

**MINUTES OF 35th MEETING OF THE TECHNICAL COMMITTEE HELD ON 21.09.2016
UNDER THE CHAIRMANSHIP OF DGHS FOR SUPERVISING CLINICAL TRIALS ON NEW
CHEMICAL ENTITIES IN THE LIGHT OF DIRECTIONS OF THE HON'BLE SUPREME
COURT OF INDIA ON 03.01.2013.**

Present:

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| 1. | Dr. Jagdish Prasad,
Director General of Health Services,
Nirman Bhawan, New Delhi | Chairman |
| 2. | Dr. Kamlakar Tripathi,
Prof. Department of Medicine,
Institute of Medical Sciences,
Banaras Hindu University, Varanasi. | Member |
| 3. | Dr. Yash Paul Sharma,
Prof. & Head, Department of Cardiology,
PGIMER, Chandigarh. | Member |
| 4. | Dr. 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 |
| 6. | Dr Raju Titus Chacko,
Professor& Head, Department of Medical Oncology,
Christian Medical College, Vellore | 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)

The Chairman welcomed the members of the Committee for the 35th 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, 01 case was related to clinical trials of NCEs, 03 cases were related to Global Clinical Trials (GCT), remaining 09 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 one case related to clinical trial 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 the conduct of Clinical Trial. The recommendations of the Committee are enclosed at **Annexure-I**.

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

The Committee evaluated 03 cases related to global clinical trials. After detailed deliberations, the Committee recommended approval for 03 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 09 cases of other than GCT/clinical trial of NCEs. After detailed deliberations, the Committee recommended approval for all 09 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 Drugs falling under the category of Medical Devices which have already been approved outside India:

11 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 as **Annexure-IV**.

5. Others:

1. Representation from M/s Novo Nordisk to discuss the issue related to the labeling instruction of the approved drug Insulin Degludec:

After detailed deliberation the committee recommended to amend the labeling requirement under “Warning: To be sold by retail on the prescription of a Endocrinologist and/or MD (Internal Medicine) treating diabetic patients only”.

2. Representation from M/s Novo Nordisk to discuss the issue related to the labeling instruction of the approved drug Insulin Degludec/Insulin Aspart (IDegAsp) (Ryzodeg™):

3. After detailed deliberation the committee recommended to amend the labeling requirement under “Warning: To be sold by retail on the prescription of a Endocrinologist and/or MD (Internal Medicine) treating diabetic patients only”.

4. Representation from M/s Glaxo Smith Kline to discuss the issue related to the labeling instruction of the approved drug Albiglutide:

5. After detailed deliberation the committee recommended to amend the labeling requirement under “Warning: To be sold by retail on the prescription of a Endocrinologist and/or MD (Internal Medicine) treating diabetic patients only”.

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 35th Meeting

Proposal No	Details of the proposal	Assessment of the Proposal <i>vis –a vis</i> specified Parameters	Recommendation 1. Subject Expert Committee 2. Technical Committee
1.	<p>Name of the Drug: Oral Semaglutide</p> <p>Date of Application: 19/04/2016</p> <p>Protocol No: NN9924-4221</p> <p>Phase of the trial: IIIa</p> <p>Name of the Applicant: Novo Nordisk India Private Ltd, Plot No. 32, 47 - 50, EPIP Area, Whitefield, Bangalore - 560 066, Karnataka, India</p> <p>Name of the Sponsor: Novo Nordisk India Private Ltd, Plot No. 32, 47 - 50, EPIP Area, Whitefield, Bangalore - 560 066, Karnataka, India.</p> <p>Name of the Manufacturer: Novo Nordisk A/S, Novo AlléDK-2880, Bagsværd, Denmark</p> <p>Title: A trial investigating the cardiovascular safety of Oral Semaglutide in subjects with Type 2</p>	<p>Risk versus benefit to the patients- The safety profile of the test drug from preclinical toxicity studies including repeat dose toxicity, genotoxicity, carcinogenicity study and clinical phase I, II studies justify the conduct of the study.</p> <p>Innovation vis-a-vis existing therapeutic option The purpose of study is to investigate the cardiovascular safety of oral Semaglutide in subjects with type 2 diabetes.</p> <p>Unmet need in the country- The test drug may be an alternative treatment option in subjects with type-2 diabetes at high risk of cardiovascular events.</p>	<p>1. The proposal was deliberated in SEC (Endocrinology) held on 14/06/2016.</p> <p>After the detailed deliberation the committee recommended the conduct of the trial subject to the following condition</p> <ol style="list-style-type: none"> i. Primary responsibility for the Standard of Care should be with the trial investigator ii. The HbA1c at inclusion must be between 7 to 10 % iii. The hypoglycemic criteria and rescue medication should be clearly defined under the protocol. iv. The OADs be provided free of cost. <p>The proposal was Re-deliberated in SEC (Endocrinology) held on 22/08/2016.</p> <p>After detailed deliberation the committee approved the study as the points raised earlier have been complied with. The firm further clarified that the patients with Type 2 diabetes with HbA1C \geq10.0 % will receive standard of care along with Insulin and the study</p>

	diabetes.		<p>medication.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Rajesh Rajput, Senior Professor & Head, Dept. of Endocrinology, PGIMS, Medical Road, Rohtak-124001 2. Dr. Anil Bhansali, Additional Prof. & HOD, Endocrinology, PGIMER, Sector-12, Chandigarh. 3. Dr. Richa Dewan, Director and Professor, Dept. of Medicine, MAMC, New Delhi. 4. Dr. Lalit Kumar Gupta, Professor Dept. of Pharmacology, Lady Harding Medical College, New Delhi. <p>2. Recommendation of the Technical Committee:</p> <p>The Committee noted that clinical trial proposal rightly excluded chronic heart failure New York Heart Association (NYHA) class IV patients from the study in the interest of the patient safety and therefore after detailed deliberations, the committee agreed with the recommendation of the SEC and recommended for the approval of the study.</p>
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Annexure-II

List of 03 cases of Clinical Trial proposals of GCT along with evaluations and recommendations of the Technical Committee in 35th Meeting.

