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, Chairman Director General of Health Services, Nirman Bhawan, New Delhi

2. Dr. Kamlakar Tripathi, Member Prof. Department of Medicine, Institute of Medical Sciences, Banaras Hindu University, Varanasi.

3. Dr. Nandini Kumar, Former Dy. Dire. Gen. Sr. Grade, Member Adjunct Professor, KMC, Manipal, 5/1 (New) Padmalaye Apt. Chennai.

4. Dr. Rajutitus Chacko, Prof. & Head, Dept. of Medical Member Oncology, CMC, Vellore.

5. Dr. Yash Paul, Member Prof. & Head, Dept. of Cardiology, PGIMER, Chandigarh.

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)
- 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

40th Technical Committee Meeting -03.05.2017

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 40^{th} Meeting held on 03.05.2017:

specified Parameters 2.7	•
	2. Technical Committee
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 ODJ UK GlaxoSmithKline LLC, 1250 South Collegeville Road Collegeville PA 19426 -0989, USA Protocol Title: A Phase 3 Randomized, Open-label (Sponsor) kidney disease a day 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 opposite kidney disease.	Professor, Vardhman Mahavir Medical College, New Delhi- 110029.

Dialysis Subjects With Anemia Associated With Chronic Kidney Disease to Evaluate the Safety and Efficacy of Daprodustat Compared to Recombinant Human Erythropoietin, Following Switch Erythropoietin-From stimulating Agents. (Protocol #: 200807)

2. Recommendation of the Technical Committee meeting held on 03.05.2017:

After detailed deliberation. the with committee agreed the recommendation of the SEC and recommended the approval of the study.

2. Name of the Drug:

Date of Application: 23/9/2016

Protocol No: 200808

Phase of the trial: III

the **Applicant:** M/s PPD Pharmaceutical Development India Pvt. Ltd., India

Innovation vis-à-vis **Existing Therapeutic Option:** To compare Daprodustat to rhEPO for cardiovascular (CV) safety (noninferiority). And compare to Daprodustat to rhEPO for hemoglobin efficacy (non inferiority)

Assessment of Risk vs.

Benefit to the patients:

The safety profile of the

drugs

studies including Single

developmental toxicity,

tolerance and clinical

conduct of the trial.

tests.

iustify

from

toxicology

toxicity,

Dermal

local

the

and

toxicity, repeat

study

dose

dose

preclinical

reproductive

genotoxicity,

toxicity

studies

Unmet Medical Need in the country: The test drug may potentially provide alternative treatment in dialysis subjects with anemia associated with chronic kidney disease

Daprodustat

of Name

Name of the Sponsor:

GlaxoSmithKline Research Development Limited, 980 Great West Road. Middlesex, Brentford, 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

1. Recommendation of the **SEC** (Cardiovascular & Renal) on 09/02/2017.

detailed deliberation After 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 Delhi-College, New 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 the Department, Dept. 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 randomized, open-(sponsor-blind), label activecontrolled, parallel-group, multicenter, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease 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, genotox icity 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 8.Hence the detailed visit 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 recognized a 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 protocol to the 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 opined risk committee that the management plan/revised protocol is acceptable. Hence the committee recommended the conduct of the study (protocol amendment no: 2, version 3.0.

SEC Experts:

			 Dr. MD. Ashraf Ganie, Dept. of Endocrinology, SKIMS, K&K Dr. Bikash MEdhi, Dept. of Pharmacology, PGIMER, Chandigarh. Dr. Rajesh Khadgawat, Professor, Dept. of Endocrinology, AIIMS, New delhi. Dr. MAnoj Chadha, Dept. of Endocrinology P.D Hinduja National Hospital MAhim, Mumbai. Dr. Deepak Khandelwal, Consultant, dept. of Endocrinology, Maharaja Agrasen Hospital New Delhi. 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: Α 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.

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 Selonsertibin of **Subjects** with Nonalcoholic Steatohepatitis (NASH) and Bridging (F3)

Fibrosis.

phase Ι Π and 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 Compensated with Cirrhosis due to

Nonalcoholic

(NASH)

Steatohepatitis

bridging fibrosis.

