MINUTES OF 34th MEETING OF THE TECHNICAL COMMITTEE HELD ON 15.07.2016 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. S. N. Gaur, Professor and Head, Department of Respiratory Medicine, VP Chest Institute, New Delhi.	Member
5.	Dr. Nandani Kumar, Former Dy. Director General Sr. Grade, Adjunct Professor, KMC, Manipal, Chennai.	Member

From CDSCO:

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

Special Invitees:-

1. Prof. Manjari Tripathi,
   AIIMS, New Delhi.
2. Prof. Debashish Chowdhory,
   MAMC, New Delhi.

The Chairman welcomed the members of the Committee for the 34th meeting. Thereafter, the Committee discussed the clinical trial proposals and other agenda one after another as under:

The Committee deliberated 08 cases related to approval of clinical trials. Out of these 08 cases, 01 case was related to clinical trials of NCEs, 04 cases were related to global clinical trials (GCT), remaining 03 cases were related to clinical trials for approval of New Drugs and Biologicals.

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

The Committee evaluated 01 case 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 the case of NCE. The recommendations of the Committee are enclosed at **Annexure-I.**

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

The Committee evaluated 04 cases related to global clinical trials. After detailed deliberations, the Committee recommended conduct of 04 clinical trial proposals of GCT. 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 03 cases of other than GCT/clinical trial of NCEs. After detailed deliberations, the Committee recommended 01 case, and not recommended 02 cases. The recommendation of the Committee is enclosed at **Annexure-III.**

Thus, the Committee recommended 06 out of 08 cases of clinical trial proposals and not recommended 2 proposals.

4. **Waiver of Clinical Trial in Indian population for approval of New Drugs and Drugs falling under the category of Medical Devices which have already been approved outside India:**

09 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 recommendation of the SEC are annexed at **Annexure-IV.**

The meeting ended with vote of thanks to the Chair.

Annexure-I

Proposal of clinical trial of NCEs along with their evaluations and recommendations of the Technical Committee in its 34th Meeting.

Proposal No	Details of the proposal	Assessment of the Proposal *vis –a vis* specified Parameters	1. Recommendation of the Subject Expert Committee /IND Committee 2. Recommendation of the Technical Committee
1.	**Name of the Drug:** Oral Semaglutide **Date of Application:** 07/Dec/2015 **Protocol No:** NN9924-4222 **Phase of the trial:** IIIa **Name of the Applicant:** Novo Nordisk India Private Ltd, Plot No. 32, 47 - 50, EPIP Area, Whitefield, Bangalore - 560 066, Karnataka, India. **Name of the Sponsor:** Novo Nordisk India Private Ltd, Plot No. 32, 47 - 50, EPIP Area, Whitefield, Bangalore - 560 066, Karnataka, India. **Name of the Manufacturer:** Novo Nordisk A/S, Novo Allé, DK-2880, Bagsværd, Denmark. **Title:** Efficacy and Long-Term Safety of Oral Semaglutide	**Risk versus benefit to the patients-** The safety profile of the test drug from preclinical toxicity studies including repeat dose toxicity, genotoxicity, carcinogenicity 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 efficacy and long-term safety of oral Semaglutide versus Sitagliptin in subjects with type 2 diabetes. **Unmet need in the country-** The test drug may be an alternative treatment option in subjects with type-2 diabetes.	**1. Recommendation of SEC (Endocrinology) held on 22-03-2016.** After detailed deliberations the committee noted that there is no justification for dose escalation irrespective of glycemic control. It should be based on glycemic target rather than fixed dose escalation. Subjects with fasting glucose level more than 270mg/dl at the time of randomization should be excluded from the study. Hence the committee did not recommend the conduct of the study in its presented form. **The proposal was re-deliberated in SEC (Endocrinology) held on 14-06-2016.** The proposal was deliberated in SEC held on 22/03/2016. After detailed deliberation the committee noted that there is no justification for dose escalation irrespective of glycemic control. It should be based on glycemic target rather than fixed dose escalation. Subjects with fasting glucose level more than 270mg/dl at the time of randomization should be excluded from the study.

	Versus Sitagliptin in Subjects with Type 2 Diabetes.		Hence the committee did not recommend the conduct of the study in its presented form. After detailed deliberation, the justification furnished by the firm was found acceptable. The committee recommended the conduct of the study subject to the condition that the OADs be provided free of cost. **2. Recommendation of the Technical Committee-** After detailed deliberations, the Committee agreed with the recommendations of the SEC and recommended for the approval of the study.

