MINUTES OF 36th MEETING OF THE TECHNICAL COMMITTEE HELD ON 20.10.2016 UNDER THE CHAIRMANSHIP OF DGHS FOR SUPERVISING CLINICAL TRIALS ON NEW CHEMICAL ENTITIES IN THE LIGHT OF DIRECTIONS OF THE HON'BLE SUPREME COURT OF INDIA ON 03.01.2013.

Present:

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

From CDSCO:

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

The Chairman welcomed the members of the Committee for the 36th meeting. Thereafter, the Committee discussed the clinical trial proposals and other agenda one after another as under:

The Committee deliberated 13 cases related to approval of clinical trials. Out of these 13 cases, 03 cases was related to clinical trials of NCEs, 04 cases were related to Global Clinical Trials

(GCT), remaining 06 cases were related to clinical trials for approval of New Drugs and Biologicals.

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

The Committee evaluated three cases related to clinical trials of NCEs and made recommendations considering all aspects of safety, efficacy especially in terms of the three parameters viz. risk versus benefit to the patients, innovation vis-a-vis existing therapeutic option and unmet medical need in the country. After detailed deliberations, the Committee recommended approval for three 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 four cases related to global clinical trials. After detailed deliberations, the Committee recommended approval for three proposals of clinical trials and one proposal was withdrawn by the firm. 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 six cases of other than GCT/clinical trial of NCEs. After detailed deliberations, the Committee recommended approval for six proposals. The recommendation of the Committee is enclosed as **Annexure-III.**

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

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

It was opined by the Chairman of the Committee that those members who are unable to attend the meeting of Technical Committee may be replaced with the new members.

Annexure-I

Proposals of clinical trial of NCEs along with their evaluations and recommendations of the Technical Committee in its 36th Meeting held on 20.10.2016:

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:** Avelumab is the proposed International Non-proprietary Name (INN) for the anti-PD-L1 monoclonal antibody, MSB0010718C. **Date of Application:** 25/06/2016 **Protocol No**: B9991001 **Phase of the trial:** III **Name of the Applicant:** M/s Pfizer Limited, The Capital, 1802/1901, Plot No. C-70, G Block, Bandra Kurla Complex, Bandra (East), Mumbai 400051, Maharashtra, India **Name of the Sponsor:** M/s Pfizer Inc., 235 East 42nd Street, New York, NY 10017, USA **Name of the Manufacturer:** M/s	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drugs from preclinical safety pharmacology and toxicology studies and clinical studies justify the conduct of the trial. **Innovation vis-avis Existing Therapeutic Option:** To demonstrate the benefit of maintenance treatment with Avelumab plus BSC vs BSC alone in prolonging overall survival (OS) in patients with unresectable locally advanced or metastatic US whose disease did not progress on or following completion of first-line platinum-containing chemotherapy in each co-primary UC patient population: 1) patients determined to have PD-L1-positive tumors (including infiltrating immune cell) by a verified GMP PD-L1 1HC test, and 2) all randomized patients.	**1. The proposal was deliberated in SEC (Oncology) held on 27/09/2016.** After detailed deliberation the committee recommended the conduct of the study. **SEC Expert List:** **1.** Dr. Sameer Bakshi, Professor, dept. of Medical Oncology, AIIMS, New Delhi. **2.** Dr. C.K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata. **3.** Dr. Sanjay Kumar Singh, Dept. of Medical Oncology, Gajara Raja Medical College, Veer Savarkar Marg, Gwalior-474009 Gwalior. **4.** Dr. Prantar Chakroborty, Dept. of Hematology, NRS Medical College, Kolkata 700014. **5.** Dr. Renu Saxena, Prof. and Head, Dept. of Hematology, AIIMS, New Delhi. **6.** Dr. Bikas Medhi, Pharmacology, PGIMER, Sector 12, Chandigarh. **7.** Dr. K.V. Anand, HOD, Dept. of Vascular Surgery, Army Hospital, R & R, New Delhi. **2. Recommendation of the**

