MINUTES OF 40th MEETING OF THE TECHNICAL COMMITTEE HELD ON 03.05.2017 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:

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. Nandini Kumar, Former Dy. Dire. Gen. Sr. Grade, Adjunct Professor, KMC, Manipal, 5/1 (New) Padmalaye Apt. Chennai.	Member
4.	Dr. Rajutitus Chacko, Prof. & Head, Dept. of Medical Oncology, CMC, Vellore.	Member
5.	Dr. Yash Paul, Prof. & Head, Dept. of Cardiology, PGIMER, Chandigarh.	Member

From CDSCO:

1. Dr.G.N. Singh
   Drugs Controller General (India)
2. Dr. V.G. Somani,
   Joint Drug Controller (India)
3. Mrs. Rubina Bose
   Deputy Drugs Controller (India)
4. Mr. Jayant Kumar
   Assistant Drugs Controller (India)
5. Mr. Sushant Sharma
   Assistant Drugs Controller (India)
6. Mr. Ankit Sharma
   Assistant Drugs Controller (India)

The Chairman welcomed the members of the Committee for the 40th technical committee meeting. Thereafter, Drugs Controller General (India) apprised the Chair to streamline the process of approval of clinical trial in line with the timelines, procedures of clinical trial conducted globally and the Chair agreed to hold a meeting of all stakeholders to discuss the

matter. Also the Chair expressed that surprise risk based inspection of selected clinical trial sites may be conducted based on number of trial undertaken a the particular site, number of subjects enrolled in the site, dropouts, reported serious adverse events (SAEs) etc.

The Committee deliberated 23 cases related to approval of clinical trials. Out of these 23 cases, 05 cases were related to clinical trials of NCEs, 06 cases were related to Global Clinical Trials (GCT), remaining 12 cases were related to clinical trials for approval of Subsequent New Drugs, Fixed Dose Combination Drugs and Biologicals.

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

The Committee evaluated five 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 five 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 12 cases of other than GCT/clinical trial of NCEs. After detailed deliberations, the Committee recommended approval for 11 proposals. For the remaining proposal (Proposal No 12 of **Annexure-III**), the committee has recommended to present the proposal by the firm before the committee for certain clarification. The recommendation of the Committee is enclosed as **Annexure-III.**

Annexure I

Proposals of clinical trial of NCEs along with their evaluations and recommendations of the Technical Committee in its 40th Meeting held on 03.05.2017:

Proposal No	Details of the proposal	Assessment of the Proposal *vis –a vis* specified Parameters	Recommendations 1. Subject Expert Committee 2. Technical Committee
1.	**Name of the Drug:** Daprodustat **Date of Application:** 16/9/2016 **Protocol No**: 200807 **Phase of the trial:** III **Name of the Applicant:** M/s PPD Pharmaceutical Development India Pvt. Ltd., India **Name of the Sponsor:** GlaxoSmithKline Research & Development Limited **Name of the Manufacturer:** Glaxo Operations UK Ltd (trading as Glaxo Wellcome Operations), Priory Street Ware, Hertfordshire SG12 0DJ UK GlaxoSmithKline LLC, 1250 South Collegeville Road Collegeville PA 19426 -0989, USA **Protocol Title:** A Phase 3 Randomized, Open-label (Sponsor-blind), Active-controlled, Parallel-group, Multi-center, Event Driven Study in	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drugs from preclinical toxicology studies including Single dose toxicity, repeat dose toxicity; reproductive and developmental toxicity, genotoxicity, Dermal toxicity tests, local tolerance and clinical studies justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option:** To compare Daprodustat to rhEPO for cardiovascular (CV) safety (noninferiority). And to compare Daprodustat to rhEPO for hemoglobin efficacy (non inferiority) **Unmet Medical Need in the country:** The test drug may potentially provide alternative treatment in dialysis subjects with anemia associated with chronic kidney disease.	**1. Recommendation of SEC (Cardiovascular & Renal) on 09/02/2017.** After detailed deliberation the committee opined that the proposal may be approved subject to final opinion from Nephrologist. The same proposal was earlier deliberated in the SEC Cardiovascular and Renal dated 09.02.2017 and after review by the Nephrologist during this meeting the committee recommended the conduct of the study. **SEC Experts:** 1. Dr. Sandeep Bansal, HOD, VMMC, Sufdurjung Hospital, New Delhi 2. Dr. A. H. Ansari, Assistant Professor, Vardhman Mahavir Medical College, New Delhi-110029. 3. Dr. K.M.K. Reddy, Dept. of Cardiology, Osmania Medical College, Koti Hyderabad-500095. 4. Dr. K.H. Reeta, professor, Dept. of Pharmacology, AIIMS, New Delhi. 5. Dr. S.K. Agarwal, Professor & Head of the Department, Dept. of Nephrology, AIIMS, New Delhi. 6. Dr. R K Sharma, Professor, Dept. of Nephrology, SGPGI, Lucknow.

