MINUTES OF 38th MEETING OF THE TECHNICAL COMMITTEE HELD ON 22.12.2016 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, Ex. Head of the Dept., Prof. Department of Medicine, Institute of Medical Sciences, Banaras Hindu University, Varanasi.	Member
3.	Dr. Nandini Kumar, Former Dy. Director General Sr. Grade, Adjunct Professor, KMC, Manipal, Chennai	Member
4.	Dr. Ashok Kumar Das, Professor of Medicine & Professor and Head, Department of Endocrinology, Pondicherry Institute of Medical Sciences, Pondicherry.	Member

From CDSCO:

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

The Chairman welcomed the members of the Committee for the 38th meeting. The chairman reviewed the approval of the new drug process in the country. After deliberations, the Committee recommended that both

1. Inspection for Research and Development of batches proposed for regulatory approval and
2. BA/BE studies should be mandatory for all new drugs including parenterals introduced for first time in India and manufactured locally (after obtaining waiver).

Thereafter, the Committee discussed the clinical trial proposals and other agenda one after another as under:

The Committee deliberated 09 proposals related to approval of clinical trials other than GCT/NCEs

1. **Proposals of Clinical Trials other than GCT/ NCEs recommended by SECs.**

The Committee evaluated nine proposals of other than GCT/clinical trial of NCEs. After detailed deliberations, the Committee recommended approval for eight proposals. The recommendation of the Committee is enclosed as **Annexure-I.**

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

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

3. **Others:**

a) **Request to removal of condition imposed in permission granted for conduct of Post Marketing Surveillance Study of Prasugrel Hydrochloride 10mg + Aspirin 75mg capsules.**

Recommendation of the Committee: After detailed deliberation, the Committee has agreed with the recommendation of the SEC.

b) The chairman desired that the proposal for waiver of local clinical trial for the drug Teriflunamide of M/s Sanofi Syntholab indicated for the treatment of Multiple Sclerosis be placed in the agenda of the next Technical Committee meeting.

c) The Committee also deliberated on the requirement of local clinical trial of Benzocaine impregnated condoms which was taken *suo moto* as a special agenda based on the advice of the Chair as it was requested in earlier technical committee meeting but was not reflected in the decision.

After detailed deliberations, the experts recommended that no local clinical trial is required in all such cases as both, condoms and Benzocaine are approved individually in the country as risk involved is much less and no meaningful data will be generated. Also it is approved in other countries.

Annexure-I

Proposals of clinical trial of other than NCE/GCT along with their evaluations and recommendations of the Technical Committee in its 38th Meeting held on 22.12.2016:

S.No.	Name of the Drug	Firm Name	Recommendations: 1. Subject Expert Committee 2. Technical Committee
1	Lorcaserin HCL 10mg Tablets	M/s Dr. Reddy's Laboratories Ltd.	**1. SEC recommendation on 08.11.2016:** Firm presented the CT and BE protocol and after detailed deliberation committee approved the protocols with following modifications 1. The patients with thyroid diseases on medications with stable thyroid functions for more than three months can be included in the study. 2. Inclusion of check list of known adverse events in the protocol. **Action Taken:** Accordingly, the firm had submitted the revised protocol with above modification. **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
2	VPM1002 (rBCG) Vaccine for Tuberculosis	M/s Serum Institute of India Pvt. Ltd.	**SEC recommendation:** The firm has presented the protocol for Phase III clinical trial which was deliberated by the committee and the committee recommended the following: 1. The firm should amend the protocol to conduct Phase II/III clinical trial. 2. The phase II shall be conducted in minimum of 200 subjects and present its clinical data to the committee before commencing the Phase III clinical trial. **Action Taken: The firm has submitted the revised protocol accordingly.**

			Expert Committee Members: **1.** Dr. Ramesh Aggarwal, Additional Professor, Vaccine & Neonatology, AIIMS, New Delhi110029. **2.** Dr. Anita Chakravarty, Dir. Prof. & HOD, Microbiology Maulana Azad Medical College, New Delhi **3.** Dr. Savita Verma, Pharmacology, PGIMS **4.** Dr. Veena Verma, Department of Pharmacology VMMC & Safdurjung Hospital, New Delhi. **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee recommended that the firm should make a presentation specifically on immunity generated in patients, primary objective of the study etc., before the Committee. The committee also desired that two experts viz Dr. R Sarin, (National Institute of Tuberculosis, New Delhi) and Dr. D. Behara (PGIMER, Chandigarh) should be invited during the presentation.
3	Diphtheria, Tetanus, Acellular Pertussis, Inactivated Poliomyelitis and *Haemophilus influenzae* type b conjugate vaccine adsorbed (DTaP-IPV+ Hib)	M/s Serum Institute of India Pvt. Ltd.	**Recommendation of the SEC:** The Phase I clinical trial protocol was deliberated in detail and the committee recommended for approval of the study. **Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
4	Glycopyrronium 12.5mcg and Formoterol fumarate 12 mcg Powder for Inhalation	M/s Glenmark Pharmaceuticals Limited,	**1. Recommendation of the SEC** Firm presented the revised protocol before the committee as the comparator in the study has been revised from Glycopyrronium 12.5mcg bid to Glycopyrronium 50mcg od. Committee recommended for proposed study with the condition that the proposed study should be double blind and accordingly revised