	Merck Serono S.A., Succursale d'Aubonne, Zone Industrielle del'Ouriettaz, CH-1170 Aubonne, Switzerland **Title:** A Phase 3, multicentre, multinational, randomized, open-label, parallel-arm study of Avelumab plus best supportive care versus best supportive care alone as a maintenance treatment in patients with locally advanced or metastatic urothelial cancer whose disease did not progress after completion of first line platinum-containing chemotherapy.	**Unmet Medical Need in the Country:** The test drug may potentially provide alternative treatment of subjects with locally advanced or metastatic urothelial cancer.	**Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
2.	**Name of the Drug:** Sarizotan Hydrochloride **Date of Application:** 21/04/2016 **Protocol No**: Sarizotan/001/II/2015 **Phase of the trial:** II **Name of the Applicant:** M/s CliniRx Tangent Research India Private Limited Patriot House, 4th Floor, 3 BSZ Marg, New Delhi – 110 002 **Name of the Sponsor:** Newron Pharmaceuticals	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drug from preclinical pharmacology, single dose, repeat dose toxicity, carcinogenotoxicity, reproductive toxicity and Phase I clinical studies justify the conduct of the trial. **Primary objective:** To evaluate the effect of Sarizotan (5 to 10mg bid), compared to placebo, on reducing the number of apnea episodes, during awake time, in patients with RTT with respiratory abnormalities.	**1. The proposal was deliberated in SEC (Neurology & Psychiatry) held on 26/08/2016.** After detailed deliberation the committee has recommended the following conditions: **1.** The title of the study should be phase II instead of phase II/III. **2.** Description and composition of placebo and the justification for use of placebo considering the Rett Syndrome to be a rare condition. **3.** Specify the exact number of the patients to be recruited from India

	S.p.A. Via Ludovico Ariosto 21 20091 Bresso (Milano) Italy **Name of the Manufacturer:** Merck KGaA **Address:** Frankfurter Str. 250, 64293 Darmstadt, Germany **Title** A Randomized, Double-Blind, Placebo-Controlled, Six-Month Study to Evaluate the Efficacy, Safety and Tolerability of Sarizotan in Patients with Rett Syndrome with Respiratory Symptoms	**Unmet Medical Need in the country:** The test drug may provide alternate treatment option in in Patients with Rett Syndrome with Respiratory Symptoms.	**Action Taken:** 1. In rare diseases such as Rett Syndrome, where the prevalence of the disorder is low i.e. 1 in 10000-20000 patients, ICH/FDA guidelines accepts the principle to perform a combined phase II/III program instead of sequential program. The study has been approved by health authorities in Germany, Spain, UK, Canada & USFDA. However in deference to the recommendations, the sponsor agrees to the development of phase II programme. **2.** Placebo capsules contain small amount of micro crystalline cellulose. Currently there are no approved treatments for respiratory abnormalities in RTT patients, therefore a placebo control rather than an active control is being used in this study. **3.** They are requested for 55 patients to be recruited from India. **SEC Expert List:** **1.** Dr. Shruti Srivastava, Professor Department of Psychiatry, Uniersity College of Medical Sciences, New Delhi. **2.** Dr. M.V. Padma, Department of Neurology, AIIMS Hospital, New Delhi. **3.** Dr. Bikash Medhi, Dept. of Pharmacology, PGIMER, Sector 12, Chandigarh. **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC

			and recommended the approval of the study
3.	**Name of the Drug:** LY2835219(Abemaciclib) **Date of Application:** 21/06/2016 **Protocol No**: 13Y-CR-JPBQ **Phase of the trial:** III **Name of the Applicant:** Eli Lilly and Company (India) Pvt. Ltd. Gurgaon – 122001, Haryana **Name of the Sponsor:** Eli Lilly and Company (India) Pvt. Ltd. Gurgaon – 122001, Haryana **Name of the Manufacturer: :** Eli Lilly and Company, Lilly Technology Center, Indianapolis, Indiana 46221, USA **Title** I3Y-CR-JPBQ: A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Compare NSAI plus Abemaciclib, a CDK4 and CDK6 Inhibitor, or plus Placebo and to Compare Fulvestrant plus Abemaciclib or plus Placebo in Postmenopausal Women with Hormone Receptor-	**Risk versus benefit to the patients** The safety profile of the test drug from pre-clinical toxicity including repeat dose toxicity, genotoxicity, carcinogenotoxicity studies and clinical phase I, II studies justify the conduct of the study. **Innovation vis-a-vis existing therapeutic option** The purpose of study is to compare treatment with Abemaciclib plus NSAI(anastazole or letrozole) therapy versus placebo plus NSAI therapy with respect to PFS in post menopausal women with HR+ HER2 metastatic breast cancer. **Unmet need in the country-** The test drug may be an alternative treatment in subjects with metastatic breast cancer.	**1. The Proposal was deliberated in SEC (Oncology) held on 23/08/2016.** After detailed deliberation the committee recommended the conduct of phase III clinical trial. However, the committee raised the query regarding the rationale/justification of recruiting only 45 patients out of 450 patients recruiting globally. **Action Taken:** The above study is competitive enrolling study & in case patient recruitment at the approved Indian sites will happen at fast pace we may seek approval for more patients in future. Secondly Lilly India will also attempt to bring further trials of Abemaciclib in India in future. **SEC Expert List:** **1.** Dr. Sameer Bakshi, Prof. Dept. of Medical Oncology, AIIMS, New Delhi. **2.** Dr. H.P. Pati, Professor, Dept. of Hematology, AIIMS, New Delhi 110010. **3.** Dr. Prantar Chakra borty, Dept. of Hematology, NKS Medical College, Kolkata-700014. **4.** Dr. C.K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer

	Positive, HER2-Negative Locoregionally Recurrent or Metastatic Breast Cancer.		Research Institute, Kolkata. **5.** Dr. H.S. Rehan, Professor and Head, Dept. of Pharmacology, Lady Harding medical college, New Delhi. **6.** Dr. Renu Saxena, Professor and Head, Dept. of Hematology, AIIMS, New Delhi. **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.

Annexure-II

Proposals of clinical trial of GCTs along with their evaluations and recommendations of the Technical Committee in its 36th Meeting held on 20.10.2016:

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:** Forb 100 HFA (Generic name: Budesonide+Formoterol) **Date of Application:** 18/05/2016 **Protocol No**: MA/0715-4 **Phase of the trial:** III **Name of the Applicant:** IC Bio Clinical Research Pvt. Ltd #16 & 18 IC Bio Tower, Yelahanka Main Road, Chikkabettahalli, Vidyaranyapura, Bangalore - 560 097, India **Name of the Sponsor:** RUS Biopharm LLC, Russia **Name of the Manufacturer:** Midas Care Pharmaceuticals Pvt. Ltd. Lotus Corporate Park, B Wing, 3rd Floor, Jay Coach, Western Express Highway, Goregaon (E), Mumbai-400063, India **Title** Open Label,	**Risk vs. benefit to the patients:** In light of the fact that the FDC is approved and marketed the safety profile of the test drugs justify the conduct of the trial. **Innovation vis a vis existing therapeutic option-** The purpose of the study is to assess the efficacy and safety of therapy with Forb 100 HFA (Budesonide + Formoterol) metered dose aerosol for inhalation 100+6µg/dose (Midas Care Pharmaceutical Pvt. Ltd. India) compared to ForadilCombi set of capsules with inhalation powder 200+12µg/caps dose (Novartis Pharma AG, Switzerland) in patients with partially controlled asthma **Unmet need.** The test drug may be an alternate treatment option in patients with partially controlled asthma.	**1. The Proposal was deliberated in SEC (Pulmonary) held on 25/07/2016** After detailed deliberation the committee recommended conduct of the study subject to the following conditions: **1.** All the three trial sites are situated in Bangalore. It is recommended to make it a multicentric trial. **2.** All the investigators must be qualified in concerned specialty (MD Medicine/Respiratory). **Action Taken:** The firm has submitted the revised list of trial sites & all the investigators are qualified in MBBS, MD medicine and one investigator with MD in TB & Chest **SEC Expert List:** 1. Dr. Subash Kumar, Assistant Professor, Dehradun 2. Dr. Sushant H. Meshram, Professor, Government Medical College and Hospital, Nagpur. 3. Dr. J.C. Suri, Professor, VMMC and Safdurjung Hospital, New Delhi.