	Dialysis Subjects With Anemia Associated With Chronic Kidney Disease to Evaluate the Safety and Efficacy of Daprodustat Compared to Recombinant Human Erythropoietin, Following a Switch From Erythropoietin-stimulating Agents. (Protocol # : 200807)		**2. Recommendation of the Technical Committee meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
2.	**Name of the Drug:** Daprodustat **Date of Application:** **23/9/2016** **Protocol No**: 200808 **Phase of the trial:** III **Name of the Applicant:** M/s PPD Pharmaceutical Development India Pvt. Ltd., India **Name of the Sponsor:** GlaxoSmithKline Research & Development Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS UK **Name of the Manufacturer:** Glaxo Operations UK Ltd (trading as Glaxo Wellcome Operations), Priory Street Ware, Hertfordshire SG12 0DJ UK GlaxoSmithKline LLC, 1250 South Collegeville	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drugs from preclinical toxicology studies including Single dose toxicity, repeat dose toxicity, reproductive and developmental toxicity, genotoxicity, Dermal toxicity tests, local tolerance and clinical studies justify the conduct of the trial**.** **Innovation vis-à-vis Existing Therapeutic Option:** To compare Daprodustat to rhEPO for cardiovascular (CV) safety (noninferiority). And to compare Daprodustat to rhEPO for hemoglobin efficacy (non inferiority) **Unmet Medical Need in the country:** The test drug may potentially provide alternative treatment in dialysis subjects with anemia associated with chronic kidney disease	**1. Recommendation of the SEC (Cardiovascular & Renal) on 09/02/2017.** After detailed deliberation the committee opined that the proposal may be approved subject to final opinion from Nephrologist. The same proposal was earlier deliberated in the SEC Cardiovascular and Renal dated 09.02.2017 and after review by the Nephrologist during this meeting the committee recommended the conduct of the study. **SEC Expert:** 1. Dr. Sandeep Bansal, HOD, VMMC, Sufdurjung Hospital, New Delhi 2. Dr. A. H. Ansari, Assistant Professor, Vardhman Mahavir Medical College, New Delhi-110029. 3. Dr. K.M.K. Reddy, Dept. of Cardiology, Osmania Medical College, Koti Hyderabad-500095. 4. Dr. K.H. Reeta, professor, Dept. of Pharmacology, AIIMS, New Delhi. 5. Dr. S.K. Agarwal, Professor & Head of the Department, Dept. of Nephrology, AIIMS, New Delhi. 6. Dr. R K Sharma, Professor, Dept. of Nephrology, SGPGI, Lucknow.

	Road Collegeville PA 19426 -0989, USA **Protocol Title:** A phase 3 randomized, open-label (sponsor-blind), active- controlled, parallel-group, multi-center, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to darbepoetin alfa. (# 200808)		**2. Recommendation of the Technical Committee meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
3.	**Name of the Drug:** Oral Semaglutide **Date of Application:** 04/10/2016 **Protocol No**: **NN9924-4280** **Phase of the trial:** IIIa **Name of the Applicant:** Novo Nordisk India Private, Bangalore -560 066, Karnataka, India **Name of the Sponsor:** Novo Nordisk India Private Ltd, Bangalore -560 066, Karnataka, India. **Name of the Manufacturer:** Novo	**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	**1. Recommendations of Subject Expert Committee SEC (Endocrinology and Metabolism) held on 20.12.2016.** After detailed deliberation the committee opined that the patients in the placebo arm will be at risk of hyperglycemia due to 20% insulin reduction during at randomization till visit 8.Hence the detailed risk management plan should be submitted till the visit 9. Accordingly the firm should submit revised protocol for further review. **The firm has submitted response for above recommendation,** **1.** Protocol title has been changed to " A 52 week randomized, double-blind, placebo-controlled trial, four armed, parallel-group, multicenter, multinational trial. This trial will compare the study, Efficacy of three dose levels of once-daily oral Semaglutide versus placebo in subjects

	Nordisk A/S, Clinical Supplies Packaging, Novo Nordisk Park, B5.S.09. DK-2760, Måløv, Denmark. **Title:** Efficacy and Safety of Oral Semaglutide versus Placebo in Subjects with Type 2 Diabetes Mellitus treated with insulin.	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.	with type-2 diabetes mellitus treated with insulin. **2.** Additional eye examination was added in Amended protocol. **3.** The criteria for subject completion, withdrawal and lost to follow up respectively are clarified and have been made consistent across sections. **4.** Transient worsening of diabetic retinopathy is a recognized complication in selected patients with diabetes after initiation of intensive antidiabetic treatment. Information to the investigators and subjects related to diabetic retinopathy has been added to the protocol and subject information. **5.** As per agreement with the FDA, text is added to highlight the investigator's responsibility in relation to further evaluation of potential incidental thyroid nodules discovered at the physical examination. **6.** For the pattern mixture model using multiple imputation, the number of imputations will be increased from 100 to 1000 data sets, to ensure a greater precision of the estimates. **7.** Regulatory approval status of the study8/9 countries approved **2. Recommendations of Subject Expert Committee SEC in (Endocrinology and Metabolism) held on 10.02.2017.** 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. **SEC Experts:**

			1. Dr. MD. Ashraf Ganie, Dept. of Endocrinology, SKIMS, K&K 2. Dr. Bikash MEdhi, Dept. of Pharmacology, PGIMER, Chandigarh. 3. Dr. Rajesh Khadgawat, Professor, Dept. of Endocrinology, AIIMS, New delhi. 4. Dr. MAnoj Chadha, Dept. of Endocrinology P.D Hinduja National Hospital MAhim, Mumbai. 5. Dr. Deepak Khandelwal, Consultant, dept. of Endocrinology, Maharaja Agrasen Hospital New Delhi. **3. Recommendation of the Technical Committee meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
4.	**Name of the Drug:** Selonsertib (SEL) 6 mg / 18 mg Tablet **Date of Application:** 16/02/2017 (Online Submission) **Protocol No**: GU-US-384-1944, Version Original, Dated 19/12/16. **Phase of the trial:** III **Name of the Applicant:** KlinEra Corporation India, 401, Hill view	**Risk vs Benefit to the patients:** The safety profile of the test drug from various preclinical pharmacology, toxicity studies and phase I and II clinical studies justifies the conduct of this phase III trial. **Innovation vis a vis existing therapy:** The data from the studies conducted so far with the IMP alone and in	**1. Recommendation of the SEC (Gastroenterology) held on 23/March/2017** After detailed deliberation the committee recommended the conduct of the study. **SEC expert:** 1. Dr. Bikash Medhi, Professor, Dept. of Pharmacology, PGIMER, Chandigarh. 2. Dr. Anoop Saraya, Professor, Dept. of Gastroenterology, AIIMS, New Delhi. 3. Dr. Sudhir Gupta, Professor and Head, Government Medical