Proposal No.	Details of the proposal	Assessment of the Proposal <i>vis – a vis</i> specified Parameters	Recommendation 1. Subject Expert Committee 2. Technical Committee
1.	<p>Name of the Drug: Peginterferon α-2a Injection [(Pegasys®); 180 μg/ml]</p> <p>Date of Application: 13/05/2015</p> <p>Protocol No: NV25361</p> <p>Phase of the trial: IIIb</p> <p>Name of the Applicant: Roche Products (India) Pvt. Ltd. 1503, 15th Floor, "The Capital" Bandra Kurla Complex, Bandra (East), Mumbai 400 051, India.</p> <p>Name of the Sponsor: F. Hoffmann - La Roche Ltd, Grenzacherstrasse 124, CH-4070 Basel, Switzerland.</p> <p>Name of the Manufacturer: F. Hoffmann - La Roche Ltd, Grenzacherstrasse 124, CH-4070 Basel, Switzerland.</p> <p>Title: Phase IIIb, Randomized, Open-Label Study of Pegylated Interferon alfa-2a in Combination with Lamivudine or Entecavir Compared with untreated Control Patients in Children with HBE Ag-positive</p>	<p>Risk versus Benefit to the patients- In light of the fact that the study drug is old drug and marketed in India, the safety profile of the test drug justify the conduct of the trial.</p> <p>Innovation vis a vis existing therapeutic option- The Primary objective of the study to evaluate the efficacy of Pegasys® + Lamivudine compared with an untreated control in children with CHB, as measured by loss of HBsAg 24 weeks post-end of treatment/end of untreated observation.</p> <p>Unmet need- The test drug may be an alternative treatment option in patients with Chronic Hepatitis b in the Immune-Tolerant Phase.</p>	<p>1. The proposal was deliberated in SEC (Gastroenterology) held on 27/08/2015.</p> <p>The proposed trial is a phase IIIb, randomized open label study of 8-week Lamivudine followed by 48 weeks of interferon vs no treatment in children aged 3-17 years with immune tolerant hepatitis B virus infection (HBs Ag and HBe Ag positive for 6 months, HBV DNA >2000 IU/mL, normal ALT on 3 occasions).</p> <p>The committee deliberated the proposal and raised the following concerns:</p> <p>a. Lamivudine has a high propensity to lead to drug resistance. This risk is particularly high in those with high viral load, as is seen in children with immune tolerant phase.</p> <p>b. In children with lower viral load, the need for treatment itself may be weaker, because their natural history is milder.</p> <p>c. The study is proposed to be done in children with a broad age range (3-17 years).</p> <p>In younger age groups, safety concerns would be higher.</p> <p>Hence, this protocol is not approved in this form at this stage.</p> <p>(Dr. Shobhna Bhatia, one of the proposed investigators, did not</p>

	Chronic Hepatitis b in the Immune-Tolerant Phase		<p>participant in decision making process.)</p> <p>The proposal was Re-deliberated in SEC (Gastro) held on 04/07/2016.</p> <p>The proposal was deliberated in previous SEC held on dt. 27.08.2015 where in the experts recommended for certain changes to the protocol. The SEC has considered the revised protocol and recommended for the approval of the clinical trial subject to the following conditions:</p> <ol style="list-style-type: none"> 1. At least two Sites from Eastern part of India should be included as there is no representation from that region. 2. Clearance from the Ethics Committee from the respective sites for the revised protocol to be submitted to this office. <p>(Dr. Shobhna Bhatia has not participated in the deliberations.)</p> <p>SEC Experts List:</p> <ol style="list-style-type: none"> 1. Dr. A. Saraya, Professor, Dept. of Gastroenterology AIIMS, New Delhi-110029. 2. Dr. Shobha Bhatia, Professor, Dept. of Gastroenterology and Hepatology Seth GS Medical College and KEM Hospital, Parel, Mumbai-400012. 3. Dr. Rakhi Maiwal, Professor, Institute of Liver and Biliary Sciences, D-1, Vasant Kunj, New Delhi-110010. 4. Dr. Manoj Kumar, Professor, Institute of Liver and Biliary Sciences, d-1, Vasant Kunj, New Delhi-110010. 5. Dr. K.H Reeta, Additional
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			<p>Professor, Department of Pharmacology, AIIMS, New Delhi.</p> <p>2. Recommendation of the Technical Committee:</p> <p>After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study. The Committee also opined that, the practice of inviting experts from the same institution in the SEC meeting shall be reviewed and it is advisable to call the experts from different institutions.</p>
2.	<p>Name of the Drug: BCD-055 - Infliximab</p> <p>Date of Application: 17/12/2015</p> <p>Protocol No: BCD-055-3/LIRA</p> <p>Phase of the trial: III</p> <p>Name of the Applicant: Biocad India Private Limited. #163/C, 3rd cross, 3rd Phase, J.P Nagar. Bengaluru 560078.</p> <p>Name of the Sponsor: CJSC BIOCAD, Russia. Mailing address: Petrovo - Dalneye, Krasnogorsk District, Moscow Oblast 143422.</p> <p>Name of the Manufacturer: Biocad has</p>	<p>Risk versus Benefit to the patients The safety profile of the test drug from pre-clinical studies including pharmacokinetic study, repeat dose toxicity and clinical phase I study, justify the conduct of the study.</p> <p>Innovation vis a vis existing therapeutic option- The purpose of the study is to compare the efficacy and safety of BCD-055 (biosimilar of Infliximab) with Remicade (Infliximab) in combination with Methotrexate in patients with active rheumatoid arthritis.</p> <p>Unmet need- Multisource availability of Infliximab may benefit Indian patients.</p>	<p>1. The proposal was deliberated in SEC (Analgesics) held on 17/03/2016.</p> <p>After detailed deliberation the committee opined that the protocol needs to be revised</p> <ol style="list-style-type: none"> 1. Changes in inclusion and exclusion criteria in respect of LFT, KFT, Haematogram etc . 2. Screening for latent TB should be carried out by Gold Quantiferone test. 3. Site should include rheumatologists as Investigator preferably. 4. ACR 70 response should be primary objective 5. Methotrexate dose should be more than 15 mg/week. <p>Accordingly the firm should submit revised protocol and list of sites to CDSCO for further review by the committee.</p> <p>The proposal was Re-deliberated in SEC (Analgesics) held on 08/06/2016.</p> <p>After detailed review of the</p>