and

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.
- Dr. Anoop Saraya, Professor, Dept. of Gastroenterology, AIIMS, New Delhi.
- 3. Dr. Sudhir Gupta, Professor and Head, Government Medical College and Super Speciality, Nagpur.
- Dr. P. Shravan Kumar, Professor, HOD of Gastroenterology, Gandhi Medical College and Hospital, Secunderabad, Telengana.
- 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 40^{th} 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:	Risk versus benefit to the patients - The safety profile of the study drugs from preclinical safety pharmacology and toxicology studies	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.
	Quintiles Research India Private Limited, Ahmedabad. Name of the Sponsor:	including Single dose toxicity, repeat dose toxicity, local tolerance & immune toxicity and clinical studies justify	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
	Archigen Biotech Limited, UK	the conduct of the trial. Innovation vis-a-vis existing therapeutic	 Dr. Arunanshu Talukdar, MD, Prof., Dept. of Medicine, Medical College, Kolkata-700073 Dr. Amita Aggarwal, Prof. & Head, Dept. of Clinical Immunology,
	Name of the Manufacturer: Rentschler Biotechnologie GmbH Erwin-Rentschler-Strasse 2188471 Laupheim, Germany	option- To compare the PK of SAIT101 versus MabThera® versus Rituxan® in patients with rheumatoid arthritis.	 SGPGI, Lucknow Dr. Uma Kumar Head & Prof. Rheumatology Division, Dept. of Medicine, AIIMS, New Delhi Dr. Anjan Trikha, Dept. of Anesthesiology, AIIMS, New Delhi Dr. Lalit Kumar Kumar Gupta, Dept. of Pharmacology, LHMC, New Delhi
	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)	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.	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:	Risk versus benefit to	1. Recommendation of the SEC
	LCZ696	the patients - In light of	(Cardio) held on 21/02/2016.
	Date of Application:	the fact that the of	After detailed deliberation the
	25/10/2016	Atumumab is already	committee recommended for the
	Protocol No:	approved in India, the	conduct of the study in its presented
	CLCZ696G2301 Phase of the trial: III	safety profile of the	form.
	Name of the Applicant:	study drug justify the conduct of the trial.	SEC Expert:
	Name of the Applicant.	conduct of the trial.	1. Dr. Shyam Sunder Kothari, Prof.
	Novartis Healthcare	Innovation vis-a-vis	Dept of C, AIIMS, New Delhi.
	Private Limited,	existing therapeutic	2. Dr. S.K. Agarwal, Professor &
	Sandoz House, Shivsagar	option- The objective of	Head of the department, Dept. of
	Estate, Dr. Annie Besant	the study is to	Nephrology AIIMS, New Delhi.
	Road, Worli, Mumbai -	investigate the efficacy	3. Prof. Dr.K.M.K. Reddy, Dept. of
	400 018.	and safety of Dabigatran	Cardiology, Osmania Medical
	Name of the Common of	Etexilate versus dose-	College, Koti, Hyderabad-500095
	Name of the Sponsor: Novartis Healthcare	adjusted Warfarin in patients with cerebral	4. Dr. R K Sharma, Professor, Dept. of
	Private Limited,	venous and dural sinus	Nephrology SGPGI, Lucknow.
	Sandoz House, Shivsagar	thrombosis.	5. Dr. C.D. Tripathi, Professor. Dept.
	Estate, Dr. Annie Besant		of Pharmacology, VMMC, New Delhi.
	Road, Worli Mumbai -	Unmet need in the	Deim.
	400 018.	country- The test drug	2. Recommendation of the
		may be an alternative	Technical Committee meeting
	Name of the	treatment in patients	held on 03.05.2017:
	Manufacturer:	with cerebral venous and dural sinus	After detailed deliberation, the
	Novartis Pharma Stein AG Schaffhauserstrasse	and dural sinus thrombosis.	committee agreed with the
	CH-4332 Stein,	unomoosis.	recommendation of the SEC and
	Switzerland Site is GMP		recommended the approval of the
	certified and registered		study.
	with DCGI.		3
	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.		

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</u> 100mg Oral tablet

M/s Kemwell Biopharma Pvt. Ltd. 34th KM, Tumkur Road

Teppada Begur Nelamangala Taluk Bangalore – 562 123 India.

For 20mg Dispersible Tablet

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 24week 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 the patients background treatment regimen should current as per 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:

- 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
- 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. 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