	Industrial Estate, Ghatkopar (West), Mumbai, 400086 India **Name of the Sponsor:** Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404. **Name of the Manufacturer:** Gilead Sciences, Inc., 333 Lakeside Drive, Foster City, CA 94404, USA. Gilead Alberta, ULC, 1021 Hayter Road NW, Edmonton, Alberta, Canada, T6S 1A1 **Protocol Title:** A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertib in Subjects with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis (NASH)	combination with other drugs indicates that The study drug may provide a better/ specific treatment option for patients with Cirrhosis due to Nonalcoholic Steatohepatitis (NASH) **Unmet need:** Study drug may provide a better treatment options as there is no first line treatment option available for Cirrhosis due to Nonalcoholic Steatohepatitis (NASH).	College and Super Speciality, Nagpur. 4. Dr. P. Shravan Kumar, Professor, HOD of Gastroenterology, Gandhi Medical College and Hospital, Secunderabad, Telengana. 5. Dr. B. D Goswami, Prof. and Head, Dept. of Gastroenerology, Seth Gauhati Medical College, Gauhati. **2. Recommendation of the Technical Committee meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
5.	**Name of the Drug:** Selonsertib (SEL) 6 mg / 18 mg Tablet **Date of Application:** 17/02/2017 (Online Submission) **Protocol No**: GU-US-384-1943,	**Risk vs Benefit to the patients:** The safety profile of the test drug from various preclinical pharmacology, toxicity studies and	**1. Recommendation of SEC (Gastroenterology) held on 23/March/17** After detailed deliberation the committee recommended the conduct of the study.

	Version Original, Dated 19/12/16. **Phase of the trial:** III **Name of the Applicant:** KlinEra Corporation India, 401, Hill view Industrial Estate, Ghatkopar (West), Mumbai, 400086 India **Name of the Sponsor:** Gilead Sciences, Inc. 333 Lakeside Drive Foster City, CA 94404. **Name of the Manufacturer:** Gilead Sciences, Inc., 333 Lakeside Drive, Foster City, CA 94404, USA. Gilead Alberta, ULC, 1021 Hayter Road NW, Edmonton, Alberta, Canada, T6S 1A1 **Protocol Title:** A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Selonsertibin Subjects with Nonalcoholic Steatohepatitis (NASH) and Bridging (F3) Fibrosis.	phase I and II clinical studies justifies the conduct of this phase III trial. **Innovation vis a vis existing therapy:** The data from the studies conducted so far with the IMP alone and in combination with other drugs indicates that the study drug may provide a better/ specifictreatment option for patients with Compensated Cirrhosis due to Nonalcoholic Steatohepatitis (NASH) and bridging fibrosis. **Unmet need:** Study drug may provide a better treatment options as there is no first line treatment option available for fibrosis regression and reduce progression to cirrhosis associated complications in subjects with NASH and bridging (F3) fibrosis.	**SEC expert:** 1. Dr. Bikash Medhi, Professor, Dept. of Pharmacology, PGIMER, Chandigarh. 2. Dr. Anoop Saraya, Professor, Dept. of Gastroenterology, AIIMS, New Delhi. 3. Dr. Sudhir Gupta, Professor and Head, Government Medical College and Super Speciality, Nagpur. 4. Dr. P. Shravan Kumar, Professor, HOD of Gastroenterology, Gandhi Medical College and Hospital, Secunderabad, Telengana. 5. Dr. B. D Goswami, Prof. and Head, Dept. of Gastroenerology, Seth Gauhati Medical College, Gauwhati. **2. Recommendation of the Technical Committee meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.

Annexure-II

Proposals of clinical trial of GCTs along with their evaluations and recommendations of the Technical Committee in its 40th Meeting held on 03.05.2017:

Proposal No.	Details of the proposal	Assessment of the Proposal *vis –a vis* specified Parameters	Recommendations 1. Subject Expert Committee 2. Technical Committee
1.	**Name of the Drug:** SAIT101 **Date of Application: 21/10/2016** **Protocol No**: AGB001 **Phase of the trial:** III **Name of the Applicant:** Quintiles Research India Private Limited, Ahmedabad. **Name of the Sponsor:** Archigen Biotech Limited, UK **Name of the Manufacturer:** Rentschler Biotechnologie GmbH Erwin-Rentschler-Strasse 2188471 Laupheim, Germany **Title:** A Randomized, Double-blind, Parallel Group, Multicenter Study to Compare the Pharmacokinetics, Pharmacodynamics, Safety, and Efficacy of SAIT101 versus MabThera® versus Rituxan® in Patients with Rheumatoid Arthritis (RA)	**Risk versus 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, local tolerance & immune toxicity and clinical studies justify the conduct of the trial. **Innovation vis-a-vis existing therapeutic option-** To compare the PK of SAIT101 versus MabThera® versus Rituxan® in patients with rheumatoid arthritis. **Unmet need in the country-** The test drug may potentially provide alternative treatment of patients with Rheumatoid Arthritis (RA) After detailed deliberation committee approved the trial with advice to include at least 100 Indian subjects on the study drug.	**1. Recommendation of the SEC (Analgesic) held on 28/02/2017.** After detailed deliberation committee approved the trial with advice to include at least 100 Indian subjects on the study drug. **SEC Experts**: 1. Dr. S.K. Das, Prof. & Head, Dept. of Rheumatology, KGMC, Lucknow-226003 2. Dr. R.K.Arya, Dept. of Orthopedics, RML Hospital, New Delhi 3. Dr. Arunanshu Talukdar, MD, Prof., Dept. of Medicine, Medical College, Kolkata-700073 4. Dr. Amita Aggarwal, Prof. & Head, Dept. of Clinical Immunology, SGPGI, Lucknow 5. Dr. Uma Kumar Head & Prof. Rheumatology Division, Dept. of Medicine, AIIMS, New Delhi 6. Dr. Anjan Trikha, Dept. of Anesthesiology, AIIMS, New Delhi 7. Dr. Lalit Kumar Kumar Gupta, Dept. of Pharmacology, LHMC, New Delhi 8. Dr. C.D. Tripathi, Dept. of Pharmacology, VMMC, New Delhi (Special invitee for this proposal) **2. Recommendation of the Technical Committee meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the

			study with advice to include at least 100 Indian subjects on the study drug.
2.	**Name of the Drug:** LCZ696 **Date of Application:** 25/10/2016 **Protocol No**: CLCZ696G2301 **Phase of the trial:** III **Name of the Applicant:** Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli, Mumbai - 400 018. **Name of the Sponsor:** Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli Mumbai - 400 018. **Name of the Manufacturer:** Novartis Pharma Stein AG Schaffhauserstrasse CH-4332 Stein, Switzerland Site is GMP certified and registered with DCGI. **Title:** A multi-center, randomized, double-blind, active-controlled, parallel group Phase 3 study to evaluate the efficacy and safety of LCZ696 compared to Ramipril on morbidity and mortality in high risk patients following an acute myocardial infarction.	**Risk versus benefit to the patients** - In light of the fact that the of Atumumab is already approved in India, the safety profile of the study drug justify the conduct of the trial. **Innovation vis-a-vis existing therapeutic option-**The objective of the study is to investigate the efficacy and safety of Dabigatran Etexilate versus dose-adjusted Warfarin in patients with cerebral venous and dural sinus thrombosis. **Unmet need in the country-** The test drug may be an alternative treatment in patients with cerebral venous and dural sinus thrombosis.	**1. Recommendation of the SEC (Cardio) held on 21/02/2016.** After detailed deliberation the committee recommended for the conduct of the study in its presented form. **SEC Expert:** 1. Dr. Shyam Sunder Kothari, Prof. Dept ofC, AIIMS, New Delhi. 2. Dr. S.K. Agarwal, Professor & Head of the department, Dept. of Nephrology AIIMS, New Delhi. 3. Prof. Dr.K.M.K. Reddy, Dept. of Cardiology, Osmania Medical College, Koti, Hyderabad-500095 4. Dr. R K Sharma, Professor, Dept. of Nephrology SGPGI, Lucknow. 5. Dr. C.D. Tripathi, Professor. Dept. of Pharmacology, VMMC, New Delhi. **2. Recommendation of the Technical Committee meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.

3.	**Name of the Drug:** TMC207 (Bedaquiline) **Date of Application:** 28/09/2016 **Protocol No**: TMC207-C211 **Phase of the trial:** II **Name of the Applicant:** Johnson & Johnson Private Limited, India**.** **Name of the Sponsor:** Janssen Research & Development. **Name of the Manufacturer: <u>For 100mg Oral tablet</u>** M/s Kemwell Biopharma Pvt. Ltd. 34th KM, Tumkur Road Teppada Begur Nelamangala Taluk Bangalore – 562 123 India. **<u>For 20mg Dispersible Tablet</u>** Kemwell Biopharma Pvt. Ltd. 34th KM, Tumkur Road Teppada Begur Nelamangala Taluk Bangalore – 562 123 India. **Title:** A Phase 2, Open-	**Risk versus Benefit to the patients**- In light of the fact that the test drug is already approved in India, the safety profile of the test drug justify the conduct of the trial. **Innovation vis a vis existing therapeutic option-** Innovation over a 24 week treatment period in each age cohort. To evaluate the pharmacokinetics of TMC207 over a 24-week treatment period in the different age cohorts, and to provide vis-à-vis Existing Therapeutic Option: To evaluate the safety and tolerability of TMC207 guidance on dose selection for each of the age cohorts evaluated in this study. **Unmet need**- Unmet Medical Need in the country: The test drug may potentially provide alternative treatment of children and adolescents 0 months to <18 years of age who have confirmed or probable pulmonary MDR-TB. .	**1. Recommendation of the SEC (Antimicrobial, Antiviral, Antiparasitic and Antifungal) held on 23/02/2017.** After detailed deliberation the committee recommended the conduct of the study subject to the following conditions. 1. For MDR-TB patients the background treatment regimen should be as per current National/WHO (short course) treatment guidelines before enrollment. 2. Data from cohort 1&2 of the study to be submitted to CDSCO for review by the committee before enrolling patients in cohort 3 & 4. Accordingly the firm has accepted the SEC recommendations with above conditions. **SEC Expert:** 1. Dr. Archna Thakur, Director and Prof., Dept. of Microbiology, GB Pant Hospital, New Delhi, Delhi-110002 2. Dr. Varsha Gupta, Prof., Dept. of Microbiology, GMCH, Sector-32, Chandigarh 3. Dr. Abhishek Aggarwal, Dept. of medicine, SMS Medical college, jaipur, Rajasthan 4. Dr. Debashish Hota, Prof. & Head, dept. of Pharmacology, AIIMS, Bhuvneshwar 5. Dr. V.S Salhotra, TB Division, Nirman Bhawan, New Delhi (Special invitee for this proposal) **2. Recommendation of the**