	<p>its manufacturing facility at: 143422, Russian Federation, Moscow region, Krasnogorsky district, Petrovo Dalneye.</p> <p>Title: International comparative multicenter double-blind randomized clinical study of efficacy and safety of BCD-055 (CJSC BIOCAD, Russia) and Remicade® in combination with Methotrexate in patients with active rheumatoid arthritis.</p>		<p>justification and changes made to the protocol the committee recommended the conduct of the study subject to the condition that the investigators must be rheumatologist or qualified physician (i.e. MD Medicine). More than 50% of the patients recruited should be from the government institutions. Since the management of the SAE with the molecule may require multispecialty approach only those sites with adequate infrastructure (atleast 200 beds) and multispecialty facilities should conduct the clinical trial.</p> <p>SEC Experts List:</p> <ol style="list-style-type: none"> 1. Dr. Uma Kumar Head, Prof. Dept. of Rheumatology, AIIMS, New Delhi-110029. 2. Dr. Lalit Kumar Gupta, Prof. Dept. of Pharmacology, Lady Harding Medical College, New Delhi. 3. Dr. R.K Arya, Dept. of Orthopedics, Ram Manohar Lohia Hospital New delhi. 4. Dr. S.K. Das, Prof. & Head, Dept. of Rheumatology, KGMC, Lucknow-226003. 5. Dr. Chandralekha, Prof. & Head, Dept. of Anesthesiology AIIMS, NEW Delhi-110029. <p>2. Recommendation of the Technical Committee:</p> <p>After detailed deliberation the committee agreed with the recommendations of the SEC and recommended for the conduct of the study subject to the condition that some of the important Institutions of the country may</p>
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			also be included as trial sites.
3.	<p>Name of the Drug: Dexamethasone Sodium Phosphate</p> <p>Date of Application: 04/03/2016</p> <p>Protocol No: IEDAT-02-2015</p> <p>Phase of the trial: III</p> <p>Name of the Applicant: CliniRx Tangent Research India Pvt. Ltd, 4th Floor, Patriot House, 3 BSZ Marg, New Delhi</p> <p>Name of the Sponsor: EryDel SpA seated at Via Sasso 36, 61029 Urbino (PU), Italy.</p> <p>Name of the Manufacturer: Laboratorio Farmaceutico Milanese Srl At Address: Via Monterosso, 273, 21042 Caronno Pertusella (VA) – Italy.</p> <p>Title: A Multi-center, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Effects of Intra-Erythrocyte Dexamethasone Sodium Phosphate on Neurological Symptoms in Patients with Ataxia Telangiectasia (IEDAT-02-2015)</p>	<p>Risk versus Benefit to the patients- In light of the fact that the Dexamethasone Sodium Phosphate is old drug and marketed in India, the safety profile of the test drug justify the conduct of the trial.</p> <p>Innovation vis a vis existing therapeutic option- The purpose of the study is to evaluate the effects of Intra-Erythrocyte Dexamethasone sodium Phosphate on neurological symptoms in patients with Ataxia Telangiectasia (AT).</p> <p>Unmet need- This novel drug delivery system (Resealed erythrocytes loaded with Dexamethasone) may be an alternate treatment option for patients with Ataxia Telangiectasia.</p>	<p>1. The proposal was deliberated in SEC (Neurology) held on 26/05/2016.</p> <p>After detailed deliberation, the committee recommended the conduct of the study. Govt. of India norms to be followed for export of biological samples for clinical trial</p> <p>SEC Experts List:</p> <ol style="list-style-type: none"> 1. Dr. Bhavna Kaul, Head Dept. of Neurology, Vardhman Mahavir Medical College, New Delhi-110029. 2. Dr. D S Arya, Dept. of Pharmacology, AIIMS, New Delhi. 3. Dr. M.V Padma, Dept. of Neurology, AIIMS Hospital, New Delhi. 4. Dr. Manjari Tripathi, Dept. of Neurology, AIIMS Hospital, New Delhi. 5. Dr. Debashish Chowdhury, Dept. of Neurology, Maulana Azad Medical College, New Delhi. 6. Dr. Shruti Srivastava, Prof. Dept. of Psychiatry, University College of Medical Sciences, New Delhi. 7. Dr. Renu Saxena, Dept. of Haematology, AIIMS. <p>2. Recommendation of the Technical Committee:</p> <p>The Committee noted that no treatment is available for Ataxia Telangiectasia and therefore, after</p>

			detailed deliberations, the committee agreed with the recommendation of the SEC and recommended for the approval of the study.
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Annexure III

List of 09 cases of clinical trial proposals other than GCT/NCEs along with evaluations and recommendations of 35th Meeting.

S.No	Name of the Drug	Firm Name	Recommendations: 1. Subject Expert Committee 2. Technical Committee
1.	Recombinant Human Insulin	M/s BioGenomics Limited	<p>1. Recommendations of the SEC: After detailed deliberation, the committee Recommended for approval of presented protocol subject to the conditions or:-</p> <ol style="list-style-type: none"> 1. Site investigator should have minimum qualification of MD (Medicine) 2. Change in BMI from 27 to 25 kg/m² and clearly define biochemical assessment as part of inclusion and exclusion criteria. 3. Safety of the subject should be strictly ensured with availability of clinical person for at least 12 hours on the day of study and at least 4 hours after the completion of clamp study. <p>Action Taken: Accordingly, the firm had submitted the revised clinical trial protocol.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr.Rajesh Khadgawat, Associate Professor, Dept of Endocrinology, AIIMS, New Delhi 110029 2. Dr. Rajesh Rajpur, Senior Professor & Head Department Endocrinology & Medicine VI PGIMS, medical Road, Rohtak 124001 3. Dr. D.S Arya, Professor Dept. of Pharmacology, AIIMS, New Delhi 4. Dr. Manoj Chadha, Dept of Endocrinology P.D Hinduja National Hospital Mahim, Mumbai, Maharashtra 400016 5. Dr. Richa Dewan, Department of medicine, MAMC, New Delhi. <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study with condition to conduct PK/PD and Phase III Clinical Trial in sequential manner.</p>
2.	Omalizumab	M/s Reliance Life Sciences Private Limited	<p>1. Recommendations of the SEC: After detailed deliberation of the presented protocol, the committee recommended the study protocol.</p> <p>SEC Expert List:</p>

