

MINUTES OF 22nd MEETING OF THE TECHNICAL COMMITTEE HELD ON 11.02.2015 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 | Chairman |
| 2. | Dr. Ranjit Roy Chaudhury,
National Professor of Pharmacology,
Former Member, BOG – MCI,
Y-85, Hauz Khas, New Delhi-110 016. | Member |
| 3. | Dr.Rajutitus Chacko,
Prof. & Head, Dept. of Medical Oncology, CMC,
Vellore | Member |
| 4. | Dr. Yash Paul,
Prof. & Head, Dept. of Cardiology,
PGIMER, Chandigarh. | Member |
| 5. | Dr. B.L Shrerwal, Additional Medical Supdt.
Addl.M.S. (T) &Director-Professor, LHMC,
Delhi | Member |
| 6. | Dr. S.N. Gaur,
Professor & Head,
Dept. of Respiratory, Medicine,
VP Chest Institute, New Delhi. | Member |

From CDSCO:

1. Dr. G.N Singh
Drugs Controller General of India
2. Dr.V.G.Somani,
Joint Drugs Controller (India)

3. R. Chandrashekar
Deputy Drugs Controller (India), CDSCO HQ
4. Mrs. A Visala
Deputy Drugs Controller (India)
5. Mrs. Rubina Bose
Asst. Drugs Controller (India)
6. Mr. Sanjeev Kumar
Asst. Drugs Controller (India)

Dr. G.N Singh, DCG (I) welcomed the members of the meeting and thereafter, Dr. V.G. Somani, JDC (I) with the permission of the Chairman, initiated the proceeding of the Committee as per the agenda.

The Committee then discussed the clinical trial proposals one by one as under:

1. Proposals of Clinical Trials recommended by SEC / IND.

The Committee deliberated 28 cases related to approval of clinical trials. Out of these 28 cases, 03 cases were related to clinical trials of NCEs and 05 cases were related to global clinical trials (GCT). Remaining 20 cases were related to clinical trials for approval of New Drugs including fixed dose combination, subsequent new drugs and biologicals.

The Committee evaluated the 03 cases related to clinical trial of NCEs one by one 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 of all 03 cases. The recommendations of the Committee in respect of these 03 cases related to clinical trial of NCEs are enclosed as **Annexure-I**.

Thereafter, the Committee evaluated and recommended 05 cases related to global clinical trial. The recommendations of the Committee in respect of these 05 cases related to GCTs are enclosed as **Annexure-II**

The Committee also evaluated the remaining 20 cases of other than GCT/clinical trial of NCEs. After detailed deliberation, the Committee recommended for approval of 19 out of 20 cases. For one case of the clinical trial proposal at S. No. 20 of Annexure-III, the Committee has sought additional information and deferred the proposal to the next meeting. The recommendations of the Committee in respect of these 20 cases are enclosed as **Annexure-III**.

The Committee recommended for approval of 27 cases, out of total 28 cases of clinical trial proposals.

2. Waiver of Clinical Trial in Indian population for approval of new drugs, which have already been approved outside India

As per the Drugs & Cosmetics Rules, for new drugs substance approved in other countries, phase III clinical trial is required before granting permission to manufacture / import of finished formulation of the new drug.

However, requirements of local clinical trial may be waived off / relaxed under certain conditions as per Drugs & Cosmetics Rules (122 A (2) ,122 B (3) & clause 1 (3) of Schedule Y as mentioned above depending on nature of drugs and diseases for which it is indicated.

Under Rule-122A(2) & Rule-122B(3) of Drugs & Cosmetics Rules the requirement of submitting the results of local clinical trials may not be necessary if the drug is of such a nature that the licensing authority may, in public interest decide to grant such permission on the basis of data available from other countries. Further the submission of requirements relating to animal toxicology data may also be modified or relaxed under the same rules in case of new drugs approved and marketed for several years in other countries and adequate published evidence regarding the safety of the drug is available.

As per clause 1(3) of Schedule Y to Drugs & Cosmetics Rules, for drugs indicated in life threatening / serious diseases or diseases of special relevance to the Indian health scenario, the toxicological and clinical data requirements may be abbreviated, deferred or omitted, as deemed appropriate by the Licensing Authority.