	label, Multicenter, Single-arm Study to Evaluate the Pharmacokinetics, Safety, Tolerability and Anti-mycobacterial Activity of TMC207 in Combination With a Background Regimen (BR) of Multidrug Resistant Tuberculosis (MDR-TB) Medications for the Treatment of Children and Adolescents 0 Months to <18 Years of Age Who Have Confirmed or Probable Pulmonary MDR-TB.		**Technical Committee meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
4.	**Name of the Drug:** QMF149 (Indacaterol acetate / Mometasone furoate) **Date of Application:** 19/12/2016 (Online Submission) **Protocol No**: CQVM149B2303, version 00 (Original Protocol), dated 19/April/16. **Phase of the trial:** III **Name of the Applicant:** Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli Mumbai - 18. **Name of the Sponsor:** Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli Mumbai - 18.	**Risk versus Benefit**: - The safety and efficacy of the individual ingredients of FDC QMF149 as well as in combination in preclinical and clinical studies justify the conduct of the study. **Innovation vis-à-vis Existing Therapeutic Option:-** The proposed study will evaluate once daily LABA/ICS (QMF149-Mometasone + Indacaterol) fix dose combination for asthma patients **Unmet Medical Need in the Country: -** Development of once daily FDC QMF149 may provide convenience to the patients as compared to twice daily dosing. At present twice daily dosage long-acting beta	**1. Recommendation of the SEC (Pulmonary) held on 07/April/2017** After detailed deliberation the committee recommended the conduct of the study. **SEC Expert**: 1. Dr. Randeep Gularia, Professor, AIIMS, Ansari Nagar, New Delhi. 2. Dr. Shalini Chawla, Director , Professor, Pharmacology, MAMC, New Delhi. 3. Dr. S. Vinod Kumar, Professor and Head, JIPMER, Puducherry. 4. Dr. Professor Ashok K. Janmeja, Professor, Government Medical College and Hospital, Sector-32, Chandigarh-160030. 5. Dr. Sushant H. Meshram, Professor, Government Medical College and Hospital Nagpur. 6. Dr. Raj Kumar, Professor, Vallabh bhai Patel Chest Institute, University of Delhi. 7. Dr. Subodh Kumar, Assistant

	Name of the Manufacturer: Novartis Pharma Stein AG Schaffhauserstrasse CH-4332 Stein, Switzerland **Protocol Title:** A multi-center, randomized, 12-week treatment, double blind study to assess the efficacy and safety of QMF149 (150/80 microgram) compared with MF Twisthaler® (200 microgram) in adult and adolescent patients with asthma.	2-agonists are approved for treatment of Asthma.	Professor, AIIMS, Rishikesh. 8. Dr. J.C. Suri, VMMC and Safdurjung Hospital, Delhi 2. **Recommendation of the Technical Committee meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
5.	**Name of the Drug:** SAIT101 (proposed rituximab biosimilar) **Date of Application:** 19/12/2016 (Online Submission) **Protocol No**: AGB 002, Amendment 01, dated 07/10/16 **Phase of the trial:** III **Name of the Applicant:** Quintiles Research India Private Limited**.** **Name of the Sponsor:** Archigen Biotech Limited1 Francis Crick Avenue Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom **Name of the Manufacturer:** Rentschler Biotechnologie GmbH Erwin-Rentschler-Strasse 21 88471 Laupheim, Germany **Protocol Title:** A Randomized, Double-blind, Multi-center,	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drug from preclinical toxicology studies and clinical studies justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option:** First line rituximab monotherapy may delay chemotherapy treatment in patients with LTBFL. **Unmet Medical Need in the country:** There is unmet medical need for treatment options including biosimilar of rituximab for the growing FL/LTBFL population.	**1. Recommendation of the SEC (Oncology) held on 21/March/17** After detailed deliberation the committee recommended the conduct of the study. **SEC Expert:** 1. Dr. Sameer Bakshi, Professor, Dept. of Oncology, AIIMS, New Delhi. 2. Dr. REnu Saxena, Professor and Head of Dept., of Hematology, AIIMS, New delhi. 3. Dr. H.P Pati, Professor, Dept. of Hematology, AIIMS, New Delhi. 4. Dr. Sanjay Kumar Singh, Dept. of Medical Oncology, Gajara Raja Medical College, Veer Savarkar Marg, Gwalior. 5. Dr. Raju Titus Chacko, Dept. of Medical Oncology, Christian Medical College, Vellore-632004. 6. Dr. S.D. Banavali, Professor, Dept. of Oncology, KEM Mumbai. 7. Dr. P.K. Gogoi, Professor and Head of Dept., Gauhati Medical College and Hospital, Guwahati. 8. Dr. K.H Reeta, Professor, Dept. of Pharmacology, AIIMS, New Delhi. 2. **Recommendation of the Technical Committee meeting held on 03.05.2017:** After detailed deliberation, the