	Multicenter, Randomized, Comparative study to Evaluate the efficacy and safety of drugs Forb 100 HFA (Generic name: Budesonide+Formoterol), metered dose aerosol for inhalation100+6 µg/dose (Midas Care Pharmaceuticals Pvt. Ltd., India) and Foradil Combi, set of capsules with inhalation powder 200+12 µg/caps (dose) (Novartis Pharma AG, Switzerland) in patients with partially controlled asthma.		4. Dr. S Vinod Kumar, Professor and Head, JIPMER, Puducherry. 5. Dr. C D Tripathi, Professor and Head Department of Pharmacology, VMMC, New Delhi. 6. Dr. B. Gupta, Hindurao Medical College, New Delhi. **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study
2.	**Name of the Drug:** Insulin Glargine (Injection in pre-filled syringe) **Date of Application:** 07/06/2016 **Protocol No**: EFC12814 **Phase of the trial:** III **Name of the Applicant:** Sanofi-Synthelabo (India) Private Limited Mumbai 400 072, India **Name of the Sponsor:** Sanofi-aventis recherché & Developpement, 1, Avenue Pierre Brossolette, 91380	**Risk versus benefit to the patients-** The safety profile of the test drug from pre-clinical toxicity including repeat dose toxicity, carcinogenotoxicity studies and clinical phase I, II studies justify the conduct of the study. **Innovation vis-a-vis existing therapeutic option** The purpose of study is to investigate the efficacy of new formulation of Insulin Glargine (HOE901-U300) and lantus in terms of change of HbA1c from baseline to endpoint (scheduled at month 6, week 26) in subjects with type 2 diabetes mellitus. **Unmet need in the country-** The test drug may be an	**1. The Proposal was deliberated in SEC (Endocrinology) held on 22/08/2016.** After detailed deliberation the committee recommended the conduct of the study subject to the following conditions: **1.** The term "Non Insulin Anti Hyperglycemic agents" be changed to "Anti Diabetic agents other than Insulin" **2.** The other Anti Diabetic agents that can be given along with Insulin have to be clearly written. **3.** Inclusion and Exclusion criteria should be clearly defined and needs to be India specific. **Action Taken:** 1. Non insulin anti

	Chilly-Mazarin, France **Name of the Manufacturer: :** Sanofi-Aventis Deutschland GmbH Industriepark Hochst 65926 Frankfurt, Germany **Title** 6-Month, Multicenter, Randomized, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insulin Glargine and Lantus® in Insulin-Naïve Patients with Type 2 Diabetes Mellitus not Adequately Controlled with Non-Insulin Anti-hyperglycemic Drugs.	alternative treatment in subjects with type-2 diabetes mellitus.	hyperglycemic agents refers to anti diabetic agents other than insulin and it has been stated in memo document. **2.** The firm has submitted the list of drugs other than anti diabetic agents that can be prescribed along with Insulin Glargine. They also submitted the list of drugs that cannot be prescribed with Glargine. **3.** Legal age of childhood for India refers to Age of 18 years and above. The same has also been explained in the revised Informed consent form. **SEC Expert List:** **1.** Dr. Rajesh Rajput, Senior Professor and Head Department Endocrinology, PGIMS, Medical Road, Rohtak-124001. **2.** Dr. Anil Bhansali, Additional Prof. and Head of Dept., Endocrinology, PGIMER, Sector-12, Chandigarh. **3.** Dr. Richa Dewan, Director and Professor, Department of Medicine, MAMC, New Delhi. **4.** Dr. Lalit Kumar Gupta, Professor Dept. of Pharmacology, Lady Harding Medical College, New Delhi. **2. Recommendation of Technical Committee:** The firm has withdrawn the application vide its letter dated 20.10.2016 to DGHS and CDSCO.
3.	**Name of the Drug:** MYL-1402O **Date of Application:** 23/06/2016	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drugs from preclinical safety	**1. The proposal was deliberated in SEC (Oncology) held on 27/09/2016** After detailed deliberation the