			<ol style="list-style-type: none"> 1. Dr. Sushant. H. Mesharam, Professor, Government Medical College & Hospital ,Nagpur 2. Dr .J.C .Suri ,Professor, VMMC & Safdurjung Hospital, new delhi 3. Dr .Kamal Kishor, Professor, Department of Clinical Pharmacology, AIIMS ,New Delhi 4. Dr. S.K Sharma, Department of Medicine ,AIIMS ,New Delhi <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study with condition to conduct PK/PD and Phase III Clinical Trial in sequential manner.</p>
3.	Trastuzumab	M/s Glenmark Pharmaceuticals Limited	<p>1. Recommendations of the SEC: After detail deliberation of the Phase III CT protocol, committee recommended the following suggestion-</p> <ol style="list-style-type: none"> 1. The test drug has to be supplied free of cost to the participants who are responders even after completion of the study till disease progression. 2. All the sites should have medical oncologist, either as Investigator or Co-Investigator. 3. The DSMB should be constituted as per the standard recommendations. 4. The clinical trial permission may be considered subject to satisfactory review of Physicochemical, biochemical characterization of the proposed Biosimilar drug and fulfilment of the regulatory requirements of approval of Biosimilar drug in India. <p>Action Taken: Accordingly, the firm had submitted the satisfactory reply to this office.</p> <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study with condition to conduct PK/PD and Phase III Clinical Trial in sequential manner.</p>
4.	Influenza Vaccine (Human, Live Attenuated) Liquid (Type A & B) (Seasonal,	M/s Serum Institute of India Private Limited	<p>1. Recommendations of the SEC: The proposal of the firm was deliberated in detail and the committee recommended the proposal for approval of protocol with a condition that the firm will include a minimum of 100 subjects in the following 3 age categories:</p>

	Quadrivalent)		<p>a) Between 2-17 years b) Between 18-49 years c) 50 years & above</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. A. P. Dubey, Prof & Head, Dept. of Pediatric, Maulana Azad Medical College & LNJP Hospital, Delhi. 2. Dr. Veena Verma, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi 3. Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi. <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study with condition that all the PI's should be clinicians, preferably, MD Pediatrics, so that clinical examination and evaluation of sign/symptoms and its clinical management of patients can be carried out.</p>
5.	Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertusis Vaccine, Adsorbed	M/s Serum Institute of India Private Limited	<p>1. Recommendations of the SEC: The proposal of the firm was deliberated in detail and the committee recommended for approval</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 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. 4. Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi 5. Dr. Veena Verma, Professor, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendations of the SEC and recommended the approval of the study.</p>
6.	Ivermectin 1% Cream	M/s Ajanta Pharma Limited	<p>1. Recommendations of the SEC: Firm presented the Phase III CT protocol for the approval of proposed drug and indication. The committee after</p>

			<p>detailed deliberation recommended for grant of permission for the conduct of the clinical trial as per the proposed protocol.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. D M Thappa, Professor and Head, Dept. of Dermatology, JIPMER, Pondicherry- 605006 2. Dr. SanjeevHanda, Professor and Head, Dept of Dermatology, PGIMER, Sector 12, , Chandigarh, 16001212 3. Dr. S.N. Bhattacharya, Prof & Head, Dept. of Dermatology, University College of Medical Sciences, New Delhi 4. Dr. D S Arya , Prof Dept. of pharmacology, AIIMS, New Delhi 5. Dr. Binod K Khaitan, Professor and Head, Dept. of Dermatology, AIIMS, New Delhi <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
7.	Iguratimod Tablets 25 mg	M/s Ajanta Pharma Limited	<p>1. Recommendations of the SEC: The firm presented the revised Phase III clinical trial protocol. After detailed deliberation, the Committee recommended that BE study should be conducted before the Phase III clinical trial. The permission for conduct of Phase III trial may be permitted after submission of the satisfactory result of BE study, subject to the following conditions :-</p> <ol style="list-style-type: none"> 1. The comparator drug in the BE study should be that of the innovator only. 2. DMARD failure will be defined as failure to achieve remission on 15mg/week of Methotrexate for atleast 3 months. 3. The trial will be an add on therapy of the study over Methotrexate at a stable dose of 15mg/week versus Methotrexate 25mg/week. <p>Accordingly, the firm shall submit revised clinical trial protocol to DCG(I) office. The firm has submitted the revised Clinical Trial Protocol.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr Uma Kumar, Head, Professor, Department of Rheumatology, AIIMS, New Delhi-110029. 2. Dr Lalit Kumar Gupta, Professor, Department of Pharmacology, LHMC, New Delhi

			<p>3. Dr R K Arya, Department of Orthopedics, RML Hospital, New Delhi</p> <p>4. Dr S K Das, Professor and Head, Department of Rheumatology,, KGMC, Lucknow – 226003</p> <p>5. Dr Chandralekha, Professor and Head, Department of Anesthesiology, AIIMS, New Delhi-110029</p> <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
8.	Nepafenac Ophthalmic Suspension 0.3%w/v	M/s Ajanta Pharma Limited	<p>1. Recommendations of the SEC: The CT Should be double blind. Patients with Diabetic Retinopathy, Glaucoma and any other Neurological condition should be excluded from the study.</p> <p>Action Taken: The firm has submitted the revised CT Protocol accordingly.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. R.K. Jain, Professor, Lady Harding Medical College, New Delhi. 2. Dr. D.S. Arya, Professor, Department of Pharmacology, AIIMS, New Delhi. 3. Dr. Arjun Ahuja, Professor & Head, Seth G.S. Medical College & KEM Hospital, Mumbai. <p>2. Recommendation of the Technical Committee: After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.</p>
9.	Diphtheria, Tetanus, Pertusis (Whole cell), Hepatitis B (rDNA), Haemophilus Influenza Type b Conjugate and Poliomyelitis (Inactivated) Vaccine (Adsorbed)	M/s Shantha Biotechnics Private Limited	<p>1. Recommendations of the SEC: The proposal of the firm was deliberated in detail and the committee recommended for approval. (Dr. A.P. Dubey being one of the Principal Investigator did not participate in the deliberations)</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 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. 4. Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi 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.
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Annexure-IV

