <p>2. Recommendation of the Technical Committee:</p> <p>After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
2	<p>Tetanus Vaccine (Adsorbed) I.P.</p> <p>Date of Application: 12.08.2016</p> <p>Phase - I</p>	<p>M/s Seasons Biologicals Private Limited</p> <p>Indication - Tetanus Vaccine (Adsorbed) I.P. is intended for</p>	<p>1. Recommendation of the SEC:</p> <p>The Phase I study protocol submitted by the firm has been deliberated in detail and recommended for approval with the exception of generating immunogenicity data. Accordingly, firm shall submit the revised protocol removing the efficacy assessment as the objective of the study.</p>

37th Technical Committee Meeting -28.11.2016

		immunization against tetanus infection.	<p>Action Taken: The firm has submitted the revised protocol as per SEC recommendation to the office of DCG (I).</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi 110029. 2. Dr. A. P. Dubey, Prof & Head, Dept. of Pediatric, Maulana Azad Medical College & LNJP Hospital, Delhi. 3. Dr. Savita Verma, Pharmacology, PGIMS 4. Dr. Veena Verma, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. 5. Dr. P.P. Gupta, Department of Pharmacology, B.R.D Medical College & Nehru Hospital, Patna <p>2. Recommendation of the Technical Committee:</p> <p>After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
3	<p>Alfuzosin Hydrochloride Extended Release and Tadalafil Tablets</p> <p>Date of Application: 09.11.2015</p> <p>Phase - III</p>	<p>M/s Sun Pharma Laboratories Limited</p> <p>Indication:- For the treatment of lower urinary tract infection associated with BPH.</p>	<p>1. Recommendation of SEC (Reproductive and Urology) held on 25th May 2016:</p> <p>“The committee recommended the Phase III clinical trial with the conditions that the study protocol be modified as a randomized double blind study. Accordingly the revised clinical trial protocol may be submitted to the DCGI office for approval.</p> <p>The committee recommended the proposed bioequivalence study. The results of the bioequivalence study as well as clinical trial shall be presented before the committee for further perusal.”</p> <p>The revised data are submitted by applicant (as per SEC recommendations).</p> <p>SEC Expert List:</p>

37th Technical Committee Meeting -28.11.2016

			<ol style="list-style-type: none"> 1. Dr. N. K. Mohanty, Prof & Head, Dept. of Urology, Vardhman Mahavir Medical College & Safdurjung Hospital, New Delhi. 2. Dr. Rajeev Sood, Prof & Head Dr. RML Hospital & PGIMER, Baba Kharak Singh Marg, Type 3, President's Estate. 3. Dr. Anup Kumar Kundu, Professor & Head, PGIMER & SSKM, Kolkata, West Bengal-700020. 4. Dr. Pikee Saxena, Assistant Professor, Lady Harding College, New Delhi-110001. 5. Dr. Bikas Medhi, Department of Pharmacology, PGIMER, Chandigarh, PIN - 160 012. 6. Dr. Amlesh Seth, Professor & Head Department of Urology, AIIMS, New Delhi. 7. Dr. Alka Kriplani, Professor & Head Department of Gynecology, AIIMS, New Delhi-110 038. <p>2. Recommendation of the Technical Committee:</p> <p>After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
4	<p>Heparin sodium (Additional indication)</p> <p>Date of Application: 30.05.2016</p> <p>Phase - III</p>	<p>M/s Troikaa Pharmaceuticals Limited</p> <p>Indication:- Prevention of infusion associated phlebitis.</p>	<p>1. Recommendation of the SEC: After detailed deliberation the committee recommended to conduct proposed Phase III CT.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Sameer Bakshi, Professor, Dept. of Medical Oncology, AIIMS, New Delhi. 2. Dr. C. K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata. 3. Dr. Sanjay Kumar Singh, , Dept. of Medical Oncology, Gajara Raja Medical College, Veer Savarkar Marg, Gwalior – 474009, Gwalior. 4. Dr. Prantar Chakroborty, Dept of Hematology, NRS Medical College, Kolkata-700014. 5. Dr. Renu Saxena, Professor and Head, Dept of Hematology, AIIMS, New Delhi. 6. Dr. Bikash Medhi, Pharmacology, PGIMER, Sector-12, Chandigarh.