	Protocol No: MYL-1402O-3001 **Phase of the trial:** III **Name of the Applicant:** M/s Cliantha Research Limited , Ahmedabad - 380 054 Gujarat, India **Name of the Sponsor:** M/s Mylan GmbH Thurgauerstrasse, 40 CH-8050 Zürich, Switzerland **Name of the Manufacturer: :** Test product manufactured by Biocon Ltd, Bengaluru, India, and Reference product of Roche Registration Limited, Manufacture at 6 Falcon WayShire Park, Welwyn Garden City, AL7 1TW, United Kingdom **Title** Multicenter, Double-Blind, Randomized, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin®, in the First-line Treatment of Patients with Stage IV Non- Squamous Non-Small Cell Lung Cancer.	pharmacology and toxicology studies, local tolerance and clinical studies justify and conduct of the trial. **Innovation vis-à-vis existing therapeutic option: To** compare the overall response rate (ORR) of MYL-14020 with that of Avastin, in combination with Carboplatin and Paclitaxel chemotherapy during the first 18 weeks of first-time treatment in patients diagnosed with stage IV ns NSCLC. **Unmet Medical Need in the country:** The test drug may potentially provide alternative treatment of subjects with Stage IV Non-Squamous Non-Small Cell Lung Cancer.	committee recommended the conduct of the study. **SEC Expert List:** **1.** Dr. Sameer Bakshi, Professor, dept. of Medical Oncology, AIIMS, New Delhi. **2.** Dr. C.K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata. **3.** Dr. Sanjay Kumar singh, Dept. of Medical Oncology, Gajara Raja Medical College, Veer Savarkar Marg, Gwalior-474009 Gwalior. **4.** Dr. Prantar Chakroborty, Dept. of Hematology, NRS Medical College, Kolkata 700014. **5.** Dr. Renu Saxena, Prof. and Head, Dept. of Hematology, AIIMS, New Delhi. **6.** Dr. Bikas Medhi, Pharmacology, PGIMER, Sector 12, Chandigarh. **7.** Dr. K.V. Anand, HOD, Dept. of Vascular Surgery, Army Hospital, R & R, New Delhi. **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study

4.	**Name of the Drug:** Vedolizumab (Humanized IgG_1 monoclonal antibody to the human $\alpha_4\beta_7$ integrin) **Date of Application:** 20/07/2016 **Protocol No**: Vedolizumab – 4013 **Phase of the trial:** IIIb/IV **Name of the Applicant:** PPD Pharmaceutical Development India Private Limited, Andheri East, Mumbai- 400099, **Name of the Sponsor:** Takeda Development Centre Asia, Pte. Limited North Tower, Level 4, Singapore 138567 **Name of the Manufacturer: :** Hospira, Inc., 1776 North Centennial Drive, McPherson, KS 67470, USA **Title** Entyvio ® (Vedolizumab IV) Extended Access Program in Ulcerative Colitis and Crohn's Disease	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drugs from preclinical safety pharmacology and toxicology studies including Single dose toxicity, repeat dose toxicity, reproductive toxicity, and phase I, II clinical studies justify the conduct of the trial. **Innovation vis-à-vis Existing Therapeutic Option:** The primary objective of the study is to monitor ongoing safety in subjects with ulcerative colitis and crohn's disease. **Unmet Medical Need in the country:** The test drug may potentially provide alternative treatment of subjects with macular edema associated with Ulcerative colitis and Crohn's disease.	**1. The Proposal was deliberated in SEC (Gastroeneterology) held on 09/09/2016** The Committee discussed the protocol and recommended the conduct of this study. **SEC Expert List:** **1.** A. Saraya, Professor, Dept. of Gastroenterology AIIMS, New Delhi-110029. **2.** Dr. Rakesh Aggarwal, Professor of Gastroenterology, SGPGI, Lucknow. **3.** Dr. P. Shravan Kumar, Professor, HOD of Gastroenterology, Gandhi Medical College and Hospital, Secunderabad, Telangana. **4.** Dr. Shalini Chawla, Professor, Department of Pharmacology, MAMC, New Delhi. **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.

Annexure III

Proposals of clinical trial of other than NCE/GCT along with their evaluations and recommendations of the Technical Committee in its 36th Meeting held on 20.10.2016:

S.No.	Name of the Drug	Firm Name	Recommendations: 1. Subject Expert Committee 2. Technical Committee
1	**Comvac4**: The proposed vaccine is a tetravalent vaccine, composed of DTP components and HIB (PRP) available in a single dose, prefilled syringe containing 0.5 mL liquid suspension. **Date of Application:** 02.08.2016	M/s Bharat Biotech International Limited	**1. Recommendation of the Subject Expert Committee (Vaccine) dated 30.08.2016:** After detailed deliberation the committee recommended with following suggestion- That there should be at least one center each from North, West and East regions of India. **Subject Expert List:** **1.** Dr. A.P. Dubey, Prof & Head, Pediatrics, MAMC, New Delhi **2.** Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi **3.** Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi. **4.** Dr. Savita Verma, Professor, Pharmacology, PGIMS, Rohtak **5.** Dr. Veena Verma, Professor, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. **2. Recommendation of the Technical Committee:** After detailed deliberation, the Committee agreed with the recommendation of the SEC and recommended the approval of the study.
2	ROTAVAC5CM **Date of Application:** 01.08.2016	M/s Bharat Biotech International Limited	**1. Recommendation of the Subject Expert Committee (Vaccine) 30.08.2016:** After detailed deliberation the committee recommended with