It would thus be observed that there are certain conditions specified in the Drugs & Cosmetics Rules under which the licensing authority may grant permission to manufacture / import of new drugs without local clinical trials.

However, Parliamentary Standing Committee in its 59th report has raised concerns on approval of certain new drugs in the country without local clinical trials. In light of the same the Ministry constituted a Committee under chairmanship of Prof. Ranjit Roy Chaudhury, the Committee submitted its report. The action to be taken on the recommendations of the Expert Committee has been finalized by the Ministry of Health & Family Welfare.

As per the action, “The waiver of Clinical Trial in Indian population for approval of new drugs, which have already been approved outside India, can be considered only in cases of **national emergency, extreme urgency, epidemic and for orphan drugs for rare diseases and drugs indicated for conditions/diseases for which there is no therapy.**

The Apex Committee in its meeting held on **24.01.2014** has recommended that waiver of local clinical trial of such cases should be granted only under the criteria as already decided by the Ministry viz national emergency, extreme urgency, epidemic and for orphan drugs for rare diseases and drugs indicated for conditions/diseases for which

there is no therapy. In case local clinical trial waiver is required for any other category, the matter should be brought before the Committee for consideration along with the recommendations of the Technical Committee.

Following 06 proposals (05 from New Drug and 01 from Medical device) have been recommended by the SECs for their approval for manufacture/ import for marketing in the country without local clinical trial. The details of the same along with recommendations of SEC were placed before the Committee for perusal and comments. The recommendation of the Technical Committee is as under:

Sr. no.	Drug Name	Name of the Firm	Indication	Recommendations
1.	Pralatrexate Injection 20mg/mL & 40mg/2mL	M/s. Hetero Drugs Limited	For the treatment of patients with relapsed or refractory peripheral T-cell Lymphoma (PTCL).	<p>Recommendation: After detailed deliberation, the Committee recommended the waiver of local clinical trial as per the recommendation of the SEC.</p> <p>SEC Recommendation: After detailed deliberation, the Committee observed that incidence of PTCL in the Country is very rare and is an Orphan disease. The Committee recommended that local clinical trial waiver may be granted for the said Indication with a condition that a PK study on 12 subjects should be conducted before issuing permission for marketing the drug in the country and a Phase IV post marketing trial should be conducted on 100 patients in the country. The PK study data should be submitted before the Committee for review.</p>
2.	Ceritinib Hard Gelatin Capsule 150 mg	M/s. Novartis Healthcare Pvt. Ltd	The treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive	<p>Recommendation: After detailed deliberation, the Committee recommended the waiver of local clinical trial as per the recommendation of the SEC.</p> <p>SEC Recommendation: The firm has applied for grant of permission to import and market the drug in the country with local clinical trial waiver. The firm has presented that the drug was approved in USA as an orphan drug for the said indication. Further the firm has submitted that ALK positive patients are only 3% of total NSCLC patients and hence would qualify as Orphan drug in the country. The firm has also presented the safety and efficacy data generated in other countries. The Committee deliberated the proposal in detail and recommended for import and marketing of the drug in the country subject to condition that the firm should actively follow up first 50 patients and collect safety and efficacy data and submit before the Committee</p>