	Multi-national Trial to Evaluate the Efficacy, Safety, and Immunogenicity of SAIT101 Versus Rituximab as a First-line Immunotherapy Treatment in Patients with Low Tumor Burden Follicular Lymphoma.		committee agreed with the recommendation of the SEC and recommended the approval of the study.
6.	**Name of the Drug:** Eltrombopag film-coated tablets (12.5 mg, 25 mg, 50 mg and 75 mg) **Date of Application:** 16/12/2016 (Online Submission) **Protocol No**: CETB115E2403, Version 00 (Original Protocol), Dated 12/10/16. **Phase of the trial:** II **Name of the Applicant:** Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli Mumbai - 400 018. **Name of the Sponsor:** Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli Mumbai - 400 018. **Name of the Manufacturer:** M/s Glaxo Operations UK Ltd, Priory Street, Ware Hertfordshire, SG 12, 0DJ, UK. **Protocol Title:** SOAR Trial, A two-part study: Interventional phase II single-arm trial to assess	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drug from preclinical toxicology studies including Single dose toxicity, repeat dose toxicity, reproductive and developmental toxicity, genotoxicity, Dermal toxicity tests, local tolerance and clinical studies justify the conduct of the trial**.** **Innovation vis-à-vis Existing Therapeutic Option:** Eltrombopag may be effective in IST refractory patients. **Unmet Medical Need in the country:** The current standard of care is Stem cell transplant. The proposed trial is to include Eltrombopag in combination with CsA as first line therapy in Severe Aplastic Anaemia.	**1. Recommendation of the SEC (Oncology) held on 21/March/2017** After detailed deliberation the committee recommended the conduct of the study only in the patients in whom HLA matching has been done and either do not have a HLA match or are not medically fit for Transplant. Same should be clarified in the Inclusion/ Exclusion criteria as SOC for curative intent is Stem cell transplant. The firm has agreed for the submission of revised protocol as per SEC recommendation. **SEC Expert:** 1. Dr. Sameer Bakshi, Professor, Dept. of Oncology, AIIMS, New Delhi. 2. Dr. Renu Saxena, Professor and Head of Dept., of Hematology, AIIMS, New delhi. 3. Dr. H.P Pati, Professor, Dept. of Hematology, AIIMS, New Delhi. 4. Dr. Sanjay Kumar Singh, Dept. of Medical Oncology, Gajara Raja Medical College, Veer Savarkar Marg, Gwalior. 5. Dr. Raju Titus Chacko, Dept. of Medical Oncology, Christian Medical College, Vellore-632004. 6. Dr. S.D. Banavali, Professor, Dept. of Oncology, KEM Mumbai. 7. Dr. P.K. Gogoi, Professor and Head of Dept., Gauhati Medical College

	efficacy and safety of Eltrombopag combined with cyclosporine as first line therapy in patients with severe acquired aplastic anemia, and an extension with up to 60-months follow-up.		and Hospital, Guwahati. 8. Dr. K.H Reeta, Professor, Dept. of Pharmacology, AIIMS, New Delhi. 2. **Recommendation of the Technical Committee meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.

Annexure III

Proposals of clinical trial of other than NCE/GCT along with their evaluations and recommendations of the Technical Committee in its 40th Meeting held on 28.03.2017:

S.No.	Name of the Drug	Recommendations: 1. Subject Expert Committee 2. Technical Committee
1.	Denosumab **Date of Application:** 11.07.2016. **Name of the firm:** M/s Reliance Life Sciences Pvt. Ltd.	**1. Recommendation of SEC (Analgesic & Rheumatology) meeting held on 06.12.2016**: After detailed deliberation of the revised protocol, the committee recommended the approval of the protocol provided the firm shall make the following changes in the protocol: 1) Inclusion criteria should clearly define the post menopausal women (post menopausal phase of 5 years or more). 2) Primary end point should include percentage changes in T score. 3) Dexa scan should only be done at 6 and 12 months period at hip, spine and distal radius. 4) Total body dexa scan should be removed from the assessment criteria. Accordingly, the firm should submit the revised protocol to CDSCO. **Action Taken: The firm has submitted the revised clinical trial protocol.** **SEC Expert List:** 1. Dr. R. K. Arya, Prof and Head, Department of Orthopedics, RML Hospital, New Delhi. 2. Dr. S. K. Das, Prof and Head, Department of Rheumatology, KGMC, Lucknow-226003. 3. Dr Arunagshu Talukdar, MD, Professor, Department of Medicine, Medical College, Kolkata-700073. 4. Dr Uma Kumar, Prod and Head, Dept. of Rheumatology Division, AIIMS, New Delhi-110029. 5. Dr K. H. Reeta, Dept. of Pharmacology, AIIMS, New Delhi-110029.

		2. Recommendation of the Technical Committee on 03.05.2017: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
2.	Hepatitis A (Live) Vaccine, Freeze-dried **Date of Application: 19.02.2016** **Name of the firm:** M/s JSS Medical Research India Limited	**1. Recommendation of the SEC (Vaccine) on 17.06.2016:** The committee deliberated the proposal in detail and recommended for conduct of clinical trial (Phase II/III) as per the submitted revised protocol in response to recommendation of earlier SEC on 05.04.2016 to revise their the then protocol of Phase II/III as per Schedule Y including the comparator. **SEC Expert List:** **1.** Dr. A. P. Dubey, Prof& Head, Dept. of Pediatric, Maulana Azad Medical College & LNJP Hospital, Delhi. **2.** Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi. **3.** Dr. P.P. Gupta, Department of Pharmacology, AIIMS, Patna. **2. Recommendation of the Technical Committee Meeting held on 15.07.2016:** The committee recommended for conduct of Phase II clinical trial and requested to submit data for consideration of the proposal for conduct of Phase III clinical trial. Now, the firm has requested to again review the decision and allows them to carryout Phase III trial instead of earlier recommended Phase II trial. **Recommendation of the Technical Committee Meeting held on 03.05.2017:** Committee reviewed the representation of the firm along with protocol, which is proposed for bridging Phase III local clinical trial of already approved vaccine outside India and not for Phase II. Since, no dose finding is proposed and as vaccine is

