

**MINUTES OF 42<sup>nd</sup> MEETING OF THE TECHNICAL COMMITTEE HELD ON 25.09.2017 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,<br>Director General of Health Services,<br>Nirman Bhawan, New Delhi  | Chairman |
| 2. | Dr. Kamlakar Tripathi,<br>Prof. Department of Medicine,<br>Institute of Medical Sciences,<br>Banaras Hindu University, Varanasi. | Member   |
| 3. | Dr. P.K. Dalal,<br>HOD, Dept. of Psychiatry,<br>KGMU Medical College, Lucknow.   | Member   |
| 4. | Dr. Rajutitus Chacko, Prof. & Head, Dept. of Medical Oncology,<br>CMC, Vellore.  | Member   |
| 5. | Dr. Yash Paul,<br>Prof. & Head, Dept. of Cardiology,<br>PGIMER, Chandigarh.  | Member   |
| 6. | Dr. B. L. Sherwal,<br>Director, RIMS, Ranchi   | Member   |

**Special Invitee (for proposal no. 07 of clinical trial waiver):**

Dr. Arjun Ahuja,  
Prof. & HOD, Seth GS Medical College and KEM Hospital, Mumbai.

**From CDSCO:**

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

6. Mr. Sanjeev Kumar,  
Deputy Drugs Controller (India)
7. Mr. Sunil Kulshreshtha,  
Assistant Drugs Controller (India)

The Chairman welcomed the members of the Committee for the 42<sup>nd</sup> meeting and after deliberations with members made the following recommendations in general:-

1. Policy matters for bringing ease in approval of clinical trial and new drugs should be placed before Technical Committee for deliberation and further consideration by the Ministry.
2. The members of the Technical Committee (TC) shall be dynamic & it shall be reviewed/ revised at regular interval for smooth functioning of Committee. Chairman may call the experts from specific therapeutic categories from the pool of experts as per need. Proposal in this regard shall be moved as required.
3. Uniform implementation of regulatory regime with stringent regulatory body, to be adopted.
4. For manufacture for sale of any new drug, after grant of new drug permission, the manufacturing license should be issued on the basis of checklist & joint inspection/ evaluation of the manufacturing facility by the State & Centre regulator. Measures should be initiated for consideration and approval of the Ministry in this regard.
5. Any firm intending to market a new drug which is being developed outside the country, should include Indian patients in the Global Clinical Trial and proposal of such Global Clinical Trial, when approved in ICH countries, shall be reviewed on priority and considered for approval by CDSCO, without referring to SEC, unless there is some specific reasons which should be recorded in writing.
6. CDSCO officials shall be usually be involved in technical evaluation of new drug, clinical trial etc. may not involve directly in financial and administrative matter for construction of office building etc. under 12<sup>th</sup> five year plan.

The Committee deliberated 02 cases related to approval of clinical trials.

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

The Committee deliberated 02 cases related to approval of clinical trials of other than GCT/NCEs which were earlier deliberated in the Technical Committee. Based on the recommendation of the Technical Committee, these two proposals were placed before the Committee.

**I. Combined Diptheria-Tetanus -Acellular Pertusis-Inactivated Poliovirus and Haemo philus Influenza Type b Conjugate Vaccine (Infanrix -IPV /Hib) of M/s Glaxo SmithKline Pharmaceuticals Ltd.**

The Technical Committee in its meeting dated 03.05.2017 had noted that the vaccine is approved in countries like USA and Europe, however various events of fatal outcome after administration of vaccine have been reported and the clinical trials has been proposed in two centres for which committee opined that the firm may asked to provide clarification and make a presentation before the committee.

Accordingly, the firm made their presentation before the Committee and it was clarified by the firm that the fatal outcomes are reported as part of various clinical trials reports conducted with vaccines since 2002 and are not related to the vaccines. After deliberation, the Committee recommended for the conduct of Phase III clinical trial.

**II. Regen D 10 of M/s Bharat Biotech International Ltd.,**

The proposal of the firm was deliberated in the Technical Committee in its meeting on 31.05.2017 and committee recommended for certain amendments in the protocol. The firm represented for reconsideration of the recommendation of the committee and the firm was asked to present their proposal before the Committee.