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. 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 Limited Francis Crick Avenue Cambridge Biomedical Campus, Cambridge CB2 0AA, United Kingdom Name of the Manufacturer: Rentschler-Strasse 21 88471 Laupheim, Germany Protocol Title: A Randomized, Double-Met Met Protoc		Name of the	2 aganists are approved	Professor AIMS Dishilash
Pharma Stein AG Schaffhauserstrasse CH- 4332 Stein, Switzerland Protocol Title: A multi-center, randomized, 12-weck 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 sasthma. 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. 1. Recommendation of the SEC and recommended the approval of the study. 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. In Recommendation of the SEC and recommended the approval of the study. In Recommendation of the SEC and recommended the approval of the study. In Recommendation of the SEC and recommended the approval of the study. In Recommendation of the SEC and recommended the approval of the study. In Recommendation of the SEC and recommended the approval of the study. In Recommendation of the SEC (Oncology) held on 21/March/17 After detailed deliberation the committee recommended the conduct of the study after flexible study after flexible study. In Recommendation of the SEC (Oncology) held on 21/March/17 After detailed deliberation of the SEC (Oncology) held on 21/March/17 After detailed deliberation of the SEC Expert: In Dr. Sameer Bakshi, Professor, Dept. of Oncology, AIIMS, New Delhi. In Dr. Renu Saxena, Professor, Dept. of Oncology, AIIMS, New Delhi. Dr. Renu Saxena, Professor, Dept. of Pharmacology, AIIMS, New Delhi. Dr. Renu Saxena, Professor, Dept. of Pharmacology, AIIMS, New Delhi. Dr. P.R. Gogoi, Professor, Dept. of Pharmacology, AIIMS, New Delhi. Dr. P.R. Gogoi, Professor and Head of Dept., Gauhati Medical College and Hospital, Guwahati. Dr. K.H Reeta, Professor, Dept. of Pharma			2-agonists are approved	Professor, AIIMS, Rishikesh.
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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 Medical College, Vellore-632004. rituximab for the growing FL/LTBFL population. 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:			•	
Cambridge CB2 0AA, United Kingdom Name of the Manufacturer: Rentschler Biotechnologie GmbH Erwin-Rentschler-Strasse 21 88471 Laupheim, Germany Protocol Title: A Randomized, Double- Hind Manufacturer growing FL/LTBFL population. FL/LTBFL 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:			_	23,
United Kingdom Name of the Manufacturer: Rentschler Biotechnologie GmbH Erwin-Rentschler-Strasse 21 88471 Laupheim, Germany Protocol Title: A Randomized, Double- Hind Manufacturer: 20 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. 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. 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. 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. 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. 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.		. .		_
Name of the Manufacturer: Rentschler Biotechnologie GmbH Erwin-Rentschler-Strasse 21 88471 Laupheim, Germany Protocol Title: A Randomized, Double- Hind Manufacturer: 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:				
Manufacturer: Rentschler Biotechnologie GmbH Erwin-Rentschler-Strasse 21 88471 Laupheim, Germany Protocol Title: A Randomized, Double- Hind Multi center Manufacturer: 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:		C	population.	
Rentschler Biotechnologie GmbH Erwin-Rentschler-Strasse 21 88471 Laupheim, Germany Protocol Title: A Randomized, Double- Hind Multi contact Rentschler 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:				
Biotechnologie GmbH Erwin-Rentschler-Strasse 21 88471 Laupheim, Germany Protocol Title: A Randomized, Double- Hind Multi content				
Erwin-Rentschler-Strasse 21 88471 Laupheim, Germany Protocol Title: A Randomized, Double- Hind Multi content Pharmacology, AIIMS, New Delhi. 2. Recommendation of the Technical Committee meeting held on 03.05.2017:				_
21 88471 Laupheim, Germany Protocol Title: A Randomized, Double- Hind Multi content 2. Recommendation of the Technical Committee meeting held on 03.05.2017:				_
Germany Protocol Title: A Randomized, Double- Hind Multi content 2. Recommendation of the Technical Committee meeting held on 03.05.2017:				Pharmacology, AIIMS, New Delhi.
Protocol Title: A Randomized, Double- Hind Multi content Technical Committee meeting held on 03.05.2017:				
Randomized, Double-		I		2. Recommendation of the
hind Multi-content				Technical Committee meeting
blind. Multi-center.				held on 03.05.2017:
After detailed deliberation, the		blind, Multi-center,		After detailed deliberation, the

Medical College, Vellore-632004.

6. Dr. S.D. Banavali, Professor, Dept.

7. Dr. P.K. Gogoi, Professor and Head

of Dept., Gauhati Medical College

of Oncology, KEM Mumbai.

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

Protocol Title: SOAR

Trial, A two-part study:

Interventional phase II

single-arm trial to assess

40th Technical Committee Meeting -03.05.2017

efficacy and safety of	and Hospital, Guwahati.
Eltrombopag combined	8. Dr. K.H Reeta, Professor, Dept. of
with cyclosporine as first	Pharmacology, AIIMS, New Delhi.
line therapy in patients with severe acquired aplastic anemia, and an extension with up to 60-months follow-up.	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 40^{th} Meeting held on 28.03.2017:

S.No.	Name of the Drug	Recommendations:	
		1. Subject Expert Committee	
		2. Technical Committee	
1.	Denosumab	1. Recommendation of SEC (Analgesic &	
	Date of Application:	Rheumatology) meeting held on 06.12.2016:	
	11.07.2016.		
	Name of the firm: M/s Reliance Life Sciences Pvt. Ltd.	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:	
		 Dr. R. K. Arya, Prof and Head, Department of Orthopedics, RML Hospital, New Delhi. Dr. S. K. Das, Prof and Head, Department of Rheumatology, KGMC, Lucknow-226003. Dr Arunagshu Talukdar, MD, Professor, Department of Medicine, Medical College, Kolkata-700073. Dr Uma Kumar, Prod and Head, Dept. of Rheumatology Division, AIIMS, New Delhi- 110029. 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