Recommendation of the 11 cases of Clinical Trials waiver in Indian Populations of 35th Technical Committee Meeting:

S. No.	Drug Name	Indication	1. Recommendations of the SEC 2. Recommendation of Technical Committee
1.	<p>Name of the Drug: Hydralazine tablet 25 mg/50 mg</p> <p>Name of the Firm: M/s Cadila Pharmaceuticals</p> <p>Regulatory status in India: Approved as FDC (37.5 mg)</p> <p>Regulatory status in other countries: US and EU (for the proposed indication)</p>	<p>For the treatment of moderate to severe hypertension (essential hypertension) alone or as adjunct</p>	<p>1. Recommendations of SEC: The proposal was deliberated in SEC (Cardiovascular) held at CDSCO (HQ) on 05.07.2016. The firm presented the Bioequivalence study data with internationally approved product. The committee also noted that the product Hydralazine 25 mg/50 mg tablets is approved in USFDA and E.U, however the drug has not been in use in India, for last many years. Therefore the committee recommended for the manufacturing and marketing permission with the condition that Phase IV study is to be conducted and accordingly firm shall submit Phase IV protocol within 3 months.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Shyam Sunder Kothari, Prof. Dept of Cardiology, AIIMS, New Delhi. 2. Dr. D S Arya, Dept. of Pharmacology, AIIMS, New Delhi 3. Dr. Sandeep Bansal HOD, Department of Cardiovascular, VMMC & Safdurjung Hospital, New Delhi 4. Dr. S.K. Agrawal, Professor & Head of the department, Dept. Of Nephrology AIIMS, New Delhi. 5. Dr. A.H.Ansari, Assistant Professor, Vardhman Mahavir Medical College, New Delhi-110029 <p>2. Recommendation of Technical Committee:</p> <p>The committee opined that the said drug is approved in India as parenteral and also as</p>

			<p>an ingredient in and FDC. After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial with the condition that-</p> <ol style="list-style-type: none"> 1. The drug should not be used as first line therapy and the indication should be revised as "for moderate to severe hypertension (in conjunction with a β-adrenoreceptor blocking agent or diuretic) and hypertensive crisis". 2. A systematic Phase IV study should be done for which protocol should be submitted to the office of CDSCO.
2.	<p>Name of the Drug: Dengue Tetravalent Vaccine (Live, Attenuated)</p> <p>Name of the Firm: M/s Sanofi Pasteur India Private Limited</p> <p>Regulatory status in other countries: Brazil, Philippines and Mexico</p>	<p>The vaccine is intended for the prevention of Dengue disease caused by dengue virus serotypes 1, 2, 3 and 4 in individuals 9 through 60 years of age living in endemic areas</p>	<p>1. Recommendation of SEC: The firm's proposal was earlier deliberated in SEC dated 12.01.16 wherein the committee deliberated the proposal of the firm in detail and opined that the firm has conducted Phase II clinical trial in the age group of 18-45 years in India and the results were accepted by the SEC dated 08.04.15. Now, the firm has requested for Marketing Authorization of the vaccine without conduct of Phase III trial. The firm has submitted published data of Phase III trials from other Asian and Latin American countries (Thailand, Brazil, and Mexico etc.) based on which the vaccine has been approved in Mexico, Philippines and Brazil. Although, the vaccine does not qualify the requirements of waiver of clinical trial, considering the fact that Dengue is a health problem of major concern in the country and can be life threatening in certain cases, the committee recommends for Market Authorization of the vaccine in the age group of 18-45 years only with the condition to conduct Phase IV clinical trial in time bound manner (Protocol submission within 3 months of marketing of the product)."</p> <p>The proposal was further deliberated in the Technical committee dated 01.02.2016</p>

			<p>wherein the committee after detailed deliberation, recommended for waiver of local clinical trial as per SEC recommendation.</p> <p>As per the procedure, the proposal was forwarded to Apex committee dated 06.04.2016 for their opinion wherein the committee after due deliberation had noted that the evidence in the case is not sufficient to waive conduct of clinical trial. Accordingly, firm was informed about the decision of the committee.</p> <p>Now, the firm has requested for reconsideration of the same in public interest as it will delay the availability of vaccine to Indian patients.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. A.P. Dubey, Prof & Head, Paediatrics, MAMC, New Delhi 2. Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi 3. Dr. Savita Verma, Professor, Pharmacology, PGIMS, Rohtak. <p>2. Recommendation of Technical Committee:</p> <p>The Committee noted that there is no alternate treatment/ therapy available for Dengue and it is also a life threatening disease. Further, due to frequent outbreaks of Dengue and the vaccine being approved and marketed in other countries including Brazil, Mexico, Philippines etc., after detailed deliberations, the committee agreed with the recommendation of earlier SEC dated 12.01.2016 and recommended for waiver of local clinical trial,</p>
3.	Name of the Drug: Idarucizumab (Praxiband)	Idarucizumab is a specific reversal agent for Dabigatran and is indicated in patients treated with	<p>1. Recommendation of SEC: The proposal was deliberated in 30th SEC (Cardiovascular and Renal)_held at CDSO (HQ) on 31.05.2016. The committee after deliberation observed that</p>