3.	Ibutilide Fumarate Injection 0.1mg/ml	M/s Zuventus Healthcare Ltd	For the rapid conversion of atrial fibrillation or atrial flutter of recent onset to sinus rhythm	<p>Recommendation: After detailed deliberation, the Committee recommended the waiver of local clinical trial as per the recommendation of the SEC.</p> <p>SEC Recommendation: In response to the SEC recommendation of 30/09/2014 the firm has requested for waiver of local clinical trial. Earlier the firm was granted NOC for conduct of clinical trial and it was further mentioned that after one year no patients could be recruited. The Committee deliberated on this issue and decided that the company should provide specific reason with evidence from all the approved centers, and comments for non-recruitment of the trial patients and as per SEC recommendation of 16.12.2014, the firm presented its proposal in detail, it was noted that the firm has not yet submitted the specific reason(s) for non-recruitment of subject in clinical trial from the five investigating sites with information to respective Ethics Committee by investigator(s) as communicated earlier. The SEC recommended that the firm may be asked to submit the above documents from all sites as per the recommendation of the SEC meeting held on 30.09.2014. In response the firm has submitted comments of 4 out of 5 investigators out of which 3 have categorically stated that they have not recruited any subject in the said study. One of the Investigator site has clearly sited difficulty in obtaining consent in emergent situations as the reason for non recruitment. The firm has submitted this in reply dated 15.01.2015. The Committee further deliberated on the matter in details. It was noted that 1. Atrial fibrillation / flutter is a condition needing urgent treatment 2. There is no satisfactory drug for pharmacological cardio version in this situation (Atrial fibrillation / flutter). 3. The said drug is approved by USFDA for the new onset atrial fibrillation since 1995. 4. In certain specific situation like atrial fibrillation in post surgery patients and congenital heart disease, this is established as drug of choice. 5. Hence it may be categorized as a drug to be used in condition of extreme urgency category. Considering all the above conditions, the Committee recommended for a waiver of local clinical trial. The Committee however recommended that a Phase- IV clinical trial in minimum 120 patients be conducted. Accordingly the firm shall submit the protocol.</p>
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4.	Ibrutinib 140 mg Capsules	M/s Johnson & Johnson Ltd	For the treatment of Mantle cell Lymphoma, Chronic Lymphocytic Leukemia and Chronic Lymphocytic Leukemia with 17p deletion.	<p>Recommendation: After detailed deliberation, the Committee recommended the waiver of local clinical trial as per the recommendation of the SEC subject to the condition that the firm shall submit outcome of the post-marketing trial annually till the completion of the study to DCG (I).</p> <p>SEC Recommendation: After detailed deliberation of the proposal the Committee observed the following:-</p> <ol style="list-style-type: none"> 1. The drug has been approved by USFDA, EMA, and Swiss medic as an orphan drug. The drug is indicated for the treatment of adult patients with Mantle Cell Lymphoma who have received at least one prior therapy, for the treatment of patients with chronic lymphocytic leukemia who have received at least one prior therapy and for the treatment of patients with chronic lymphocytic Leukemia with 17p deletion. 2. The firm presented data to show that the drug is effective in the above indications with acceptable toxicity. The drug will address the Unmet Medical Need of the Indian patients. However, the Committee noted that Indian patients have not yet been exposed to the drug. Therefore, the Committee recommended the waiver of the clinical trial and import and marketing permission of the drug with the condition that the firm shall conduct Phase IV clinical trial.
5.	Bovine lung surfactant—a drug powder lyophilisate for intratracheal instillation 54 mg/0.7 mL	M/s Bharat Serum and Vaccine Ltd	For the treatment of respiratory distress syndrome in the pre-term new born infants.	<p>Recommendation: After detailed deliberation, the Committee recommended the waiver of local clinical trial as per the recommendation of the SEC.</p> <p>SEC Recommendation: The proposal was deliberated in the NDAC (Now renamed as SEC) in its meeting held on 28.01.2012</p> <p>Recommendation of SEC (Pulmonary): After detailed deliberation the Committee recommended that phase III clinical trial with the drug should be conducted. Accordingly protocol etc. should be submitted for consideration of the Committee. The protocol etc. would be deliberated in the next meeting. Two neonatologists should also be invited in the deliberation in the next meeting.</p>