		manufactured for more than 12 years wherein 49 million doses have been produced and 54% were supplied to EPI programme since its introduction in 2008 in EPI in the country of origin, committee agreed with the recommendation of SEC and recommended for approval of local phase III clinical trial.
3.	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (With preservative) **Date of Application :** 26.04.2016 **Name of the firm:** M/s Biological Evans Ltd, Hyderabad	**1. Recommendation of the SEC (Vaccine) held on 30.03.2017:** The Committee recommended for approval of the protocol with the following conditions: 1. The protocols for with and without Thiomersal in the vaccine be submitted separately. 2. Phase - I study will be conducted only for safety and reactogenicity and not immuno-genicity. 3. Equal number shall be enrolled at two study sites. Accordingly, the firm has submitted the revised protocol with proposing both "**Safety, reactogenicity and immunogenicity**" in Phase I protocol. **Expert Committee Members:** 1. Dr. P.P. Gupta, Department of Pharmacology, AIIMS, Patna. 2. Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi110029. 3. Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi 4. Dr. Savita Verma, Pharmacology, PGIMS 5. Dr. Veena Verma, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. 6. Dr. A.P. Dubey, Prof & Head, Paediatrics, MAMC, New Delhi **2. Recommendation of the Technical Committee Meeting held on 03.05.2017:** After reviewing the representation of the firm & requirement of GCP guidelines, Schedule Y under Drugs & Cosmetics Act and Rules and WHO guidelines for the conduct of Phase I clinical trials of vaccines, the committee has recommended the revised protocol for Phase I Clinical trial submitted by the firm

		including the immunogenicity study as secondary endpoint.
4.	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (Without preservative) **Date of Application:** 26.04.2016 **Name of the firm:** M/s Biological Evans Ltd, Hyderabad	**1. Recommendation of the SEC (Vaccine) held on 30.03.2017:** The Committee recommended for approval of the protocol with the following conditions: 1. The protocols for with and without Thiomersal in the vaccine be submitted separately. 2. Phase - I study will be conducted only for safety and reactogenicity and not immuno-genicity. 3. Equal number shall be enrolled at two study sites. Accordingly, the firm has submitted the revised protocol with proposing both "**Safety, reactogenicity and immunogenicity**" in Phase I protocol. **Expert Committee Members:** 1. Dr. P.P. Gupta, Department of Pharmacology, AIIMS, Patna. 2. Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi110029. 3. Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi 4. Dr. Savita Verma, Pharmacology, PGIMS 5. Dr. Veena Verma, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. 6. Dr. A.P. Dubey, Prof & Head, Paediatrics, MAMC, New Delhi **2. Recommendation of the Technical Committee Meeting held on 03.05.2017:** After reviewing the representation of the firm & requirement of GCP guidelines, Schedule Y under Drugs & Cosmetics Act and Rules and WHO guidelines for the conduct of Phase I clinical trials of vaccines, the committee has recommended the revised protocol for Phase I Clinical trial submitted by the firm including the immunogenicity study as secondary endpoint.
5.	Ranibizumab **Name of the applicant** :	**1. Recommendation of the SEC (Ophthalmology) held on 13.01.2017:** After detailed deliberation of study protocol,

	Reliance Life Sciences Pvt. Ltd **Date of Application:** 05.08.2016	committee noted the following- 1. Diabetic patients should be excluded. 2. Primary end point should be established at 16 weeks and design in the protocol should be made accordingly. 3. Criteria for size of the choroidal neovascular membrane thickness and the leakage should be deleted. 4. Secondary objective should include Optical Coherence Tomography to assess central Macular thickness. 5. After completion of 16 weeks, data should be presented before committee for review. 6. CMC equivalence by LCMS with sufficient number of batches of API of proposed drug with the comparator with validation of analytical kits including methods used and statistical margins for the proposed equivalence in kinetics and efficacy need to be clarified and submitted as the proposed study is for intravitreal use. Committee recommended for submission of revised protocol with above cited changes and approval after incorporation of suggested changes. Accordingly, firm shall submit the revised protocol. **Accordingly, firm has submitted the revised protocol in line with the recommendation of SEC held on 13.01.2017.** **2. Recommendation of the Technical Committee Meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
6.	Measles & Rubella vaccine (Live) I.P. (Freeze Dried) – Single Dose and Multi Dose formulations. **Name of the firm :** M/s Cadila Healthcare Limited **Date of Application:** 30.12.2016	**1. Recommendation of the SEC (Vaccine) held on 31.03.2017:** The firm has applied for permission to conduct clinical trial phase-II/III for Measles and Rubella vaccine (Live) and presented Phase-I clinical trial study report. After detailed deliberation the Committee recommended for approval of the protocol. **Expert Committee Members:** 1. Dr. P.P. Gupta, Department of Pharmacology, AIIMS, Patna. 2. Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi-