			following suggestion- **1.** There should be at least one center each from North, and East regions of India. **2.** Remove the blood withdrawal after the second dose of the vaccination. **Subject Expert List:** **1.** Dr. A.P. Dubey, Prof & Head, Pediatrics, MAMC, New Delhi **2.** Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi **3.** Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi. **4.** Dr. Savita Verma, Professor, Pharmacology, PGIMS, Rohtak **5.** Dr. Veena Verma, Professor, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
3	DTaP combined vaccine (0.5 ml/vial) - DTaP+Hib **Date of Application:** 29.03.2016	Wockhardt Limited	**1. Recommendation of the Subject Expert Committee (Vaccine) dated 29.08.2016:** After detail deliberation the Committee recommended the revised protocol for Phase II/III with following conditions: **1.** The routine doses of OPV have to be administered at 6, 10, and 14 weeks of age in both the arms (to make it consistent with the National Immunization Schedule). **2.** Phase-II CT report shall be submitted before initiating Phase III.

			Subject Expert List: 1. Dr. A.P. Dubey, Prof & Head, Pediatrics, MAMC, New Delhi 2. Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi 3. Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi. 4. Dr. Savita Verma, Professor, Pharmacology, PGIMS, Rohtak 5. Dr. Veena Verma, Professor, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
4	Bilastine Tablets 20 mg **Date of Application:** 23.11.2015	M/s Ajanta Pharma Limited	**1. Recommendation of the Subject Expert Committee (Pulmonary) dated 25.07.2016 :** The firm has applied for grant of permission to manufacture and market Bilastine 20 mg tablets for the indication for symptomatic treatment of allergic rhinoconjunctivitis (Seasonal and perennial). The firm made presentation on the proposed clinical trial design and BE study. The Committee deliberated the proposal in detail and recommended for the conduct of the CT/BE study subject of the following conditions: 1 Only freshly diagnosed allergic rhinoconjunctivitis patients should be enrolled in the study. 2 The patients who are removed from the study due to lack of efficacy of the

			investigational drug should be made part of the evaluable patients. 3 The clause discretion of investigator should be omitted. Accordingly the firm should submit the revised CT protocol to the office of DCGI. **Action Taken:** Accordingly the firm has submitted the revised CT Protocol to the office of DCG (I) **Subject Expert List:** **1.** Dr Subodh Kumar, Assistant Professor, Dehradun **2.** Dr Sushant H Meshram, Professor, GMCH, Nagpur **3.** Dr J C Suri, Professor, VMMC and Safdurjung Hospital, New Delhi **4.** Dr S Vinod Kumar, Professor and Head, Department of Pharmacology, VMMC, New Delhi **5.** Dr CD Tripathi, Professor and Head, Department of Pharmacology, VMMC, Safdurjung, New Delhi **6.** Dr B Gupta, Hindurao Medical College, New Delhi. **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
5	Vardenafil Tablets 10 mg & 20 mg **Date of Application:** 02.12.2015	M/s Ajanta Pharma Limited	**1. Recommendation of the Subject Expert Committee (Reproductive & Urology) dated 30.08.2016:** Firm made an application for the grant of permission to manufacture and market Vardenafil Tablets indicated for the treatment of Erectile Dysfunction in adult men. The firm proposed to conduct clinical trial entitled "A randomized, double blind, non-inferiority clinical study for