				<p>The proposal of the firm was then referred to SEC vaccine where neonatologist was present</p> <p>Recommendation of SEC (Vaccine) 12.01.2015: The committee deliberated the proposal in detail. The firm has stated that the drug qualifies to be considered as Orphan Drug based on the published data and the firm has presented the proposed drug in a lyophilised formulation with better shelf life than the existing liquid formulation available in India and can be stored at 25°C. Further, the drug is reported to have been approved in Germany and many other countries.</p> <p>The committee recommended for the grant of Permission for Marketing Bovine Lung Surfactant in the Country with the condition that PMS data on at least 100 patients to be submitted within a year to get more safety data.</p>
6.	BST Car Gel	M/s Piramal Healthcare Pvt., Ltd	It is intended to promote hyaline cartilage regeneration when used in conjunction with the bone marrow stimulation technique such as microfracture or drilling for the repair of damaged articular cartilage in the adult knee	<p>Recommendation: After detailed deliberation, the Committee recommended the waiver of local clinical trial as per the recommendation of the SEC.</p> <p>SEC Recommendation: The firm made a presentation before the committee. After detailed examination of the available clinical materials provided by the company, the committee came to the conclusion that permission for import & marketing of the product under Rule-122A of D & C Act & Rules may be granted with a condition to carry out Phase-IV clinical trial in Indian population. Accordingly the firm should submit the study protocol within a period of 6-months w.e.f. the date of approval for further deliberation in the SEC.</p>

Annexure-I

List of 03 cases of clinical trials of NCEs along with their evaluations and recommendations of the Technical Committee in its 22nd Meeting.

Sr No.	Name of the Drug	Name of Firm	PROTOCOL	Parameters	Recommendation
1	LEE011	Novartis Healthcare Private Limited	CLEE011A21 15C	<p>1. risk versus benefit to the patients</p> <p>2. innovation vis-a-vis existing therapeutic option</p> <p>3. unmet medical need in the country</p> <p>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 and phase I,II clinical studies, justify the conduct of this study.</p> <p>Innovation vis-à-vis Existing Therapeutic Option: The purpose of the study is to estimate the maximum tolerated dose (MTD) and/or recommended phase II dose (RP2D) of the combination of letrozole and LEE011 in postmenopausal patients with HR+/HER2-negative advanced breast cancer.</p> <p>Unmet Medical Need in the country: The test drug may provide an alternative option for the treatment of postmenopausal women with hormone receptor positive, HER2-negative, advanced breast cancer.</p>	<p>Recommendations: After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.</p> <p>SEC Recommendations: After detailed deliberation the committee recommended for conduct of the trial.</p>
2.	Bococizumab (PF-04950615)	M/s Pfizer Ltd,	B1481022	<p>Assessment of Risk vs. Benefit to the patients: The safety profile of the study drug from preclinical pharmacology, single dose, repeat dose toxicity, reproductive toxicity and phase I, II clinical studies justify the conduct of the trial.</p> <p>Innovation vis-à-vis Existing Therapeutic Option: The purpose of the study is to compare the efficacy, safety, and tolerability of bococizumab (pf-04950615), in reducing the occurrence of major cardiovascular events in high risk subjects.</p> <p>Unmet Medical Need in the country: The</p>	<p>Recommendations: After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.</p> <p>SEC Recommendations: The committee recommended for</p>

				test drug may potentially provide alternative treatment option in patients with major cardiovascular events.	conducting the proposed clinical trial as presented by the firm.
3.	Bococizumab (PF-04950615)	M/s Pfizer Ltd,	B1481038	<p>Assessment of Risk vs. Benefit to the patients: The safety profile of the study drug from preclinical pharmacology, single dose, repeat dose toxicity, reproductive toxicity and phase I, II clinical studies justify the conduct of the trial.</p> <p>Innovation vis-à-vis Existing Therapeutic Option: The purpose of the study is to evaluation of the efficacy, safety, and tolerability of bococizumab (pf-04950615), in reducing the occurrence of major cardiovascular events in high risk subjects.</p> <p>Unmet Medical Need in the country: The test drug may potentially provide alternative treatment option in patients with major cardiovascular events.</p>	<p>Recommendations:</p> <p>After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.</p> <p>SEC Recommendations:</p> <p>The committee recommended for conducting the proposed clinical trial as presented by the firm</p>

Annexure-II

List of 05 cases of Global Clinical Trials along with their evaluations and recommendations of the Technical Committee in its 22nd Meeting.