37th Technical Committee Meeting -28.11.2016

			<p>7. Dr. K.V.Anand, HOD, Dept. of Vascular Surgery, Army Hospital, R&R, New Delhi</p> <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
5	<p>Tramadol Hydrochloride 0.1% w/v Infusion</p> <p>(Additional indication)</p> <p>Date of Application: 19.11.2013</p> <p>Phase - III</p>	<p>M/s Akums Drugs & Pharmaceuticals Limited</p> <p>Indication – For short term treatment of postoperative pain.</p>	<p>1. Recommendation of 25th SEC- (Analgesics, and Rheumatology) dated 03-08-2016: The firm presented the protocol before the committee. After detailed deliberation the committee recommended the following:</p> <ol style="list-style-type: none"> The study (Phase A) may be approved with the modification of the inclusion criteria i.e <ol style="list-style-type: none"> Hips/Knee Arthroplasty Open cholecystectomy. Only drugs approved by CDSCO, India should be used as a rescue medication. <p>Action Taken: Accordingly, the firm has submitted the reply as per SEC recommendation.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> Dr. H S Rehan ,Professor & Head, Department of Pharmacology ,Lady Harding medical college New Delhi. Dr. S.K. Das, Professor & Head, Department of Rheumatology, KGMC, Lucknow-226003 Dr R.K Arya , Department of Orthopedics, RML Hospital New Delhi Dr Arunagshu Talukdar, Professor, Department of Medicine, Medical College, Kolkata-700073 Dr. Chandralekha, Head, Dept. of anesthesiology AIIMS, New Delhi-110029. <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
6	Fimasartan Tablets	M/s Ajanta Pharma	1. Recommendation of SEC dated

37th Technical Committee Meeting -28.11.2016

	<p>60 mg and 120 mg</p> <p>Date of Application: 22.12.2015</p> <p>Phase - III</p>	<p>Limited</p> <p>Indication:- for the treatment of hypertension and heart failure</p>	<p>31.05.2016</p> <p>The firm applied for grant of permission to manufacture and market Fimasartan tablets 30/60/120mg to be indicated for the treatment of hypertension and heart failure. The firm in its presentation requested to revise the indication to mild hypertension instead of the aforesaid indication. The firm presented the Phase-III clinical trial protocol. After the detailed deliberations the committee recommended conduct of the clinical trial subject to the following conditions:</p> <ol style="list-style-type: none"> 1. The protocol title should be revised to reflect the study design. 2. The inclusion criteria should be revised with respect to the BP to 140- 159 mmHg for systolic and 90-99 for Diastolic. 3. The firm should use accredited arm BP apparatus as per standard guidelines. 4. The indication should be revised accordingly. 5. The dose and frequency of Losartan should be as per the recommendation in the prescribing information of the Innovator. 6. The firm may conduct BE Study as per the proposed protocol before initiation of the clinical trial. <p>Accordingly the firm should submit revised protocol for approval.</p> <p>Action Taken: The firm has submitted the revised clinical trial protocol to this office.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Shashi Mohan Sharma, Professor, Department of Cardiology, SMS Medical College J.L.N. Marg, Jaipur 2. Dr. Shyam Sunder Kothari, Department of Cardiology, AIIMS, New Delhi
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37th Technical Committee Meeting -28.11.2016