However, the firm did not turn up for presentation and accordingly, the committee deferred the proposal for next meeting of Technical Committee.

**2. 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:**

7 proposals were placed before the Committee for consideration of permission for manufacture/import for marketing in the country with waiver of local clinical trial which were not considered by the SEC. The details of recommendations of the Committee along with recommendation of the SEC are annexed as **Annexure-I**.

The meeting ended with vote of thanks to the Chair.

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Recommendation of the 07 cases of Clinical Trials waiver in Indian Populations of 42<sup>nd</sup> Technical Committee Meeting:

S. No.	Drug Name	Indication	1. Recommendations of the SEC 2. Recommendation of Technical Committee
1.	<p><b>Name of the Drug:</b> FDC of Dapagliflozin 5mg/ 5mg/ 10mg/ 10mg + Metformin HCl ER tab 500mg/1000mg/500mg/1000mg film coated tablet.</p> <p><b>Name of the Firm:</b> M/s AstraZeneca Pharma India Ltd.</p> <p><b>Regulatory status in other countries:</b> US, EMA and Health Canada.</p>	FDC indicated as an adjunct to diet and exercise to improve glycemic control in adult with type 2 diabetes mellitus.	<p><b>1. Recommendation of the SEC:-</b></p> <p><b>Recommendation of the SEC (Endocrinology) held on 22.12.2015:</b></p> <p>“Firm presented clinical data on various studies carried out in Dapagliflozin with Metformin (IR as well as ER) as a background add-on therapy as a part of Global Clinical trial where Indian patients were also included. The strength of Dapagliflozin in these studies was 10 mg per day as OD dosage. However, firm did not present any data on the proposed strengths of the drug as FDC in 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 (Phase III) protocol for further consideration by the committee.”</p> <p><b>SEC Expert List:</b></p> <ol style="list-style-type: none"> <li>1. Dr. Rajesh Khadgawat, Professor, Dept. of Endocrinology, AIIMS, New Delhi-110029</li> <li>2. Dr. Rajesh Rajput, Senior Prof. &amp; Head, Dept. of Endocrinology, PGIMS, Medical Road, Rohtak-124001.</li> <li>3. Dr. Lalit kumar Gupta, Professor, Pharmacology, Lady Hardinge Medical College, New Delhi.</li> <li>4. Dr. Richa Dewan, Department of Medicine, MAMC New Delhi.</li> </ol>