Sr No.	Name of the Drug	Name of Firm	PROTOCOL	Parameters	Recommendation
1	Gemcitabine 1000 mg/m ² + Capecitabine 1660 mg/m ² versus Gemcitabine alone.1000 mg /m ²	Dr. Shailesh Vinayak Shrikhande	ESPAC4	<p>1. risk versus benefit to the patients</p> <p>2. innovation vis-a-vis existing therapeutic option</p> <p>3. unmet medical need in the country</p> <p>Assessment of Risk vs. Benefit to the patients: In light of the fact that the test drugs are already approved in India, the safety profiles of the drugs justify the conduct of the trial.</p> <p>Innovation vis-à-vis Existing Therapeutic Option: The purpose of the study is to compare combination of Gemcitabine and Capecitabine therapy with Gemcitabine alone in patients with either pancreatic ductal adenocarcinoma or peri-ampullary carcinoma who have undergone curative resection.</p> <p>Unmet Medical Need in the country: Capecitabine in combination with Gemcitabine may provide an alternative treatment option for pancreatic ductal adenocarcinoma or peri-ampullary carcinoma who have undergone curative resection.</p>	<p>Recommendation: After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.</p> <p>SEC Recommendation: After deliberation, the Committee recommended for the conduct of the trial.</p>
2.	PF-05280586 (Rituximab-Pfizer)	M/s Pfizer Ltd	B3281006	<p>Assessment of Risk vs. Benefit to the patients: The safety profile of the study drug from preclinical pharmacology, single dose, repeated dose toxicity studies and clinical PK/PD, phase I/II studies justify the conduct of this study.</p> <p>Innovation vis-à-vis Existing Therapeutic Option: The purpose of the study is to compare the efficacy of Rituximab-Pfizer to Rituximab EU Mab-Thera when administered as a first-line treatment to patients with CD20-positive, low tumour burden, follicular lymphoma</p>	<p>Recommendation: After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.</p> <p>SEC Recommendation: After detailed deliberation, the Committee recommended for the conduct of the trial.</p>

				(LTB-FL). Unmet Medical Need in the country: The test drug may provide an alternative treatment option for patients with CD20-positive, low tumour burden, follicular lymphoma (LTB-FL).	
3.	Intravenous Fibrinogen Grifols Human Fibrinogen	M/s Max Neeman	IG0902	Assessment of Risk vs. Benefit to the patients: The safety profile of the study drug from preclinical pharmacology, general toxicity, single dose, immunogenicity toxicity justify the conduct of this study. Innovation vis-à-vis Existing Therapeutic Option: The purpose of the study is to evaluate the Pharmacokinetics, Efficacy, and Safety of Human Plasma-Derived Fibrinogen (FIB Grifols) in patients with congenital afibrinogenaemia.”. Unmet Medical Need in the country: The test drug may potentially provide alternative treatment option in Patients with Congenital Afibrinogenaemia	Recommendation: After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation. SEC Recommendation: After detailed deliberation, the Committee recommended for the conduct of the trial
4.	Dabigatran Etxilate and Omeprazole	St. Johnson Health Academy, Bangalore	1160.143	Assessment of Risk vs. Benefit to the patients: In light of the fact that the IMP are already approved and marketed in India, the safety profile of the IMP justify the conduct of the trial Innovation vis-à-vis Existing Therapeutic Option: The purpose of the study is to assess the impact of Dabigatran (a direct thrombin inhibitor) and Omeprazole (a proton pump inhibitor) in patients suffering myocardial injury after non-cardiac surgery. Unmet Medical Need in the country: The IMP may provide an alternative treatment option in patients suffering myocardial injury after non-cardiac surgery (MINS). Proton pump inhibitor in patients receiving anti coagulant therapy after suffering MINS may be beneficial.	Recommendation: After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation. SEC Recommendation: The Committee recommended for conducting the proposed clinical trial as presented by the applicant.

5.	Dabigatran Etexilate	M/s Boehringer	1160.189	<p>Risk Vs Benefit to the Patients: - The safety profile of the test drug justifies the conduct of the trial.</p> <p>Innovation vis-à-vis existing therapeutic option: - The purpose of the study is to compare the efficacy and safety of the oral Thrombin inhibitor Dabigatrin Etexilate (110 mg or 150 mg, oral b.i.d) Vs Acetylsalicylic acid (100 mg oral q.d) in patients with embolic stroke of undetermined source.</p> <p>Unmet need:- The test drug may provide an alternative treatment option for patients with embolic stroke of undetermined source.</p> <p>(Dr. Sunil K Narayan did not take part in the final decision making process.)</p>	<p>Recommendation: After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.</p> <p>SEC Recommendation: After detailed deliberation the Committee recommended for the conduct of the trial as per the protocol submitted by the firm.</p>
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Annexure-III

List of 20 cases of clinical trial proposals other than GCT/NCE along with evaluations and recommendations of the Technical Committee in 22nd Meeting.