			<p>3. Dr. A.H.Ansari, CMO, VMCC, New Delhi</p> <p>4. Dr. Sandeep Bansal, HOD, Dept. of Cardiovascular, VMMC & Safdarjung Hospital, New Delhi</p> <p>5. Dr. Lalit Kumar Gupta, Pharmacologist, Lady Hardinge Medical College, Delhi</p> <p>2. Recommendation of the Technical Committee:</p> <p>After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
7	<p>Ripasudil Hydrochloride Hydrate Eye Drops 0.4% w/v</p> <p>Date of Application: 03.12.2015</p> <p>Phase - III</p>	<p>M/s Ajanta Pharma Limited</p> <p>Indication – For the treatment of glaucoma.</p>	<p>1. Recommendation of SEC on 13.10.2016</p> <p>The firm presented the revised clinical trial protocol. After detailed deliberation the Committee recommended the clinical trial subject to following clarification:-</p> <p>1. Intraocular pressure should be measured with Goldman Applanation Tonometer only. Accordingly, the firm has submitted the revised clinical trial protocol to this office</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Rohit Saxena, Associate Professor, AIIMS, New Delhi 2. Dr. R.K. Jain, Professor, Lady Hartinge Medical College, New Delhi 3. Dr. Arjun Ahuja, Professor & Head, Seth G.S. Medical College & KEM Hospital, Mumbai 4. Dr. V.S. Gupta, Professor & Head, VMMC and Safdurjung Hospital, New Delhi 5. Dr. Renuka Srinivasan, Professor, JIPMER, Pondicherry 6. Dr. D. S. Arya Professor, Department of Pharmacology AIIMS, New Delhi <p>2. Recommendation of the Technical Committee:</p> <p>After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>

Recommendation of the 05 cases of Clinical Trials waiver in Indian Populations of 37th Technical Committee Meeting held on 28.11.2016:

S. No.	Drug Name	Indication	1. Recommendations of the SEC 2. Recommendation of Technical Committee
01	<p>Name of the Drug: Argatroban Hydrate</p> <p>Name of the Firm: M/s. Natco Pharma</p> <p>Date of Application: 23.04.2016</p> <p>Regulatory status in India: Not approved</p> <p>Regulatory status in other countries: USA and Europe</p>	<p>➤ For prophylaxis or treatment of thrombosis in adult patients with Heparin-induced Thrombocytopenia (HIP)</p> <p>➤ As an anticoagulant in adults patients with or at risk for Heparin-induced Thrombocytopenia undergoing percutaneous coronary Intervention.(PCI)</p>	<p>1. Recommendation of the SEC (Oncology) dated 18.10.2016:</p> <p>Firm has made application for the grant of permission to manufacture and market Argatroban Hydrate Injection 250mg/2.5 mL indicated.</p> <p>For prophylaxis or treatment of thrombosis in adult patients with Heparin-induced Thrombocytopenia (HIT).</p> <p>As an anticoagulant in adults patients with or at risk for Heparin-induced Thrombocytopenia undergoing percutaneous coronary Intervention.(PCI)</p> <p>Firm has requested for local CT waiver and presented the toxicity data and product development data. After detailed deliberation the committee opined that the product meets the requirements of unmet medical need, as there is no alternative therapy available for Heparin-induced Thrombocytopenia (HIT). Therefore the Committee recommended CT waiver with the condition that the firm shall conduct Phase IV CT and submit protocol accordingly within 1 year of marketing permission.</p> <p>SEC Expert List:</p> <p>1. Dr. C. K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata</p>

37th Technical Committee Meeting -28.11.2016

			<ol style="list-style-type: none"> 2. Dr. Sanjay Kumar Singh, Assistant Professor, Gajara Raja Medical College, Gwalior 3. Dr. Renu Saxena, Professor & Head, AIIMS, Ansari Nagar, Delhi 4. Dr. Prantar Chakraborty, Kolkata Medical College , College Street, Kolkata 5. Dr. H.P. Pati, AIIMS, Ansari Nagar Delhi 6. Dr. D S Arya Professor, Department of Pharmacology AIIMS, New Delhi <p>2. Recommendation of Technical Committee:</p> <p>The committee noted that the application is for manufacture of generic Argatroban Hydrate Injection. After detailed deliberation, the committee recommended that firm shall conduct BA/BE study and inspection of the firm needs to be done by the CDSCO before Phase IV clinical trial can be permitted. They should have R&D for this drug.</p>
<p>02</p>	<p>Name of the Drug: Dienogest 2 mg tablet</p> <p>Name of the Firm: M/s Bayer Pharmaceutical</p> <p>Date of Application: 27.08.2015</p> <p>Regulatory status in India: Not approved</p> <p>Regulatory status in other countries: 100 countries including EU, Canada, Australia</p>	<p>For the treatment of Endometriosis</p>	<p>1. Recommendation of the SEC (Reproductive and Urology) dated 28.10.2015: This Directorate has received an application for the grant of permission to import and market Dienogest 2 mg tablets which is indicated for the treatment of Endometriosis. The firm has submitted the phase I, II and III study carried out globally and requested for waiver of local clinical trial. After the detailed deliberation the Committee opined that the firm proposal does not fit in the criteria of clinical trial waiver that is issued by office of DCGI, therefore the Committee did not recommend the</p>