Annexure-II

List of 04 case of Clinical Trial proposal of GCT along with evaluations and recommendations of the Technical Committee in 34th Meeting.

Proposal No.	Details of the proposal	Assessment of the Proposal *vis – a vis* specified Parameters	Recommendation 1. Subject Expert Committee 2. Technical Committee
1.	**Name of the Drug:** LDK378 (Ceritinib) **Date of Application:** 24/Feb/2016 **Protocol No:** CLDK378A2112 **Phase of the trial:** I **Name of the Applicant:** Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli Mumbai - 400 018. **Name of the Sponsor:** Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli Mumbai - 400 018. **Name of the Manufacturer:** Novartis Pharma AG, Lichtstrasse 35, CH-4056 Basel, Switzerland. **Title:** A multi-centre, randomized open label study to assess the systemic exposure, efficacy, and safety of 450 mg ceritinib taken with a low-fat meal and 600 mg ceritinib taken with a low-fat meal as	**Assessment of Risk vs. Benefit to the patients:** The safety profile of the study drug from preclinical pharmacology, general toxicity, single dose, repeat dose toxicity, genotoxicity, reproductive and developmental toxicity study and phase I, II, III clinical studies justify the conduct of this study. **Innovation vis-à-vis Existing Therapeutic Option:** The objective of the study is to assess the systemic exposure, efficacy and safety of 450 mg Ceritinib taken with low-fat meal and 600 mg Ceritinib taken with a low-fat meal as compared with that of 750 mg Ceritinib taken in the fasted state in adult patients with ALK rearranged (ALK-positive) metastatic non-small cell lung cancer (NSCLC). **Unmet Medical Need in the country:** A reduced dosage of 450mg or 600mg (from 750mg once daily) with similar clinical benefits can have a better impact on the general wellbeing or on the quality of life of the patient. This would have a direct impact on the overall compliance and clinical management of the patient.	**1. Recommendation of the SEC (Oncology) held on 03-05-2016** After detailed deliberations, the committee recommended the conduct of the trial. **2. Recommendation of the Technical Committee-** After detailed deliberations, the Committee agreed with the recommendations of the SEC and recommended for the approval of the study.

	compared with that of 750 mg ceritinib taken in the fasted state in adult patients with ALK rearranged (ALK-positive) metastatic non-small cell lung cancer (NSCLC).		
2.	**Name of the Drug:** Triamcinolone Acetonide Injectable Suspension (CLS-TA). **Date of Application:** 05/January/2016 **Protocol No:** CLS1001-301 **Phase of the trial:** III **Name of the Applicant:** Excel Life Sciences Pvt. Ltd. D-62, 1st Floor, Sector-2, Noida UP, India **Name of the Sponsor:** Clearside Biomedical, Inc. 1220 Old Alpharetta Rd., Suite 300 Alpharetta, GA 30005, USA **Name of the Manufacturer:** Aviro Biopharmaceuticals, LLC 4 Chrysler Irvine, CA 92618 **Title: PEACHTREE**: A Phase 3, Randomized, Masked, Controlled Clinical Trial to Study the Safety and Efficacy of Triamcinolone Acetonide Injectable Suspension (CLS-TA) for the Treatment of Subjects with Macular Edema associated with Non-Infectious Uveitis.	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, Carcinogenicity and phase I/II, II clinical studies justify the conduct of the trial. Innovation vis-à-vis Existing Therapeutic Option: The primary objective of the study is to demonstrate the efficacy of CLS-TA as shown by the change from baseline in BCVA (Best corrected Visual Acuity) in subjects with macular edema associated with noninfectious uveitis. Unmet Medical Need in the country: The test drug may potentially provide alternative treatment of subjects with macular edema associated with Non- Infectious Uveitis.	**1. Recommendation of SEC (Ophthalmology) held on 21-04-2016** After detailed deliberation the Committee has recommended the conduct of the trial subject to the following condition: Patients of known glaucoma, in spite of controlled IOP on medication and high myopes (more than -6D) should be excluded from the study. **33rd Technical Committee Minutes dated 20-5-2016:** The committee noted that a sham injection is given in the control arm. It is an invasive procedure in patients with macular odema with some risks. The members of the committee referred to the SEC for re-examination of the proposal with regards to the following points: 1. Is the comparative arm with a sham procedure required in this protocol. 2. If required, what are the likely risks/ benefits to subjects randomized to the sham injection/ control arm of the study? 3. What risk mitigation strategies are in the sham injection arm 4. Adverse events have been reported in the Phase I/II study, one of them serious besides the ocular pain in some. Due to invasive nature of sham