			protocol shall be submitted to DCGI for further action and approval. **Action Taken: The firm had submitted the revised protocol accordingly** **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and approved the study accordingly.
5	Diclofenac rectal solution	M/s Lincoln Pharmaceuticals Ltd.	**1. Recommendation of the SEC:** Firm presented the Phase III CT protocol before the committee. The committee recommended the proposed CT protocol. However, committee suggested that the proposed indication for marketing the proposed formulation in the country should be "Mild to Moderate pain only in adults". The package insert should contain diagrammatic representation of application **2.Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended the approval of the study.
6	Premix Human Insulin Biphasic 30/70	M/s M.J. Biopharm Private Limited	**1. Recommendation of the SEC:** The firm has presented their proposal to carry out Phase III clinical trial on Recombinant Human Insulin to the committee and after detailed deliberation, the committee has recommended for the Phase III clinical trial with subject to the following changes in the protocol. 1. Provision of titration plan as per the blood glucose values. 2. Change from open label to blinding of the investigational product. The revised protocol should be submitted to the CDSCO with compliance of the above.

			Action Taken: The firm has submitted the revised protocol accordingly. **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.
7	REGEN-D® 10 (Foot craks)	Bharat Biotech International Ltd	**1. Recommendation of the SEC:** After detailed deliberation, the committee recommended the phase II study protocol (Craked feet) with the following changes to be made and submit the revised protocol: 1. Placebo to be renamed as vehicle controlled 2. Standardized photography with fixed distance, lighting, camera setting and subject position at every visit of the subject. 3. Assessment parameters of fissures include number and area of fissures. 4. The subject assessment of the hyperkeratosis has to be removed 5. Exclusion criteria to include the peripheral neuropathy. **Action Taken: Accordingly, the firm has submitted the revised clinical protocol.** **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.
8	REGEN-D®10 (Wrinkle)	Bharat Biotech International Ltd	**1. Recommendation of the SEC:** After detailed deliberation, the committee recommended the phase II study protocol (Wrinkle) with the following changes to be made and submit the revised protocol: 1. Placebo to be renamed as vehicle controlled 2. Dermatoscopy has to be standardized to have a objective scoring for assessing to minimize inter user variability. 3. Standardized photography with fixed distance, lighting, camera setting and subject position at every visit of the subject. **Action Taken: Accordingly, the firm has**

			submitted the revised protocol **SEC Expert:** 1. Dr. V. K. Sharma, Professor & Head, Dept. of Dermatology, New Delhi-110029 2. Dr. Sanjeev Handa, Professor & Head, Dept. of Dermatology, PGIMER, Sector 12, Chandigarh 16001212 3. Dr. S. N. Bhattacharya, Professor & Head, Dept. of Dermatology, University of Medical College Science, New Delhi 4. Dr. Lalit Kumar Gupta, Prof. Dept. of Pharmacology, LHMC, New Delhi 5. Dr. Binod K Khaitan, Professor & Head, Dept. of Dermatology, AIIMS, New Delhi **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee recommended that the inclusion criteria should be amended such that the trial should be conducted on the subjects in the age group above 50 years. The NOC for conduct of clinical trial may be issued after submission of revised clinical protocol.
9	Teriparatide 20 mcg	M/s Enzene Biosciences Ltd.	**1. Recommendation of the SEC:** After detailed deliberation of the revised protocol, the committee recommended the approval of protocol to conduct Phase III clinical study of Teriparatide in comparison to reference product (Forteo) subject to the condition to submit the PK/PD data to the CDSCO for review. **SEC Expert:** 1. Dr. R. K. Arya, Prof. and Head Department of Orthopedics, RML Hospital New Delhi 2. Dr. S. K. Das, Professor & Head, Department of Rheumatology, KGMC, Lucknow-226003 3. Dr. Arunagshu Talukdar, MD, Professor, Departement of Medicine, Medical College, Kolkata-700073 4. Dr. Uma Kumar, Professor and Head,

			Dept of Rheumatology Division, AIIMS, New Delhi 110029 **5.** Dr. K. H. Reeta, Dept. of Pharmacology, AIIMS, New Delhi **2. Recommendation of the Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and approved the study accordingly.

Annexure-II

Recommendation of the 02 cases of Clinical Trials waiver in Indian Populations of 38th Technical Committee Meeting held on 22.12.2016:

S. No.	Drug Name	Indication	1. Recommendations of the SEC 2. Recommendation of Technical Committee
01	**Name of the Drug:** Pomalidomide Capsules 1/ 2/ 3/ 4mg Application for manufacturing and marketing **Name of the Firm:** M/s. Natco Pharma **Date of Application:** 17.06.2016 **Regulatory status in India: Not approved** **Regulatory status in other countries:** USA and Europe	For the treatment of multiple myeloma	**1. Recommendation of Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial
02	**Name of the Drug:** Bendamustine Hydrochloride injection 90mg / mL(0.5ml vial & 2 ml vial Pack size) (Additional dosage form) **Date of Application:** 05.04.2016 **Name of the Firm:** M/s Intas Pharmaceuticals Ltd. **Regulatory status in India:** Approved in India (For other strength)	• First-line treatment of chronic lymphocytic leukemia (Binet stage B or C) in patients for whom fludarabine combination chemotherapy is not appropriate. • Indolent non-Hodgkin's lymphoma (Binet stage B or C) in patients who have progressed during or within 6 months following treatment with Rituximab of Rituximab containing	**1. Recommendation of Technical Committee:** After detailed deliberation, the committee agreed with the recommendation of the SEC and recommended for waiver of local clinical trial

	Regulatory status in other countries: USA, EMA	regimen. • 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.	

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