			<p><b>Recommendation of the SEC (Endocrinology) held on 08.11.2016</b>          Firm did not bring the clinical trial protocol as per the recommendations of the previous committee, instead the firm asked for a waiver of Phase III trial. The committee insisted that as per earlier recommendations the firm should submit the protocol for Phase III trial.</p> <p><b>SEC Expert List:</b></p> <ol style="list-style-type: none"> <li>1. Dr. Richa Dewan, Department of Medicine, MAMC New Delhi.</li> <li>2. Dr. Bikash Medhi, Professor, Dept. of Pharmacology, PGIMER, Chandigarh.</li> <li>3. Dr. Md. Ashraf Ganie, Dept. of Endocrinology, AIIMS, J &amp; K.</li> <li>4. Dr. Manoj Chadha, Dept. of Endocrinology, P. D. Hinduja National Hospital Mahim, Mumbai, Maharashtra 400016.</li> </ol> <p><b>2. Recommendation of Technical Committee:-</b> The Committee discussed the justification submitted by the firm for local clinical trial waiver. Committee noted that the proposed FDC is approved in USA, EU, Canada, Australia, etc. and as per Appendix VI (b) of Drugs &amp; Cosmetics Rules, if the FDC is marketed abroad and clinical trials have been carried out with the FDC in other country, the permission for marketing may be granted based on appropriate chemical and pharmaceutical data. After detailed deliberation the committee considered the request of the firm for waiver of local clinical trial and recommended for grant of</p>
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			permission to import & market the FDC.
2.	<p><b>Name of the Drug:</b> Empagliflozin and Metformin Hydrochloride Tablets 5 mg/500 mg, 5 mg/850 mg, 5 mg/1000 mg, 12.5 mg/500 mg, 12.5 mg/850 mg, 12.5 mg/1000 mg</p> <p><b>Name of the Firm:</b> M/s. Boehringer Ingelheim India Private Limited</p> <p><b>Regulatory status in other countries:</b> USA, EU, Australia.</p>	<p>As an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus:-</p> <ul style="list-style-type: none"> <li>• when treatment with both Empagliflozin and Metformin is appropriate.</li> <li>• inadequately controlled with Metformin or Empagliflozin alone.</li> <li>• inadequately controlled with Empagliflozin or Metformin in combination with other glucose lowering products including insulin.</li> <li>• already treated with Empagliflozin and Metformin co-administered as separate tablets</li> </ul>	<p><b>1. Recommendation of the SEC</b></p> <p><b>Recommendation of SEC (Endocrinology) meeting held on 22.12.2015:-</b> In this meeting firm presented clinical data on various studies carried out 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><b>SEC Expert List:</b></p> <ol style="list-style-type: none"> <li>1. Dr. C. D. Tripathi, Professor &amp; Head Department of Pharmacology, VMMC, New Delhi.</li> <li>2. Dr. Rajesh Khadgawat, Professor, Dept. of Endocrinology, AIIMS, New Delhi-110029.</li> <li>3. Dr. Richa Dewan, Dept. of Medicine, MAMC, New Delhi.</li> <li>4. Dr. Rajesh Rajput, Senior Professor &amp; Head Department Endocrinology, PGIMS, Medical Road, Rohtak-124001.</li> </ol> <p><b>Recommendation of SEC (Endocrinology) meeting held on</b></p>

		<p><b>28.04.2016:-</b> 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><b>SEC Expert List:</b></p> <ol style="list-style-type: none"> <li>1.) Dr. C. D. Tripathi, Professor &amp; Head Department of Pharmacology, VMMC, New Delhi</li> <li>2.) Dr. Rajesh Khadgawat, Professor, Dept. of Endocrinology, AIIMS, New Delhi-110029.</li> <li>3.) Dr. Richa Dewan, Dept. of Medicine, MAMC New Delhi.</li> <li>4.) Dr. Rajesh Rajput, Senior Professor &amp; Head Department Endocrinology, PGIMS, Medical Road, Rohtak-124001.</li> </ol> <p><b>Recommendation of the Technical Committee held on 21.09.2016 –</b> After detailed deliberation, the committee endorses the recommendation of the SEC recommended for conduct of local clinical trial.</p> <p><b>2. Recommendation of Technical Committee:</b> The Committee discussed the justification submitted by the firm for local clinical trial waiver. Committee noted that the proposed FDC is approved in USA, EU, Australia, etc. and as per Appendix VI (b) of Drugs &amp; Cosmetics Rules, if the FDC is marketed abroad and clinical trials have been carried out with the FDC in other country, the permission for marketing may be granted based on appropriate chemical and pharmaceutical data.</p>
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			After detailed deliberation the committee considered the request of the firm for waiver of local clinical trial and recommended for grant of permission to import & market the FDC.
3.	<p><b>Name of the Drug:</b> FDC of Empagliflozin 10mg/25mg + Linagliptin 5mg/5mg film coated tablets.</p> <p><b>Name of the Firm:</b> M/s Boehringer Ingelheim India Pvt. Ltd</p> <p><b>Regulatory status in other countries:</b> US and EMA.</p>	The FDC is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	<p><b>1. Recommendation of the SEC:-</b></p> <p><b>Recommendation of the SEC (Endocrinology) dated 14.06.2016</b></p> <p>The firm presented the data before the committee on the proposed FDC. The Committee opined as below:</p> <ol style="list-style-type: none"> <li>Firm needs to generate and submit PK/PD data of the said FDC in Indian Patients.</li> <li>Firm need to carry out Phase-III Clinical study of the proposed FDC in the Indian Population.</li> </ol> <p>Accordingly, firm should submit the clinical trial as well as PK/PD study protocol before the committee to take further action in the matter.</p> <p><b>SEC Expert List:</b></p> <ol style="list-style-type: none"> <li>Dr. Rajesh Khadgawat, Professor, Dept. of Endocrinology, AIIMS, New Delhi-110029.</li> <li>Dr. Richa Dewan, Dept. of Medicine, MAMC New Delhi.</li> <li>Dr. Rajesh Rajput, Senior Professor &amp; Head Department Endocrinology, PGIMS, Medical Road, Rohtak-124001.</li> <li>Dr. D. S. Arya, Professor Dept. of Pharmacology, AIIMS, New Delhi.</li> <li>Dr. Manoj Chadha, Dept. of Endocrinology, P. D. Hinduja National Hospital Mahim, Mumbai, Maharashtra-400016.</li> </ol> <p><b>Recommendation of the SEC (Endocrinology) held on 20.12.2016:-</b></p> <p>The Committee opined as below:</p> <p>In the previous SEC meeting the firm</p>