			procedure in control group which procedure in control group which could also lead to severe adverse events, SEC may re-examine to see if the design can be modified to exclude this arm for risk minimization management? **The proposal was re-deliberated in SEC (Ophthalmology) held on 09-06-2016.** The firm presented the amended protocol version 2.2 dated 25/may/2016 duly incorporating the changes suggested by SEC in previous meeting dated 21-April-2016 After detailed deliberation the committee opines that the sham injection in the control arm is essentially non-invasive and therefore observations so made by Technical Committee in its 33rd meeting have been addressed and recommended the conduct of the study. **2. Recommendation of the Technical Committee-** After detailed deliberations, the Committee agreed with the recommendations of the SEC and recommended for the approval of the study.
3.	**Name of the Drug:** Ranibizumab **Date of Application:** 18/March/2016 **Protocol No:** CRFB002H2301E1 **Phase of the trial:** III **Name of the Applicant:**	**Risk versus Benefit to the patients -** In light of the fact that the test drug is already old drug and marketed in India, the safety profile of the test drug justify the conduct of the trial. **Innovation vis a vis existing therapeutic option-** The purpose of the study is to evaluate the long term efficacy and safety of	**1. Recommendation of SEC (Ophthalmology) held on 09-06-2016.** After detailed deliberation the committee recommended the extension of the study as per the protocol no CRFB002H2301E1 version 00 dated 11-12-2015 subject to the condition that the safety and efficacy data accrued until Dec 2016 globally should be submitted to CDSCO by 31st

	Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli Mumbai - 400 018. **Name of the Sponsor:** Novartis Healthcare Private Limited, Sandoz House, Shivsagar Estate, Dr. Annie Besant Road, Worli Mumbai - 400 018. **Name of the Manufacturer:** Novartis Pharma AG, Lichtstrasse 35, CH-4056 Basel, Switzerland. **Title:** RAINBOW extension study: an extension study to evaluate the long term efficacy and safety of Ranibizumab compared with laser therapy for the treatment of Infants BOrn prematurely With retinopathy of prematurity.	Ranibizumab compared with laser therapy for the treatment of infants born prematurely with retinopathy of prematurity. **Unmet Medical Need in the country:** The test drug may provide additional safety information on study drug.	January 2017. **2. Recommendation of the Technical Committee-** After detailed deliberations, the Committee agreed with the recommendations of the SEC and recommended for the approval of the study.
4.	**Name of the Drug:** Insulin degludec/liraglutide **Date of Application:** 19/April/2016 **Protocol No:** NN9068-4229 **Phase of the trial:** IIIb **Name of the Applicant:** Novo Nordisk India Private Ltd, Plot No. 32, 47 - 50, EPIP Area, Whitefield, Bangalore -560 066, Karnataka, India. **Name of the Sponsor:** Novo Nordisk India Private Ltd, Plot No. 32, 47 - 50,	**Risk vs Benefit to the patients:** In light of the fact that the test drugs are already approved and marketed in India, justify the conduct of the study. **Innovation vis-a-vis existing therapeutic option** The purpose of study is to compare glycemic control and safety of Insulin degludec/liraglutide (IDegLira) versus insulin glargine (IGlar) as add-on therapy to SGLT2i in subjects with type 2 diabetes mellitus. **Unmet need in the country-** The test drug may be an alternative treatment option in subjects with type-2 diabetes.	**1. Recommendation of SEC (Endocrinology) held on 14-06-2016.** After detailed deliberation the committee recommended the conduct of the study subject to the condition that the OADs be provided free of cost. **2. Recommendation of the Technical Committee-** After detailed deliberations, the Committee agreed with the recommendations of the SEC and recommended for the approval of the study.

	EPIP Area, Whitefield, Bangalore -560 066, Karnataka, India. **Name of the Manufacturer:** Novo Nordisk A/S, Novo Allé DK-2880, Bagsværd, Denmark **Title:** A clinical trial comparing glycaemic control and safety of insulin degludec/ liraglutide (IDegLira) versus insulin glargine (IGlar) as add-on therapy to SGLT2 in subjects with type 2 diabetes mellitus.		