	<p>Name of the Firm: M/s Boehringer Ingelheim India Private Limited</p> <p>Regulatory status in India: Not Approved</p> <p>Regulatory status in other countries: US</p>	<p>Dabigatran Etxilate capsules when rapid reversal of the anticoagulant effects of Dabigatran is required:</p> <ol style="list-style-type: none"> 1. For emergency surgery/urgent procedures 2. In life-threatening or uncontrolled bleeding 	<p>this is a specific antidote used in emergent management of bleeding due to a specific drug i.e Dabigatran.</p> <p>The efficacy and safety data of Idarucizumab was deemed adequate. There is no other specific therapy available for this indication.</p> <p>Therefore, in view of this the committee recommended for grant of marketing authorization with waiver of Phase III clinical trial on Indian subjects. The firm also required to submit detailed PMS data of first 25 patients or data generated from the patients in two years, whichever is earlier.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Shashi Mohan Sharma, Professor, Dept. of Cardiology, SMS Hospital Medical College & Attached hospitals, J.L.N. Marg, Jaipur- 302004 2. Dr. Shyam Sundar Kothari, Prof. Dept of Cardiology, AIIMS, New Delhi 3. Dr. Lalit Kumar Gupta. Professor Dept. of Pharmacology, LHMC, New Delhi 4. Dr. Sandeep Bansal HOD, Department of Cardiovascular, VMMC & Safdurjung Hospital, New Delhi 5. Dr. A.H.Ansari, Assistant Professor, Vardhman Mahavir Medical College, New Delhi-110029 <p>2. Recommendation of Technical Committee:</p> <p>The committee opined that there is an unmet need in the country for the said drug and hence after detailed deliberation, the committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial.</p>
4.	<p>Name of the Drug: Riboflavin Ophthalmic Solution 0.1%</p>	<p>To treat keratoconus and corneal ectasia pathologies. The treatment can prevent</p>	<p>1. Recommendation of SEC: The proposal was deliberated in SEC (Ophthalmology) held at CDSCO (HQ) on 09.06.2016. After deliberation the</p>

	<p>Name of the Firm: M/s. Sunways (India) Private Limited</p> <p>Regulatory status in India: Not approved</p> <p>Regulatory status in other countries: European Union, USA and Asian countries</p>	<p>the necessity of corneal transplant. It is classified as class II</p>	<p>committee opined that, the drug is being used in clinical practice worldwide and the safety proven globally. As per information provided the product is approved in USA as Orphan drug and also approved in European Union and few other Asian countries. The committee recommended the grant of permission to manufacture the product provided the firm shall submit PSUR data as per Schedule Y of Drugs and Cosmetics Act and Rules there under to the office of DCG (I) for the period of 04 years.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Rohit Saxena , Additional Prof. AIIMS, New Delhi – 110029 2. Dr. R.K. Jain, Professor, Lady Harding Medical College, new Delhi. 3. Dr. Kamallesh Khilnani, Professor SMS Medical College, New Delhi 4. Dr. Bikash Medhi, Professor, Department of Pharmacology, PGIMER, Chandigarh <p>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.</p>
5	<p>Name of the Drug: Insulin Glargine solution for Injection 300 IU/ml [Additional Strength]</p> <p>Name of the Firm: M/s Sanofi India Limited</p> <p>Regulatory status in India: Approved [100 IU/mL Strength]</p>	<p>For the treatment of Insulin dependent Diabetes Mellitus Type I and Type II</p>	<p>1. Recommendation of SEC: 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</p>

	<p>Regulatory status in other countries: EU, US and 16 other Countries</p>		<p>consideration for the grant of Marketing Authorization of the product.</p> <p>Now, the firm has requested for reconsideration of the same and hence placed before the committee for recommendations.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Rajesh Khadgawat, Associate Professor, Dept of Endocrinology, AIIMS, New Delhi – 110029 2. Dr. 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 Delhi – 110026 5. Dr. Richa Dewan, Department of Medicine, MAMC, New Delhi <p>2. Recommendation of Technical Committee:</p> <p>After detailed deliberations, the committee recommended that the firm shall give proper justification and presentation while representing the case for reconsideration in the Technical Committee.</p>
6	<p>Name of the Drug: Secukinumab 150 mg/ml powder for solution for injection [Additional Indication]</p> <p>Name of the Firm: M/s Sandoz Pvt. Limited</p> <p>Regulatory status in India: Approved for the treatment of moderate to severe plaque psoriasis in adult patients who are</p>	<p>Two additional indications where no therapy is available in patients after failure to conventional therapy including anti-TNF</p> <ul style="list-style-type: none"> • Alone or in combination with Methotrexate (MTX), for the treatment of active psoriatic arthritis in 	<p>1. Recommendation of SEC: The proposal was deliberated in 22nd SEC (Analgesics & Rheumatology)_held at CDSCO (HQ) on 17.03.2016. After detailed deliberation the committee opined the following,</p> <ol style="list-style-type: none"> 1. There is no India specific clinical data available of drug in Psoriatic arthritis and Ankylosing Spondylitis 2. As stated the drug has been launched in India for indication Plaque psoriasis only however the first PSUR data is yet to be