		<p>was requested to submit Phase-III CT as well as PK/PD study protocol in Indian population. The firm did not present the same, Instead the firm requested for waiver of the same. The committee redeliberated and did not agree for the waiver.</p> <p>SEC Expert List:</p> <ol style="list-style-type: none"> <li>1. Dr. B.Gupta, Department of Medicine, Hindu Rao Hospital, New Delhi.</li> <li>2. Dr. Md. Ashraf Gasnie, Dept. of Endocrinology, SKIMS, J&amp;K.</li> <li>3. Dr. Bikash Medhi, Dept. of Pharmacology, PGIMER, Chandigarh.</li> <li>4. Dr. S. V. Madhu, Guru Teg Bahadur Hospital, New Drug, Dilshad Garden, Shahdara, New Delhi, Delhi-110095.</li> <li>5. Dr. Rajesh Khadgawat, Prof. Dept. of Endocrinology, AIIMS, New Delhi-110029.</li> </ol> <p><b>2. Recommendation of Technical Committee:</b></p> <p>The Committee discussed the justification submitted by the firm for local clinical trial waiver. Committee noted that the proposed FDC is approved in USA, EU, etc. and as per Appendix VI (b) of Drugs &amp; Cosmetics Rules, if the FDC is marketed abroad and clinical trials have been carried out with the FDC in other country, the permission for marketing may be granted based on appropriate chemical and pharmaceutical data. After detailed deliberation the committee considered the request of the firm for waiver of local clinical trial and recommended for grant of permission to import &amp; market the FDC.</p>
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4.	<p><b>Name of the Drug:</b> FDC of Daclatasvir 60 mg + Sofosbuvir 400 mg Film coated tablets</p> <p><b>Name of the Firm:</b> M/s. Natco Pharma Limited</p> <p><b>Regulatory status in other countries:</b> Not approved.</p>	<p>It is indicated for treatment of all genotypes chronic Hepatitis C virus (HCV) infection.</p>	<p><b>1. Recommendation of the SEC:</b></p> <p><b>Recommendation of the SEC (Antimicrobial, Antiviral, Antiparasitic, Antifungal) held on 22-09-2016:</b></p> <p>The proposal was already discussed by the Committee on 23.3.2016 and the Committee recommended for approval of the FDC with Bioequivalence Study. Subsequently it was felt that a wider consultation is required as this FDC is not approved anywhere in any developed country and there could be safety concern when these two drugs are combined together. The proposal was re-examined and in the meanwhile the firm also proposed Phase-III Clinical trial. The Committee deliberated on the issue and recommended that:-</p> <ol style="list-style-type: none"> <li>i. In all the FDCs/Combikit, Firm should conduct Bioequivalence Study as well as Phase-III Clinical Trials for which protocol may be submitted.</li> <li>ii. M/s Natco Pharma informed the committee that they have already conducted a Bioequivalence Study on 24 healthy subjects for export purpose. The firm was asked to submit the BE Study data to the office of DCG(I).</li> <li>iii. M/s Natco Pharma also presented a Phase-III Clinical trial protocol in which following recommendations were made: <ol style="list-style-type: none"> <li>a. Before the start of Clinical trial, BE Study data shall be evaluated by the office of DCG(I) and if found satisfactory CT permission may be issued.</li> <li>b. In the proposed Clinical trial protocol, CKD patients with Creatinine &gt;1.5 mg should be excluded.</li> <li>c. The patients receiving Amiodarone should be excluded</li> <li>d. Cardiac evaluation including ECG and Echocardiogram</li> </ol> </li> </ol>
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		<p>should be conducted at baseline, 2weeks, 4weeks, 12 weeks and 24 weeks. e. Study duration shall be 24 weeks. f. Study shall be conducted in the sites geographically distributed in the country.</p> <p>Accordingly, the firm shall revise the Clinical trial protocol. The other two firms M/s Hetero and M/s Mylan also are required to follows the same recommendations as recommended for M/s Natco for conducting CT/BE Study. It was also observed that M/s Hetero does not have approval for Daclatasvir 30mg tablets</p> <p><b>SEC Expert List:</b></p> <ol style="list-style-type: none"> <li>1. Dr. Archana Thakur, Director and Professor, Dept. of Microbiology, G.B.Pant Hospital, New Delhi, Delhi-110002.