			<p>clinical trial waiver.”</p> <p>Recommendation of the SEC (Reproductive and Urology) dated 27.10.2016:</p> <p>The firm has presented the proposal for re-examination the waiver of local clinical trial. The Committee noted that the drug Dienogest 2 mg tablet is already marketed in more than 100 countries including EU, Canada, and Australia etc. Further firm has conducted 29 clinical trials globally. After detailed deliberation the Committee recommended that the waiver of local clinical trial may be granted subject to condition that firm should conduct Phase-IV clinical trial for which the protocol shall be submitted to the office within 06 months from the approval of the drug.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr Rajeev Sood, Prof & Head, Dr RN Hospital & PGIMER, Presidents Estate. 2. Dr Anup Kumar Kundu, , Prof & He PGIMER & SSKM, Kolkata, West Benga 3. Dr Seema Singhal, Assistant Profess Department of Gynecology, AIIMS, N Delhi. 4. Dr Pikee Saxena, Assistant Professor, La Hardinge College, New Delhi. 5. Dr Krishna Moorthy, Lourded Hospit Ernakulam, Kerala. 6. Dr Alka Kriplani, Head, Gynaecolo AIIMS, New Delhi. 7. Dr Amlesh Seth, Professor, Department Urology, AIIMS, New Delhi. 8. Dr K H Reeta, Department of Pharmacology, AIIMS, New Delhi. <p>2. Recommendation of Technical</p>
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37th Technical Committee Meeting -28.11.2016

			<p>Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial</p>
03	<p>Name of the Drug: Tacrolimus Prolong release Hard Gelatin Capsule 3 mg [Additional Strength]</p> <p>Name of the Firm: M/s Astellas Pharma India Pvt. Ltd</p> <p>Date of Application: 22.02.2016</p> <p>Regulatory status in India: Approved in India on 24.05.2010</p> <p>Regulatory status in other countries: 50 countries including Canada, France, Germany, Netherlands, Norway, Sweden, Switzerland, and United Kingdom.</p>	<p>Prophylaxis of transplant rejection in adult kidney or Liver allograft rejection</p>	<p>1. Recommendation of 34th SEC– Cardiology and Renal held on 08-11-2016. The firm presented the proposal before the committee. The firm is already holding Import registration certificate from DCGI for 0.5 mg, 1.0 mg, 5 mg prolonged release hard gelatin capsules in India. The Firm presented justification for the additional strengths of 3 mg PR capsule. After detailed deliberation the committee recommended for the proposed strength, which is intermediate to the already approved strengths. Hence the committee recommended the additional strength without local CT.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Shyam Sunder Kothari, Dept of Cardiology, AIIMS, New Delhi. 2. Dr. S.K. Agrawal, Dept. Of Nephrology AIIMS, New Delhi 3. Dr. A.H. Ansari, Assistant Professor, VardhmanMahavir Medical College, New Delhi-110029 4. Dr. Saibal Mukhopadhyay Dept. of Cardiology, GB Pant Hospital New Delhi 5. Dr. C.D.Tripathi Dept. of Pharmacology, VMMC & Safdurjung Hospital, New Delhi. <p>2. Recommendation of Technical Committee: After detailed deliberation, the</p>