	<p>candidate for systemic therapy</p> <p>Regulatory status in other countries: EMA</p>	<p>adult patients when the response to previous Disease-Modifying Anti-Rheumatic Drug (DMARD) therapy has been inadequate</p> <ul style="list-style-type: none"> • For the treatment of active Ankylosing Spondylitis in adults who have responded inadequately to conventional therapy 	<p>submitted and reviewed.</p> <p>3. Without the safety and efficacy data in Indian population, the said two indications cannot be considered.</p> <p>Now, the firm has requested for reconsideration of the same and hence placed before the committee for recommendations.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Uma Kumar Head, Professor, Clinical Immunology & Rheumatology Service, Department of Medicine, AIIMS, New Delhi – 110029 2. Dr. C.D. Tripathi, Professor & Head, Department of Pharmacology, VMMC , New Delhi 3. Dr. R. K. Arya, Department of Orthopaedics, RML Hospital New Delhi 4. Dr. P. P. Kotwal, Professor & Head, Orthopaedics, AIIMS, New Delhi – 110029 5. Dr. Anjan Trikha, Professor, Department of Anaesthesiology, AIIMS, New Delhi 6. Dr. Arunagshu Talukdar, MD, Professor, Rheumatology, Department of Medicine, medical College, Kolkata – 700073 7. Dr. S. K. Das, Professor & Head, Department of Rheumatology, KGMC, Lucknow – 226003 <p>2. Recommendation of Technical Committee:</p> <p>After detailed deliberations, the committee agreed with the observations of the SEC and recommended that local clinical trial waiver may not be considered.</p>
7	<p>Name of the Drug: Empagliflozin and Metformin Hydrochloride Tablets 5 mg/500 mg, 5 mg/850 mg, 5 mg/1000</p>	<p>As an adjunct to diet and exercise to improve glycemic control in adult patients with type 2</p>	<p>1. Recommendation of SEC: The proposal was deliberated in SEC (Endocrinology) meeting held on 22.12.2015. In this meeting firm presented clinical data on various studies carried out</p>

	<p>mg, 12.5 mg/500 mg, 12.5 mg/850 mg, 12.5 mg/1000 mg</p> <p>Name of the Firm: M/s. Boehringer Ingelheim India Private Limited</p> <p>Regulatory status in India: Not Approved</p> <p>Regulatory status in other countries: Australia, European Union (EU), United States (US), Chile.</p>	<p>diabetes mellitus</p> <ul style="list-style-type: none"> • when treatment with both Empagliflozin and Metformin is appropriate • inadequately controlled with Metformin or Empagliflozin alone • inadequately controlled with Empagliflozin or Metformin in combination with other glucose lowering products including insulin (see Clinical Trials Section) • already treated with Empagliflozin and Metformin co-administered as separate tablets 	<p>in Empagliflozin with Metformin as a background add-on therapy as a part of Global Clinical trial where Indian patients were also included. The strength of Empagliflozin in these studies was 10 mg and 25 mg per day as OD dosage. However, firm did not present any data on the proposed strengths of the drug either as FDC or as add-on therapy in Indian patients. Further, firm presented the clinical data on FDC on proposed strength from other countries but not from Indian patients. As per the current regulations for approval of new drug, firm is required to conduct the Clinical trial with proposed FDC in Indian patients. Accordingly, firm shall submit the clinical trial protocol for further consideration by the committee.</p> <p>The proposal was re-deliberated in SEC (Endocrinology) in its meeting held on 28.04.2016. The Committee noted that firm did not present any new/additional scientific data since the last presentation made by the firm on 22.12.2015. So, at present there is no justification of the proposed FDC without conducting a clinical trial.</p> <p>The firm has made an appeal to this office for placing their proposal before Technical Committee mentioning that as per CDSCO letter dated 03.07.2014, waiver of Clinical Trial in India Population for approval of new days, which have already been approved outside India, can presently be considered only in cases of national emergency, extreme urgency and epidemic and or the orphan drugs for rare diseases and days indicated for conditions/diseases for which there is no therapy.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1.) Dr. C. D. Tripathi, Professor & Head Department of Pharmacology, VMMC, New Delhi 2.) Dr. Rajesh Khadgawat, Professor,
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8.	<p>Name of the Drug: Eliglustat 84 mg Capsules</p> <p>Name of the Firm: M/s Sanofi – Synthelabo (India) Private Limited</p> <p>Regulatory status in India: Not Approved</p> <p>Regulatory status in other countries: Europe, USA, Japan, Australia, South Korea and 30 other countries</p>	<p>It is indicated for the long term treatment of adult patients with Gaucher Disease Type I (GD1) who are CYP2D6 Poor Metabolisers (PM's), Intermediate Metabolisers (IM's) or Extensive Metabolisers (EM's).</p>	<p>1. Recommendation of SEC: The proposal was deliberated in 29th SEC (Endocrinology) held at CDSCO (HQ) on 22.08.2016. The firm has applied for the grant of permission to Import and market Eliglustat 84 mg Capsules which is indicated for the long term treatment of adult patients with Gaucher disease type I (GD1) who are CYP2D6 Poor Metabolizers (PM's), Intermediate Metabolizers (IM's), or Extensive Metabolizers (EM's).</p> <p>After detailed deliberation the committee opined that the adult Gaucher disease is a rare disorder and Eliglustat for its treatment has been approved as orphan drug in 36 countries including US, EU, Japan etc. Further, the Genotype analysis of the patient is mandatory prior to initiation of treatment and the company has agreed to bear the cost of this analysis. Therefore the Committee recommended import and marketing of Eligustat for above indication without local clinical trial.</p> <p>SEC Expert List:</p> <p>1. Dr. D. S Arya, Professor, Dept. Of Pharmacology, AIIMS, New Delhi</p> <p>2. Dr R K Arya, Dept. Of Orthopaedics, RML Hospital, New Delhi</p>

			<p>3. Dr Arunagshu Talukdar, MD, Professor, Rheumatology, Dept. Of Medicine, Medical College, Kolkata-700073</p> <p>4. Dr Chandralekha, Professor and Head, Dept, of Anaesthesiology, AIIMS, New Delhi</p> <p>5. Dr Anjan Trikha, Professor and Head, Dept. of Anaesthesiology, AIIMS, New Delhi</p> <p>6. Dr Uma Kumar, Head, Professor, Rheumatology, Department of Medicine, AIIMS, New Delhi 110029</p> <p>2. Recommendation of Technical Committee: After detailed deliberation, the committee opined that Gaucher's disease is a very rare disease, and therefore agreed with the recommendation of the SEC and recommended for waiver of local clinical trial.</p>
9.	<p>Name of the Drug: Alectinib Capsules 150 mg</p> <p>Name of the Firm: M/s Roche Products (India) Private Limited</p> <p>Regulatory status in India: Not Approved</p> <p>Regulatory status in other countries: US and Japan (In patients with ALK-positive unresectable, recurrent or advanced NSCLC)</p>	<p>It is indicated for the treatment patients with Anaplastic Lymphoma Kinase ALK-positive, locally advanced or metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Crizotinib</p>	<p>1. Recommendation of SEC: The proposal was deliberated in 42nd SEC (Oncology) held at CDSCO (HQ) on 19.07.2016. After detailed deliberation the committee opined the following.</p> <p>The firm has presented proposal for clinical trial waiver of Alectinib capsules 150 mg to be indicated for the treatment of patients with anaplastic lymphoma kinase (ALK) -positive, locally advanced or metastatic nonsmall cell lung cancer (NSCLC) who have progressed on or are intolerant to Crizotinib before the Committee.</p> <p>The Committee noted that the data presented is Phase II, and it was also informed by the firm that the Phase III study is ongoing. However, the drug has received breakthrough therapy designation, orphan drug designation in the US and the current indication was approved under FDA'S Accelerated approval program (based on Overall response rate). The</p>