</li> <li>2. Dr. Varsha Gupta, Professor, Dept. of Microbiology, Govt. medical college and Hospital (GMCH), Sector 32, Chandigarh-160030.</li> <li>3. Dr. B.Gupta, Dept. of Medicione, NDMC &amp; Hindu Rao Hospital, New Delhi.</li> <li>4. Dr. S. K. Sharma, Dept. of Medicine, AIIMS, New Delhi.</li> <li>5. Dr. Amita Jain, Prof. Dept. of Microbiology, KGMC, Lucknow.</li> <li>6. Dr. S. K. Sarin, ILBS New Delhi.</li> <li>7. Dr. Y. K. Gupta, Prof. and Head, Dept. of Pharmacology, AIIMS, New Delhi.</li> </ol> <p><b>Recommendation of the SEC (Antimicrobial, Antiviral, Antiparasitic, Antifungal) held on 11-04-2017:</b></p> <p>The firm presented the BE study data conducted for export purpose as recommended by the Committee in the previous meeting held on 22.09.2016. The committee reviewed and found the BE data satisfactory. Further the firm</p>
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		<p>also requested for the CT waiver based on the recent circular issued by DCG(I) on 20.03.2017. The Committee did not recommend for the CT waiver as the proposed drug does not fall under the category of extreme urgency.</p> <p><b>SEC Expert List:</b></p> <ol style="list-style-type: none"> <li>1. Dr. Archana Thakur, Director and Professor, Dept. of Microbiology, G.B.Pant Hospital, New Delhi, Delhi-110002.</li> <li>2. Dr. Varsha Gupta, Professor, Dept. of Microbiology, Govt. medical college and Hospital (GMCH), Sector 32, Chandigarh-160030.</li> <li>3. Dr. B.Gupta, Dept. of Medicione, NDMC &amp; Hindu Rao Hospital, New Delhi.</li> <li>4. Dr. Subash C. Parija, Sr. Prof. &amp; HOD, Microbiology, JIPMER, Puducherry.</li> <li>5. Dr. Amita Jain, Prof. Dept. of Microbiology, KGMC, Lucknow.</li> <li>6. Dr. C. D. Tripathi, Department of Pharmacology VMMC &amp; Safdarjung Hospital, New Delhi.</li> <li>7. Dr. Pratip Kundu, MD Professor of Microbiology &amp; Medical Superintendent cum vice Principal, school of Tropical Medicine Chittaranjan Avenue Kolkata.</li> <li>8. Dr. Abhishek Agrawal Prof. Dept. of Medicine SMS Medical College, Jaipur 2744555.</li> </ol> <p><b>2. Recommendation of Technical Committee:</b></p> <p>The Committee discussed the justification submitted by the firm for clinical trial waiver. After detailed deliberation, the committee opined that two hepatologists may be invited in the next meeting for deliberation on the issue and the firm may be asked for presentation of their justification</p>
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			alongwith clinical trial data, if any.
5.	<p><b>Name of the Drug:</b> Nivolumab</p> <p><b>Name of the Firm:</b> M/s Bristol Myers Squibb Company.</p> <p><b>Regulatory status in other countries:</b> USA, EU, Canada, Japan, and Switzerland</p>	Phase IV	<p><b>1. Recommendation of SEC:</b></p> <p><b>Recommendation of the SEC (Oncology) held on 13-04-2017:</b> After detail deliberation of the phase IV clinical trial, committee noted that, the firm was granted permission with the waiver of Phase III trial. Accordingly, Committee recommended for approval of Phase IV protocol with condition to conduct the Phase IV trial in at least 200 subjects instead of proposed 50 subjects (in reference to Guidelines on Similar Biologics-2016).</p> <p><b>List of Experts:-</b></p> <ol style="list-style-type: none"> <li>1. Dr. Sameer Bakshi, Professor, Dept. of Oncology, AIIMS, New Delhi.</li> <li>2. Dr. C. K. Bose, Assistant Professor, Netaji Subhash Chander Bose, Cancer Research Institute, Kolkata.</li> <li>3. Dr. Renu Saxena, Prof. &amp; Head, Dept. of Haematology, AIIMS, New Delhi.</li> <li>4. Dr. H. P. Pati, Professor, Dept. of Haematology, AIIMS, New Delhi.</li> <li>5. Dr. D. S. Arya, Professor, Dept. of Pharmacology, AIIMS, New Delhi.</li> </ol> <p><b>Recommendation of the SEC (Oncology) held on 23-06-2017:</b> Firm presented the proposal to re-consider the condition recommended by the Subject Expert committee (Oncology and Hematology) dated 13-Apr-2017 for the subject numbers to be recruited in the Phase IV clinical trial (CA209887 with Nivolumab) before the committee. After detailed deliberation the committee did not agree for the reduction in the sample size from 200 to 100 as there is no obvious reason for the same and such</p>