Annexure III

List of 03 cases of clinical trial proposals other than GCT/NCEs along with evaluations and recommendations of 34th Meeting.

Sl No	Name of the Drug	Firm Name	Recommendations: 1. Subject Expert Committee 2. Technical Committee
1.	Hydroxychloroquine sulfate and Sitagliptin	M/s IPCA Laboratories Limited	**1. Recommendation of SEC (Endocrinology) held on 22.03.2016:** The firm has applied for grant of permission to conduct a Phase-III clinical trial for Hydroxychloroquine 200, 300, 400mg titled as "Efficacy and safety of Hydroxychloroquine in the treatment of Type 2 Diabetes Mellitus: A double Blind, Randomized comparison with Sitagliptin" The committee deliberated in detail and recommended for grant of approval for conduct of the trial subject to following amendments 1. Patients who are drug naive and/ or who are treated with Metformin more than 1000 mg for three months shall be recruited in the trial. Patients who are drug naive should be given a run in period of Metformin 1000 mg/day for 12 weeks. 2. The Limits of Hb1AC should be revised to 7 to 10. 3. Withdrawal and rescue criteria should be clearly specified. Accordingly revised protocol should be submitted to the office of DCGI for approval. **Accordingly firm has submitted the revised protocol and we may forward the proposal to the technical committee.** **2. Recommendation of the Technical Committee-** After detailed deliberations, the Committee recommended that a Phase II clinical trial may be conducted and submit data for consideration of the proposal for conduct of Phase III clinical trial.
2.	Hepatitis A (Live)	M/s JSS Medical	**1. Recommendation of SEC**

	Vaccine	Research India Limited	**(Vaccine) held on 17.06.2016:** The committee deliberated the proposal in detail and recommended for conduct of clinical trial as per the submitted protocol. **2. Recommendation of Technical Committee:-** After detailed deliberations, the Committee recommended that a Phase II clinical trial may be conducted and submit data for consideration of the proposal for conduct of Phase III clinical trial.
3.	Evogliptin Tablets 5 mg	M/s Alkem Laboratories Limited	**1. Recommendation of SEC (Endocrinology) held on 28.04.2016:** The firm presented the Phase III clinical trial protocol. After detailed deliberation, the Committee recommended for approval of the protocol subject to the following conditions:- 1. Study duration should be extended from 12 to 24 weeks with an optional interim analysis of the study after 12 weeks. Based on the interim analysis marketing authorization may be considered with continued study upto 24 weeks. Accordingly sample size to be revised. 2. Rescue criteria to be included in protocol. Accordingly the firm shall submit revised clinical trial protocol to the office of DCG (I). Accordingly, the firm had submitted the revised protocol. **2. Recommendation of the Technical Committee:-** After detailed deliberations, the Committee recommended for the conduct of Phase III clinical trial subject to condition that ECG and ECHO cardiogram tests should be conducted in the patients at the baseline and at the end of the study.

Recommendations of the 09 cases of Clinical trial waiver in Indian populations of 34th meeting:

S. No.	Drug Name	Indication	Recommendations of the SEC
01.	**Name of the Drug:** Pertuzumab Injection 420 mg/ 14 ml vial – **(Additional Indication)** **Name of the Firm:** M/s Roche India Pvt. Ltd., Mumbai **Regulatory status in India:** Approved dated 29.12.2014 **Regulatory status in other countries:** USA, UK, EU and Japan	In combination with Trastuzumab and chemotherapy for the neoadjuvant treatment of patients with HER2 positive, locally advanced, inflammatory, or early stage breast cancer (either >2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer"	**1. Recommendation of SEC (Oncology) held on 24.05.2016:** The committee noted that the drug Pertuzumab is approved in the neoadjuvant setting in combination with Trastuzumab and chemotherapy in locally advanced breast cancer by USFDA and 60 other countries. The drug has demonstrated significant benefit in this setting with potential to save lives. The firm also presented safety data on 37 Indian patient's from ongoing Phase IV clinical trial, and no additional safety signals have been noted. Based on this data provided by firm the SEC recommended the approval of additional indication with local clinical trial waiver in the proposed indication. **2. Recommendation of the Technical Committee:-** After detailed deliberations, the committee agreed with the recommendations of the SEC and recommended for waiver of local clinical trial.
02	**Name of the Drug:** Perampanel Tablets (2/4/6/8/10/ and 12mg) **Name of the Firm:** Eisai Pharmaceuticals India Pvt. Ltd. **Regulatory status in India:** Not Approved **Regulatory status in other countries:** EU and USA	Perampanel is a non-competitive AMPA glutamate receptor antagonist, is indicated as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy aged 12 years and older	**1. Recommendation of SEC (Neurology and Psychiatry) held on 18.03.2016** The committee made the following recommendations: Earlier the proposal of the firm was deliberated in the SEC twice and the Committee recommended the firm to conduct phase-III clinical trial as the data presented was not sufficient. During the present deliberation following clarification were sought by the Committee: i. The retention rate of the patients in the trials and reasons for high dropout rates. ii. The efficacy shown with 8mg and12mg should be supported with PK/PD data. iii. All the reported SAEs including death