			comparison of efficacy and safety of Vardenafil Tablet as compared with Sildenafil Tablet in the treatment of erectile dysfunction". After detailed deliberation, the Committee recommended for conduct of the trial subject to condition that the dosing schedule of 10mg and 20mg should be clearly specified in the protocol. Accordingly, the firm should submit the revised clinical trial protocol to the office of DCG(I). Firm has also proposed to conduct a bioequivalence study. The Committee opined that the BE study should be conducted prior to initiation of clinical trial. **Action Taken:** Accordingly the firm has submitted the revised CT Protocol to the office of DCG (I) **Subject Expert List:** **1.** Dr N K Mohanty, Prof and Head, Dept. of Urology, VMMC, Safdurjung Hospital, New Delhi **2.** Dr Rajeev Sood, Prof and Head, Dr RML Hospital & PGIMER, Baba Kharak Singh Marg, Presidents Estate. **3.** Dr Anup Kumar Kundu, Professor and Head, PGIMER & SSKM, Kolkata **4.** Dr Seema Singhal, Assistant Professor, Department of Gynaecology, AIIMs, New Delhi **5.** Dr Pikee Saxena, Professor, Lady Hardinge College, New Delhi **6.** Dr Amlesh Seth, Professor and Head, Department of Urology, AIIMS, New Delhi **7.** Dr CD Tripathi, Professor and Head, Department of Pharmacology, VMMC, Safdurjung, New Delhi **8.** Dr S K Singh, Professor, Department of Urology, PGIMER, Chandigarh 160012 **2. Recommendation of the Technical Committee:**

			After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
6	Denosumab **Date of Application:** 30.05.2016	M/s Reliance Life Sciences Private Limited	**1. Recommendation of the Subject Expert Committee (Oncology) dated 19.07.2016:** The firm presented the protocol for the conduct of the Phase III study. After detailed deliberation the committee recommended for conduct of the study with following change- **1.** Change in primary end points for skeletal related events should be change from 12 weeks to 24 weeks. **2.** The approval of pre-clinical study from RCGM should be obtained prior issue of NOC to conduct the study. The firm later submitted the revised protocol in line with the SEC recommendations. **Subject Expert List:** **1)** Dr. Sameer Bakshi, Professor ,Dept of Medical Oncology, AIIMS, New Delhi **2)** Dr.C.K.Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata **3)** Dr. Sanjay Kumar Singh, Dept of Medical Oncology, Gajara Raja Medical College, Veer Savarkar Marg, Gwalior-474009 **4)** Dr. Bikash Medhi, Dept of Pharmacology, PGIMER, Chandigarh **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.

Annexure-IV

Recommendation of the 03 cases of Clinical Trials waiver in Indian Populations of 36th Technical Committee Meeting held on 20.10.2016:

S. No.	Drug Name	Indication	1. Recommendations of the SEC 2. Recommendation of Technical Committee
01	**Name of the Drug:** Insulin Glargine solution for Injection 300 U/ml **[Additional Strength]** **Date of Application:** 16.02.2016 **Name of the Firm:** M/s Sanofi India Limited **Regulatory status in India:** Approved [100 U/mL Strength] **Regulatory status in other countries:** EU, US and 16 other Countries	For the treatment of Insulin dependent Diabetes Mellitus Type I and Type II	**1.** The proposal was deliberated in **24th SEC (Endocrinology) held at CDSCO (HQ) on 22.03.2016**. The committee opined that proposed product falls under the definition of new drug. Firm have shown the clinical trial results of said product in USA where you have shown different PK/PD properties of this drug as compared to Glargine 100 U/ml. Firm have not done any clinical trial (efficacy and safety studies) in Indian population. Therefore the **committee recommended for the conduct of local clinical trials** for consideration for the grant of Marketing Authorization of the product. The proposal was deliberated in the **35th Technical Committee Meeting held on 21.09.2016**. The committee opined that the firm shall give proper justification and presentation while representing the case for reconsideration in the Technical Committee. **SEC Expert List:** **1.** Dr. Rajesh Khadgawat, Associate Professor, Dept of Endocrinology, AIIMS, New Delhi – 110029 **2.** Dr. Rajesh Rajput, Senior Professor & Head Department Endocrinology & Medicine VI PGIMS, Medical Road, Rohtak – 124001 **3.** Dr. C. R. Jayanti, Professor & Head, Pharmacology, Bangalore medical College, Bangalore