			<p>approved indications are very common in India.</p> <p><b>SEC Expert List:</b></p> <ol style="list-style-type: none"> <li>1. Dr. (Brig.) Ajay Sharma, Prof &amp; Sr. Advisor Army Hospital (Research &amp; Referral);</li> <li>2. Dr. Sameer Bakshi, Professor, Dept. of Oncology, AIIMS, New Delhi.</li> <li>3. Dr. Shalini Chawla, Director-Professor, Dept. Of Pharmacology, MAMC, Delhi.</li> <li>4. Dr. C. K. Bose, Assistant Professor, Netaji Subhash Chander Bose, Cancer Research Institute, Kolkata.</li> </ol> <p><b>2. Recommendation of Technical Committee:</b></p> <p>The Committee deliberated the firm's request for reduction in sample size from 200 subjects to 100 subjects for Phase IV clinical trial and noted that Nivolumab of M/s Bristol Myers Squibb is the innovator's product and is not a similar biologic. Also, more than 70 clinical trials/ studies have been conducted with Nivolumab till date. Therefore, the Committee accepted the firm's request and recommended for conduct of Phase IV clinical trial in 100 subjects.</p>
6.	<p><b>Name of the Drug:</b> Coated Vicryl plus Antibacterial (Polyglactin 910) Suture (w/wo needle) (Absorbable).</p> <p><b>Name of the Firm:</b> M/s. Johnson &amp; Johnson Ltd., Mumbai.</p> <p><b>Regulatory status in India:</b> Approved</p>	<p>It is indicated for use in general soft tissue approximation and/or ligation, except for ophthalmic cardiovascular and neurological tissue.</p>	<p><b>1. Recommendation of the SEC:-</b></p> <p><b>Recommendation of the SEC (Antimicrobial &amp; Antiviral) held on 30.01.2015.</b> The committee made the following recommendations:</p> <p>“The committee recommended that the product may be continued for marketing in the country. However, the firm should carry out in-vivo controlled study to establish the duration of efficacy of the product in comparison to plain sutures in patients”.</p>