			should be submitted with causality assessment to DCG (I) office. iv. The number of Indian patients in the global trial within the dose groups (2/4/6/8/12 mg/day) are too few for any valid statistical conclusion. Therefore, the Committee recommended that the firm is required to conduct a phase-III trial in adequate number of patients. The company has represented the case to the DGHS through letter dated 17.05.2016. As desired by DGHS the proposal has been put up before the technical committee for consideration. **2. Recommendation of Technical Committee:-** The Committee has noted that the firm has conducted a Global Clinical Trial in which India was one of the sites. A total of 115 Indian Patients participated in Phase II and III clinical trials. The drug is first in its class with different mechanism of action when compared to the available drugs in the country. The drug is indicated for refractory partial onset seizures which is an orphan condition and if left untreated may lead to progressive brain damage in patients leading to increased morbidity and mortality. The drug is approved in 47 countries including EU, US, Japan, Australia, Singapore, Malaysia, Taiwan. Therefore, the Committee recommended for import and marketing of the drug with local clinical trial waiver subject to condition that the firm shall conduct a Post Marketing Surveillance for a period of one year from the date of launch of the product in the market.

3	**Name of the Drug:** Minocycline Extended Release Tablet 45/65 mg **(Additional Dosage)** **Name of the Firm:** M/s Sun Pharmaceuticals Private Limited. **Regulatory status in India:** Approved (100mg) **Regulatory status in other countries:** USA	Minocycline is prescribed for the treatment of acne viz. inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age or older	**Recommendation of SEC (Dermatology & Allergy) held on 22.06.2016,** After detailed deliberation the committee noted that- a) Minocycline ER Tablet 45/65 mg is approved in U.S.A for the proposed indication. b) The higher strength (100mg) of the same product is already approved in India for the treatment of acne. c) The excipients used in the proposed ER formulation are same as approved in U.S.A. d) The efficacy is similar to 100 mg IR formulation while the AE reported with the Minocycline ER Tablet 45/65 mg is comparatively better. In view of the above the committee is of the opinion that clinical trial will not generate any new data and recommended the manufacturing and marketing of Minocycline ER Tablet 45/65 mg for the indication of treatment of acne viz. inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age or older with the condition that package insert should highlight all the AE's in bold letters. 2. **Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial.
4	**Name of the Drug:** Dolutegravir 50 mg Tablets **Name of the Firm:** M/s. Aurobindo Pharma	Antiretroviral - Dolutegravir (DTG) is a next-generation HIV integrase strand transfer inhibitor (INSTI). Dolutegravir is indicated in combination with	1. **Recommendation of SEC (Antimicrobial and Antiviral) held on 23.05.2016.** The firm presented Global safety and efficacy data without any Indian patients, with the request for the waiver of clinical trial. After detailed deliberation the committee opined that