			4. Dr. Deepak Khandelwal, Maharaja Agrasen Hospital, West Punjabi Bagh, New Delh9i – 110026 **5.** Dr. Richa Dewan, Department of Medicine, MAMC, New Delhi. **2. Recommendation of Technical Committee:** The drug Insulin Glargine100 U/mL is already approved in India. Further, Insulin Glargine 300 U/mL is approved in USA, EU, Canada, Australia, Japan and other countries (total of 66 countries) and is marketed since one year and eight months in USA. The additional advantage of 300 U/mL is slow release leading to constant insulin supply with low variability and low risk of hypoglycemia. In patients requiring higher dose of insulin, the quantum/volume required is low. Therefore, it is beneficial for patients and the Committee recommends the grant of Marketing Authorization with waiver of local clinical trial.
02	**Name of the Drug:** Trametinib 0.5 mg & 2 mg Tablets and Trametinib in combination with Dabrafenib as 50mg/75mg Capsules **Date of Application:** 02.02.2016 **Name of the Firm:** M/s. Novartis Healthcare Private Limited **Regulatory status in India:** Not Approved	As a monotherapy or in combination with Dabrafenib for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600 mutation	**1. Recommendation of the Subject Expert Committee (Oncology) 27.09.2016:** The firm has for the grant of permission to Import and market Trametinib 0.5 mg & 2 mg Tablets: • As a monotherapy or in combination with Dabrafenib for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600 mutation with waiver of local clinical trial. After detailed deliberation, the committee observed that metastatic melanoma is a rare disease and USFDA has granted orphan drug designation to Trametinib, Dabrafenib and combination therapy. In view of above, the committee

	Regulatory status in other countries: USFDA, EMEA and Health Canada		recommended the waiver of local clinical trial as an orphan drug for the proposed indication. **SEC Expert List:** **1.** Dr. Sameer Bakshi, Professor, dept. of Medical Oncology, AIIMS, New Delhi. **2.** Dr. C.K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata. **3.** Dr. Sanjay Kumar singh, Dept. of Medical Oncology, Gajara Raja Medical College, Veer Savarkar Marg, Gwalior-474009 Gwalior. **4.** Dr. Prantar Chakroborty, Dept. of Hematology, NRS Medical College, Kolkata 700014. **5.** Dr. Renu Saxena, Prof. and Head, Dept. of Hematology, AIIMS, New Delhi. **6.** Dr. Bikash Medhi, Pharmacology, PGIMER, Sector 12, Chandigarh. **7.** Dr. K.V. Anand, HOD, Dept. of Vascular Surgery, Army Hospital, R & R, New Delhi **2.Recommendation of Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial
03	**Name of the Drug:** Daratumumab Concentrate for solution for infusion 100 mg and 400 mg **Date of Application:** 04.05.2016 **Name of the Firm:** M/s Johnson & Johnson Pvt Ltd **Regulatory status in India:** Not Approved	Daratumumab is indicated for the treatment of patients with relapsed and refractory multiple myeloma, whose prior therapy included a proteasome inhibitor and an immunomodulatory agent.	**1.** The proposal was discussed in the **SEC (Oncology)** committee meeting which was held on **27-09-2016**. The firm has presented the data as desired by the committee in the previous meeting dated 23-08-2016. After detailed deliberation, the committee recommended for marketing authorization of drug for the indication of relapsed and refractory multiple myeloma, whose prior therapy included proteasome inhibitor and immunomodulatory agent. The committee also accepted the request for waiver of phase III clinical trial in India, since the

	Regulatory status in other countries: USFDA and EU		drug is conditionally approved in USA and EMA as orphan drug and there is no therapy for this indication. However the firm is required to conduct phase IV clinical trial as per the requirements of Indian GCP and schedule Y of Drugs and Cosmetics Rules and accordingly firm should submit protocol before marketing of the said drug in India. **SEC Expert List:** **1.** Dr. Sameer Bakshi, Professor, dept. of Medical Oncology, AIIMS, New Delhi. **2.** Dr. C.K. Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata. **3.** Dr. Sanjay Kumar singh, Dept. of Medical Oncology, Gajara Raja Medical College, Veer Savarkar Marg, Gwalior-474009 Gwalior. **4.** Dr. Prantar Chakroborty, Dept. of Hematology, NRS Medical College, Kolkata 700014. **5.** Dr. Renu Saxena, Prof. and Head, Dept. of Hematology, AIIMS, New Delhi. **6.** Dr. Bikash Medhi, Pharmacology, PGIMER, Sector 12, Chandigarh. **7.** Dr. K.V. Anand, HOD, Dept. of Vascular Surgery, Army Hospital, R & R, New Delhi **2. Recommendation of Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial

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