			<p>application was granted priority review. The Committee also noted the drug is especially active for relapse of the disease in the brain, and that at present is an unmet need for ALK-positive, locally advanced or metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to Crizotinib. In view of this the Committee recommended the import and marketing permission with local clinical trial waiver along with the submission of the Phase-III report to the Committee for review and continued marketing of the drug.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr Sameer Bakshi, Professor, Dept. Of Medical Oncology, AIIMS, New Delhi 2. Dr C K Bose, Assistant Professor, Netaji Subhash Chandra Bose Cancer Research Institute, Kolkata 3. Dr Sanjay Kumar Singh, Dept. of Medical Oncology, Gajara raja Medical College, Veer Savarkar Marg, Gwalior – 474009 4. Dr Bikash Medhi, Dept. of Pharmacology, PGIMER, Chandigarh <p>2. Recommendation of Technical Committee:</p> <p>After detailed deliberation the committee opined that Alectinib is indicated in patients with ALK Positive, locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) who have progressed on or are intolerant to Crizotinib where the number of patients are very less, therefore the committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial.</p>
10	Name of the Drug: Tranexamic Acid Film Coated Tablet 1000mg	For the treatment of Menorrhagia	1. Recommendation of SEC: The proposal was deliberated in 21 st SEC (Reproductive and Urology) held on

<p>(Additional Strength)</p> <p>Name of the Firm: M/s Akums Drugs & Pharmaceuticals Limited</p> <p>Regulatory status in India: Approved</p> <p>Regulatory status in other countries: Not Approved for the proposed strength</p>		<p>30.08.2016.</p> <p>“After detailed deliberation committee recommended as this is a BCS class III drug waiver of BE study may be considered. The molecule is already approved with the same indication and also the proposed strength is within the recommended dose range, therefore marketing permission can be granted without local CT”.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. N.K. Mohanty, Prof & Head, Dept. of Urology, Vardhman Mahavir Medical College & Safdurjung Hospital, New Delhi. 2. Dr. Rajeev Sood, Prof & Head Dr. RML Hospital & PGIMER, Baba Kharak Singh Marg, Type 3, President's Estate. 3. Dr. Anup Kumar Kundu, Professor & Head, IPGMER & SSKM, Kolkata, West Bengal-700020 4. Dr. Seema Singhal, Assistant Professor, Department of Gynaecology AIIMS, New Delhi 5. Dr. Pikee Saxena, Professor, Lady Harding College, New Delhi- 110001 6. Dr. Amlesh Seth, Professor & Head Department of Urology, AIIMS, New Delhi 7. Dr.C.D.Tripathi, Professor and Head, Dept. of Pharmacology, VMMC, Safdurjung, New Delhi 8. Dr. S. K. Singh, Professor, Department Urology, PGIMER, Chandigarh-160012 <p>2. Recommendation of Technical Committee:</p> <p>After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial.</p>
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11	<p>Name of the Drug: Bendamustine Hydrochloride 100mg /vial (Additional Indication)</p> <p>Name of the Firm: M/s Johnson & Johnson Limited</p> <p>Regulatory status in India: Approved (Chronic Lymphocytic leukaemia on 16-05-2009)</p> <p>Regulatory status in other countries: UK and Germany (for the proposed indication)</p>	<p>For the treatment of Front line treatment of multiple myeloma (Durie-Salmon stage II with progress or stage III) in combination with prednisone for patients older than 65 years who are not eligible for Autologous stem cell transplantation and who have clinical neuropathy at time of diagnosis precluding the use of thalidomide or bortezomib containing treatment</p>	<p>1. Recommendation of SEC: The proposal was deliberated in SEC (Oncology & Hematology) held on 27.10.2015.</p> <p>“The firm presented the proposal before the committee. The committee noted that the proposed indication fulfils the criteria for waiver of clinical trial under rare disease condition. The committee also noted that this drug is approved for the same indication in UK, Germany etc. Hence proposed additional indication is recommended with CT waiver”.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> 1. Dr. Sameer Bakshi, Professor, Dept. of Medical Oncology, AIIMS, New Delhi 2. Dr. S.D. Banavali, Head, Dept. of Medical Oncology, Tata Memorial Hospital, Parel, Mumbai- 400 012 3. Dr. Hemant Malhotra, Head, Division of Medical Oncology, SMS Medical College, Jaipur. 4. Dr. C. K. Bose, Assistant Professor, NetajiSubhash Chandra Bose Cancer Research Institute, Kolkata. 5. Dr. Urmila Thatte, Prof. And Head, Dept. of Clinical Pharmacology, SGS Medical College, KEM Hospital, Mumbai 6. Dr. Sanjay Kumar Singh, , Dept. of Medical Oncology, Gajara Raja Medical College, Veer SavarkarMarg, Gwalior – 474009 Gwalior 7. Dr. (Brig.) Ajay Sharma, Professor, Dept of Hematology, Army Hospital (Research & Referral), Dhaula Kuan, New Delhi, Delhi 110010 8. Prof Dr. H.P. Pati, Dept of Hematology, AIIMS, Ansari Nagar Delhi-110029 9. Dr. B. Gupta ,Dept. of Medicine ,NDMC & Hindu Rao Hospital ,New Delhi
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