SI No	Name of the Drug	Firm Name	Recommendation
1.	R-TPR-018 / ENBREL® (Etanercept) Recombinant human monoclonal antibody R-TPR-018 (code for Etanercept) which is biosimilar to the innovator product Enbrel®. Powder and solvent for solution for injection, Each vial contains 25 mg of etanercept.	M/s Reliance Life Sciences	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
2.	Tacrolimus Lipid Suspension For Injection 5mg/vial	M/s Intas Pharmaceuticals Limited	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
3.	Losartan (50mg) + Amlodipine (5 mg) + Hydro chlorothiazide (12.5 mg) Tablet	M/s Micro Labs Ltd.	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation. The Committee also opined that B.P should not fall below the recent target level and in case of any illness like fever, hypovolemia, pneumonia etc., the FDC should be stopped.
4.	Transtuzumab Powder for concentrate for solution for infusion, each vial contains 150 mg of Transtuzumab and 440 mg of Transtuzumab	M/s Dr. Reddy's Laboratories Ltd.,	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
5.	Bevacizumab Concentrate for solution for infusion 25mg/mL	M/s Hetero Drugs Limited	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.

6.	r-hFSH (Recombinant Human Follicle Stimulating Hormone) Sterile powder for injection, single use-82 IU/vial, multiple use-600 IU/Vial	M/s Cadila Healthcare Limited	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
7.	Bevacizumab Concentrate for solution for infusion 25mg/mL	M/s Cadila Healthcare Limited	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
8.	Prednisone MR Tablet 5 mg	M/s Sun Pharma Laboratories Ltd.	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
9.	Tetanus vaccine (adsorbed) I.P	M/s Cadila Healthcare Ltd.,	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
10.	Diphtheria, Tetanus and Pertussis (whole cell) Vaccine	M/s Cadila Healthcare Ltd.,	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
11.	Tamoxifen tablet 20mg	Dr. Avanthi Gadipudi	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
12.	Glycerol(propane-1,2,3-triol) oral solution	Dr Ramesh Kumar R	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
13.	Metformin Tablet 20 mg	Dr. T S Ganesan	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
14.	VSL#3 sachets	Dr. Arun Bansal	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
15.	Live Attenuated human-bovine reassortant pentavalent rotavirus vaccine (BRV-PV).	M/s Serum Institute of India Ltd.	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
16.	Measles Vaccine	M/s Cadila Healthcare Pvt Ltd	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.

17.	Typhoid Vi-Capsular polysaccharide-Tetanus toxoid conjugate vaccine	M/s Cadila Healthcare Pvt	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
18.	Pseudovac vaccine	M/s AllMed International Pvt. Limited	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
19.	Liquid pentavalent vaccine (Diphtheria, Pertussis, Tetanus, Hepatitis B and Haemophilus influenza type b)	M/s Human Biologicals Institute, Hyderabad	After detailed deliberation, the Committee recommended to conduct the study as per the SEC recommendation.
20.	Darbepoetin Alfa Injection solution for injection in PFS, Dose 60mcg/0.3mL, 40 mcg/0.4mL,, 60 mcg/0.3 mL, 100 mcg/0.5 mL, 150 mcg/0.3 mL, 200 mcg/ 0.4 mL, 300 mcg/ 0.6 mL and 500 mcg/mL	Hetero Drugs Limited, Hyderabad	The Committee after deliberation observed that the study is proposed to be carried out in healthy volunteers. Therefore, the Committee opined that the firm shall submit the details of relevant studies (published in index journals such as LANCET etc) carried out with Darbepoetin in healthy human volunteers which will be discussed in the next Technical Committee meeting.