	Regulatory status in India: Not Approved **Regulatory status in other countries:** EU, USA and Canada	other antiretroviral agents for the treatment of HIV infected adults and adolescents above 12 years of age.	I. There is no Indian subject data in the global clinical trials. II. Marketing authorization permission granted in US and Europe in 2013-14 and sufficient post marketing safety data are not available for the drug. III. At present there are alternate drugs available for the proposed indication IV. Additionally, the drug doesn't meet the criteria specified for clinical trial waiver Therefore, the Committee recommended that the firms should conduct clinical trial in Indian subjects. CDSCO has received several representations directly as well as through Ministry of Health and Family Welfare to reconsider the proposal for waiver of Local Clinical trial. **2. Recommendation of the special SEC held on 04.07.2016:** Therefore, the proposal is placed before the special SEC committee for deliberation and the Committee sought the data on superiority with respect to safety, efficacy, mutation and reduction in viral load which firm have said that it is available and will be provided. As the representative from NACO was not present, the Committee also opined to obtain the opinion of the NACO on the essentiality and desirability of the drug. The Committee recommended the proposal for waiver of local clinical trial with condition that Phase IV clinical trial in 250 patients shall be conducted after approval of the drug in the country. **3. Recommendation of the Technical Committee:-** The Committee recommended that the clarifications sought by special SEC about data and opinion from NACO shall be obtained separately and the CDSCO shall evaluate the same. The approval shall be given if there are no specific observations, which indicates compulsory conduct of Phase

			III clinical trial, as the drug is already approved in more than 99 countries including US and EU. Finally, the Committee recommended the proposal as per recommendation of special SEC for waiver of local clinical trial subject to the condition that a Phase IV clinical trial in 250 patients shall be conducted after approval of the drug in the country.
5	**Name of the Drug:** Carfilzomib Injection, 60mg/vial **Name of the Firm:** M/s. Amgen Technology Pvt. Ltd **Regulatory status in India:** Not Approved **Regulatory status in other countries:** USA, European Union, Argentina, Columbia, Israel, Mexico, Kuwait, Canada, Switzerland, South Korea and Thailand	Relapsed or Refractory Multiple Myeloma Carfilzomib (Krprolis®) for Injcetion is indicated in combination with dexamethasone or with lenalidomide plus dexamethasone for the treatment of patients with relapsed or refractory multiple myeloma who received one to three lines of therapy. Carfilzomib (Krprolis®) for Injcetion is indicated as a single agent for the treatment of patients with relapsed or refractory multiple myeloma who received one to three lines of therapy.	**1. Recommendation of SEC (Oncology) held on 28.06.2016:-** The firm has applied for import and marketing of Carfilzomib for injection, 60mg/vial in the country for the proposed indication. The firm has made its presentation before the committee for marketing of the drug with local clinical trial waiver. The firm submitted that the drug was designated as orphan drug by USFDA and EMA. The Committee deliberated in details the proposal and noted that there are no satisfactory therapies for multiple myeloma and opined that the drug is suitable candidate for orphan status in the country. Therefore the Committee recommended for import and marketing of the drug with local clinical trial waiver subject to the following condition: a) A structured Phase IV clinical trial with defined inclusion and exclusion criteria should be conducted. b) The disease response evaluation should be done as per standard procedure. c) The no. of patients enrolled should not be less than 100. d) All provisions of Schedule Y should be complied with. The protocol should be submitted to the office of DCGI within six months from the date of approval for marketing the drug in the country. **2. Recommendation of the Technical Committee:-**

			After detailed deliberations, the committee agreed with the recommendations of the SEC and recommended for waiver of local clinical trial.
6	**Name of the Drug:** Lenvatinib 4mg/10mg Capsules **Name of the Firm:** M/s. Eisai Pharmaceuticals India Pvt Ltd. **Regulatory status in India:** Not Approved **Regulatory status in other countries:** US, Europe and Japan	Lenvatinib selectively inhibits the kinase activities of vascular endothelial growth factor (VEGF) receptors 1, 2 and 3 in addition to other proangiogenic and oncogenic pathway-related RTKs, including fibroblast factor (FGF) receptors, FGFR1,2,3 AND 4 the platelet-derived growth factor (PDGF) receptor, PDGFRα; KIT; and RET. Lenvatinib showed antitumor activity against various human tumor xenografts in athymic mice including thyroid cancer, heptocellular carcinoma, melanoma, ovarian cancer, non-small cell lung cancer, and colorectal and gastric cancer	**1. Recommendation of SEC (Oncology) held on 28.06.2016:-** The firm has applied for import and marketing of the drug Lenvatinib 4mg/10mg Capsules which is indicated for the treatment of unresectable thyroid cancer. The firm has made its presentation before the Committee for marketing of the drug with local clinical trial waiver. The firm submitted that the drug was designated as orphan drug by USFDA, Japan and EMA. The Committee deliberated in detail the proposal and noted that there are no satisfactory therapies for patients of differentiated thyroid cancer who have metastasis and have progressed after radioactive iodine therapy and opined that the drug is suitable candidate for orphan status in the country with local clinical trial waiver. Notably, there is no phase III data to support the use of the drug in medullary or anaplastic thyroid cancer. Therefore the Committee recommended for import and marketing with local clinical trial waiver for the indication "locally recurrent metastatic progressive radioactive iodine refractory differentiated thyroid cancer". subject to the following conditions: 1 A structured Phase IV clinical trial with defined inclusion and exclusion criteria should be conducted. 2 The disease response evaluation should be done as per standard procedure. 3 All provisions of Schedule Y should be complied with. The protocol should be submitted to the office of DCGI within six months from the date of approval for marketing the drug in the country.