(Live) 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. Pneumococcal 1. Recommendation of the SEC (Vaccine) held on 30.03.2017: Polysaccharide Conjugate Vaccine (Adsorbed) The Committee recommended for approval of the (With preservative) protocol with the following conditions: Date of Application: 1. The protocols for with and without Thiomersal in 26.04.2016 the vaccine be submitted separately. Name of the firm: 2. Phase - I study will be conducted only for safety and reactogenicity and not immuno-genicity. M/s Biological Evans

Ltd, Hyderabad

protocol with proposing both "Safety, reactogenicity and immunogenicity" in Phase I protocol.

3. Equal number shall be enrolled at two study sites.

Accordingly, the firm has submitted the revised

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	 Recommendation of the SEC (Vaccine) held on 30.03.2017: The Committee recommended for approval of the protocol with the following conditions: The protocols for with and without Thiomersal in the vaccine be submitted separately. Phase - I study will be conducted only for safety and reactogenicity and not immuno-genicity. 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. 	
		Evnout Committee Members	
		 Expert Committee Members: Dr. P.P. Gupta, Department of Pharmacology, AIIMS, Patna. Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi110029. Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi Dr. Savita Verma, Pharmacology, PGIMS Dr. Veena Verma, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. Dr. A.P. Dubey, Prof & Head, Paediatrics, 	
		MAMC, New Delhi 2. Recommendation of the Technical Committee Macting held on 03 05 2017:	
		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	1. Recommendation of the SEC (Ophthalmology)	
	Name of the applicant :	held on 13.01.2017: After detailed deliberation of study protocol,	

	D 1: T:C C:	1.1 0.11
	Reliance Life Sciences	committee noted the following-
	Pvt. Ltd	1. Diabetic patients should be excluded.
	Date of Application:	2. Primary end point should be established at 16 weeks
	05.08.2016	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
		1
		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	1. Recommendation of the SEC (Vaccine) held on
	vaccine (Live) I.P.	31.03.2017:
	(Freeze Dried) – Single	The firm has applied for permission to conduct clinical
	Dose and Multi Dose	trial phase-II/III for Measles and Rubella vaccine
	formulations.	(Live) and presented Phase-I clinical trial study report.
1	Name of the firm:	After detailed deliberation the Committee
	M/s Cadila Healthcare	recommended for approval of the protocol.
	Limited	
	Limited	Expert Committee Members:
	Data af A valland	1. Dr. P.P. Gupta, Department of Pharmacology,
	Date of Application:	AIIMS, Patna.
1	30.12.2016	2. Dr. Ramesh Aggarwal, Additional Professor,
		Vaccine & Neonatology, AIIMS, New Delhi-

		110 029.
		 Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi.
		 Dr. Savita Verma, Pharmacology, PGIMS Dr. Veena Verma, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. 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	1. Recommendation of the SEC (Vaccine) held on
	vaccine (split virion) I.P.	31.03.2017: The firm has applied for parmission to conduct phase
	(Tetravalent)	The firm has applied for permission to conduct phase- III clinical trial for Inactivated Influenza Vaccine (split
	Name of the Applicant:	virion) I.P. (Tetravalent). After detailed deliberation
	Cadila Healthcare	the Committee recommended for approval of the
	Limited	protocol. Expert Committee Members:
	Date of Application:	Expert Committee Members.
	28.11.2016	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, PGIMS5. 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	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.
	Limited	Expert Committee Members:
	Date of application: 03.01.2017	 Dr. P.P. Gupta, Department of Pharmacology, AIIMS, Patna. Dr. Ramesh Agarwal, Professor, Vaccine & Neonatology, AIIMS, New Delhi 110029. Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi Dr. Savita Verma, Pharmacology, PGIMS Dr. Veena Verma, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. 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	 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: Dr. V. K. Sharma, Professor and Head, Dept. of Dermatology, AIIMS, New Delhi 110029 Dr. D.M. Thappa, Professor and Head, Dept. of Dermatology, JIPMER, Pondicherry-605006 Dr. Sanjeev Handa, Professor and Head, Dept of Dermatology, PGIMER, Sector 12, Chandigarh Dr. D.S. Arya, Professor, Dept. of Clinical Pharmacology, AIIMS, New Delhi 110029 Dr. Binod Khaitan, Professor & Head, Dept. of Dermatology, AIIMS, New Delhi 110029. 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	 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: Dr. Shalini Chawla, Director-Professor, Pharmacology, Pharmacology, MAMC, New Delhi. Dr. Sushant H. Meshram, Professor, Government Medical College & Hospital Nagpur. 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	 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. 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