37th Technical Committee Meeting -28.11.2016

			committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial
04	<p>Name of the Drug: Ticagrelor Tablet 60 mg (Additional Strength & Additional Indication)</p> <p>Name of the Firm: M/s AstraZeneca Pharma India Limited</p> <p>Date of Application: 18.12.2015</p> <p>Regulatory status in India: Approved in India on 03-05-2012</p> <p>Regulatory status in other countries: USFDA, EU</p>	<p>It is indicated for the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with Acute coronary syndromes (ACS) unstable angina, non ST elevation myocardial infarction (NSTEMI) or ST elevation myocardial infarction (STEMI) including patients managed medically, those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG).</p>	<p>1. Recommendation of 34th SEC – Cardiology and Renal held on 08-11-2016.</p> <p>Firm presented the proposal before the committee. Ticagrelor 90mg tablet is already approved in India. The proposed additional strength I,e) Ticagrelor 60mg for the prevention of thrombotic events (cardiovascular death, myocardial infarction and stroke) in patients with a history of myocardial infarction (MI occurred at least one year ago) and a high risk of developing a thrombotic event is approved internationally. The committee recommended for proposed additional strength and indication without local clinical trial.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Shyam Sunder Kothari, Dept of Cardiology, AIIMS, New Delhi. 2. Dr. S.K. Agrawal, Dept. Of Nephrology AIIMS, New Delhi 3. Dr. A.H. Ansari, Assistant Professor, VardhmanMahavir Medical College, New Delhi-110029 4. Dr. Saibal Mukhopadhyay Dept. of Cardiology, GB Pant Hospital New Delhi 5. Dr. C.D.Tripathi Dept. of Pharmacology, VMMC & Safdurjung Hospital, New Delhi <p>2. Recommendation of Technical Committee:</p> <p>After detailed deliberation, the</p>

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			committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial
05	<p>Name of the Drug: Rosuvastatin Tablets 15 mg and 30 mg (Additional Strength)</p> <p>Name of the Firm: M/s Cadila Healthcare Private Limited</p> <p>Date of Application: 09.08.2016</p> <p>Regulatory status in India: Approved in India on 24.05.2010</p> <p>Regulatory status in other countries: Austria, Denmark, Spain, Netherlands and Czech Republic</p>	<p>a. Indicated for the treatment of the patients with primary hypercholesterolemia or mixed dyslipidaemia, homozygous familial hypercholesterolemia as an adjunct to diet, when response to diet and exercise is inadequate.</p> <p>b. As an adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia.</p> <p>c. As an adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels.</p> <p>d. Risk reduction of MI stroke and arterial revascularization procedure in patients without clinically evident</p>	<p>1. Recommendation of 34th SEC – Cardiology and Renal held on 08.11.2016</p> <p>“The firm presented the proposal before the committee. The firm is already holding the manufacturing permission from O/o DCGI for 5mg, 10mg, 20mg and 40mg tablets in India. The firm presented the justification for the additional strengths of 15mg and 30mg tablets after detailed deliberation the committee recommended the proposed strengths (15mg and 30mg) which are intermediate to the already approved strengths (5mg, 10mg, 20mg and 40mg) without local Clinical Trial”.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Shyam Sunder Kothari, Dept of Cardiology, AIIMS, New Delhi. 2. Dr. S.K. Agrawal, Dept. Of Nephrology AIIMS, New Delhi 3. Dr. A.H. Ansari, Assistant Professor, VardhmanMahavir Medical College, New Delhi-110029 4. Dr. Saibal Mukhopadhyay Dept. of Cardiology, GB Pant Hospital New Delhi 5. Dr. C.D.Tripathi Dept. of Pharmacology, VMMC & Safdurjung Hospital, New Delhi <p>2. Recommendation of Technical Committee:</p> <p>After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended for waiver of local</p>

		<p>CHD but with multiple risk factors.</p> <p>e. As an adjunct to diet for the treatment of patients with dysbetalipoproteinemia (type-III hyperlipoproteinemia)</p> <p>As adjunct to diet to reduce total-C, LDL-C and ApoB levels in adolescent boys and girls, who are at least one year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia if after and adequate trial of diet therapy the following findings are present: LDL-C > 190mg/dL or > 160mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more CVD risk factors.</p>	<p>clinical trial</p>
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