		110 029. 3. Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi. 4. Dr. Savita Verma, Pharmacology, PGIMS 5. Dr. Veena Verma, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. 6. Dr. A.P. Dubey, Prof & Head, Paediatrics, MAMC, New Delhi. **2. Recommendation of the Technical Committee Meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
7.	Inactivated Influenza vaccine (split virion) I.P. (Tetravalent) Name of the Applicant: Cadila Healthcare Limited Date of Application: 28.11.2016	**1. Recommendation of the SEC (Vaccine) held on 31.03.2017:** The firm has applied for permission to conduct phase-III clinical trial for Inactivated Influenza Vaccine (split virion) I.P. (Tetravalent). After detailed deliberation the Committee recommended for approval of the protocol. **Expert Committee Members:** 1. Dr. P.P. Gupta, Department of Pharmacology, AIIMS, Patna. 2. Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi-110 029. 3. Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi. 4. Dr. Savita Verma, Pharmacology, PGIMS 5. Dr. Veena Verma, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. 6. Dr. A.P. Dubey, Prof & Head, Paediatrics, MAMC, New Delhi. **2. Recommendation of the Technical Committee Meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
8.	Hepatitis B vaccine (rDNA) I.P	**1. Recommendation of the SEC (Vaccine) held on 31.03.2017:** The firm has applied for permission to conduct clinical

	Name of the Applicant: Cadila Healthcare Limited **Date of Application:** 30.12.2016	trial phase-II/III for Hepatitis B Vaccine (r DNA) and presented Phase-I clinical trial study report. After detailed deliberation the Committee recommended for approval of the protocol. **Expert Committee Members:** 1. Dr. P.P. Gupta, Department of Pharmacology, AIIMS, Patna. 2. Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi110029. 3. Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi 4. Dr. Savita Verma, Pharmacology, PGIMS 5. Dr. Veena Verma, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. 6. Dr. A.P. Dubey, Prof & Head, Paediatrics, MAMC, New Delhi **2. Recommendation of the Technical Committee Meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
9.	Inactivated Influenza vaccine (split virion) I.P. (Trivalent) **Name of the Applicant**: Cadila Healthcare Limited **Date of application**: 03.01.2017	**1. Recommendation of the SEC (Vaccine) held on 31.03.2017:** The firm has applied for permission to conduct phase-III clinical trial for Inactivated Influenza Vaccine (split virion) I.P. (Trivalent). After detailed deliberation the Committee recommended for approval of the protocol. **Expert Committee Members:** 1. Dr. P.P. Gupta, Department of Pharmacology, AIIMS, Patna. 2. Dr. Ramesh Agarwal, Professor, Vaccine & Neonatology, AIIMS, New Delhi110029. 3. Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi 4. Dr. Savita Verma, Pharmacology, PGIMS 5. Dr. Veena Verma, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. **6.** Dr. A.P. Dubey, Prof & Head, Paediatrics, MAMC, New Delhi

		2. Recommendation of the Technical Committee Meeting held on 03.05.2017: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
10.	Desloratadine Tablets USP 10 mg Name of the applicant: M/S Sun Pharma Laboratories Limited. Date of Application: 29.12.2016	**1. Recommendation of the SEC (Dermatology) held on 28.03.2017:** The firm presented the justification for the 10mg strength and Clinical Trial protocol before the committee. The committee after detailed deliberation recommended conduct of the Clinical Trial with Desloratadine tablet USP 10mg and waiver of BE study. **Name of the SEC Expert:** 1. Dr. V. K. Sharma, Professor and Head, Dept. of Dermatology, AIIMS, New Delhi 110029 2. Dr. D.M. Thappa, Professor and Head, Dept. of Dermatology, JIPMER, Pondicherry-605006 3. Dr. Sanjeev Handa, Professor and Head, Dept of Dermatology, PGIMER, Sector 12, Chandigarh 4. Dr. D.S. Arya, Professor, Dept. of Clinical Pharmacology, AIIMS, New Delhi 110029 **5.** Dr. Binod Khaitan, Professor & Head, Dept. of Dermatology, AIIMS, New Delhi 110029. **2. Recommendation of the Technical Committee Meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
11.	FDC of Glycopyrronium bromide/s /Formoterol fumarate Name of the applicant: m/s Cipla Limited Date of Application: 25.01.2016	**1. Recommendation of the SEC (Pulmonary) held on 07.04.2017:** The firm presented revised Clinical trial protocol before the Committee. After detailed deliberations the Committee recommended for grant of approval for conduct of phase III clinical trial with revised protocol. **Name of the SEC expert:** 1.) Dr. Shalini Chawla, Director-Professor, Pharmacology, Pharmacology, MAMC, New Delhi. 2.) Dr. Sushant H. Meshram, Professor, Government Medical College & Hospital Nagpur. 3.) Dr. Subodh Kumar, Assistant Professor, AIIMS,

		rishikesh. **2. Recommendation of the Technical Committee Meeting held on 03.05.2017:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
12.	Combined Dipitheria-Tetanus-Acellular Pertusis-Inactivated Poliovirus and Haemophilus Influenza Type b Conjugate Vaccine (Infanrix-IPV/ Hib) **Name of the applicant**: GlaxoSmithKline Pharmaceuticals Ltd **Date of Application:** 28.11.2016	**1. Recommendation of the SEC held on 31.03.2017:** The firm has applied for permission to conduct phase-III clinical trial (single arm, open-label) to evaluate the safety and immunogenicity of DTaP – IPV –Hib-TT conjugate vaccine at 6, 10 and 14 weeks of age in healthy Indian infants. After detailed deliberation the Committee recommended the approval of the protocol. **2. Recommendation of the Technical Committee Meeting held on 03.05.2017:** After detailed deliberation, the committee noted that the vaccine is approved in countries like USA and Europe, however various events of fatal outcome after administration of vaccine have been reported and the clinical trial has been proposed in two centers including are in the community medicine for which committee opined that the firm may asked to provide clarification and make a presentation before the committee.

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