			2. Recommendation of the Technical Committee:- After detailed deliberation, the committee agreed with the recommendations of the SEC and recommended for waiver of local clinical trial.
7	**Name of the Drug:** BIOPATCH Protective Disc with Chlorhexidine Gluconate **Name of the Firm:** M/s. Johnson & Johnson Limited **Regulatory status in other countries:** USA, Austria, Belgium, Germany, Denmark, Netherlands, Ireland, Australia	Surgical dressing - The product is a circular polyurethane foam impregnated with Chlorhexidine Gluconate (in a concentration of 200-300 micrograms/miligram) with a nylon-reinforced urethane film.	**1. Recommendation of SEC (Antimicrobial & Anti-viral) held on 23.03.2016.** After detailed deliberation the committee recommended that the product may be continued to be marketed in the country as per USFDA approved indications only and the firm has requested to provide efficacy data in Indian populations within 12 months for further review by the committee. **2. Recommendation of the Technical Committee:-** After detailed deliberations, the committee agreed with the recommendations of the SEC and recommended for continued marketing of the drug in the country subject to the condition that the firm should conduct PMS study for a period of one year.
8	**Name of the Drug:** Lubricated Male Natural Latex dotted containing 4.5% Benzocaine condom **Name of the Firm:** M/s. J K Ansal Private Limited **Regulatory status in India:** New Device in India	It is typically used as Male genital desensitizing product, which when comes in contact to the penis helps in temporarily slowing the onset of ejaculation. This is a single use device	**1. Recommendation of SEC (Reproductive & Urology) held on 25.05.2016.** After deliberations, the Committee observed that, the firm has not submitted the documentary clinical evidence to prove safety and efficacy of product in human beings for their claims. The firm may be advised to submit the same. **2. Recommendation of Technical Committee:-** After detailed deliberations, the Committee agreed with the recommendations of the SEC.
9	**Name of the Drug:** Tetanus Toxoid Vaccine I.P	Tetanus	**1. Recommendation of SEC (Vaccine) held on 24.02.2016:-** SEC has recommended for Marketing Authorization of finished product with the

	Name of the Firm: M/s Bio Vaccines (India) Pvt., Ltd.		following conditions: a) To conduct Phase IV clinical studies and submit protocol within 6months of marketing of drug. b) The waiver of Phase III clinical trial is granted keeping in view of the imported bulk being used by many firms in India & is from a WHO pre-qualified facility i.e PT Bio Farma, Indonesia. c) The committee opined that a GMP inspection with experts may be carried out before licensing of product. **2. Recommendation of SEC (Vaccine) held on 21.03.2016:-** The Committee overruled the decision of first SEC and recommended that the firm will only be importing the bulk Tetanus Toxoid from P.T. Biofarma, Indonesia and will undertake processing in-house to develop the final product. Since this involves addition of all excipients, preservatives along with the bulk for the development of finished formulation, it may be treated as a new drug and will undergo pre-clinical and clinical studies as per the provisions of Drugs and Cosmetics Act, 1940 and Rules, 1945 made there under The firm request to cancel the recommendations of SEC dated 21.03.2016 and to consider the recommendations of SEC dated 24.02.2016 Further this Office has received a representation from the office of DGHS submitted by the firm. Hence, the matter is put up in the technical Committee as desired. **3. Recommendation of the Technical Committee:-** After detailed deliberations, the committee agreed with the recommendation of the SEC dated 21.03.2016 and recommended that data from preclinical and clinical studies as required under the provisions of Drugs and Cosmetics Act, 1940 and Rules, 1945 should be submitted for evaluation.

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