<p><b>Regulatory status in other countries:</b> USFDA, EU, Canada, Japan and Australia.</p>	<p><b>SEC Expert List:</b></p> <ol style="list-style-type: none"> <li>1. Dr. Archana Thakur, Professor, Department of Microbiology, G. B. Pant Hospital, New Delhi.</li> <li>2. Dr. Varsha Gupta, Professor, Department of Microbiology, Government Medical College and Hospital, Chandigarh.</li> <li>3. Dr. Parija Subhash, Senior Professor &amp; Head, Department of Microbiology, JIPMER, Puducherry.</li> <li>4. Dr. Amita Jain, Professor, Department of Microbiology, KGMC, Lucknow.</li> <li>5. Dr. Priya Abrahm, HOD, department of Clinical Virology, CMC, Vellore.</li> <li>6. Dr. Bikas Medhi, Department of Pharmacology, PGIMER, Chandigarh.</li> <li>7. Dr. Kamal Kishore, Clinical Pharmacology, AIIMS, New Delhi.</li> </ol> <p><b>Recommendation of the SEC (Antimicrobial &amp; Antiviral) held on 23.03.2016.</b></p> <p>The committee recommended that the product may be continued to be marketed in the country as per USFDA approved indications only. The firm shall provide efficacy data in Indian populations within 12 months for further review.</p> <p><b>SEC Expert List:</b></p> <ol style="list-style-type: none"> <li>1. Dr. Varsha Gupta, Professor, Department of Microbiology, Government Medical College and Hospital, Chandigarh.</li> <li>2. Dr. D. S. Arya, Professor, Department of Pharmacology, AIIMS, New Delhi.</li> <li>3. Dr. B.Gupta, Dept. of Medicine, NDMC &amp; Hindu Rao Hospital, New Delhi.</li> </ol>
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			<p>4. Dr. S. K. Sharma, Dept. of Medicine, AIIMS, New Delhi.</p> <p><b>Recommendation of the 39th Technical Committee held on 06.02.2017:-</b></p> <p>The committee after detailed deliberation recommended that a report should be asked on the safety and efficacy of drug from premier institutions like AIIMS, RML hospital and Safdurjung Hospital and the report should be submitted before the committee for further deliberation.</p> <p><b>2. Recommendation of Technical Committee:</b></p> <p>After detailed deliberation and based on the recommendations made by three premier Medical Institutes, the Technical Committee recommended for continuation of the said product i.e. Triclosan coated Polyglactin/ 910 suture (Vicryl Plus) in the country and waived the conduct of efficacy data in Indian populations as recommended in the earlier SEC meetings.</p>
7.	<p><b>Name of the Drug:</b> Sodium Hyaluronate eye drops 2mg/1ml (Additional Strength)</p> <p><b>Name of the Firm:</b> M/s Ursa Pharma</p> <p><b>Regulatory status in India:</b> Sodium Hyaluronate 0.1%w/v for dry eyes on 16/01/2009 and Sodium Hyaluronate 0.18% w/v eye drops For the treatment sensation of ocular dryness, other minor complaints of no pathological significance viz. burning and ocular fatigue induced for example by dust,</p>	<p>For symptomatic use in the treatment of dry eyes (Dry eye syndrome) including severe case and after surgical interventions.</p>	<p><b>1. Recommendation of SEC:-</b></p> <p><b>Recommendation of the NDAC (Ophthalmology) held on 27.04.2013:-</b></p> <p>The proposal was deliberated in NDAC meeting held on 27/04/2013 and the committee has stated that in India, Sodium Hyaluronate eye drops is already available in 0.1% and 0.18%. It seems there will not be any significant superiority of the proposed 0.2% strength of the product over the existing 0.18%. Therefore the Committee recommended that unless superiority of the proposed product of 0.2% strength over existing 0.18% strength is</p>

	<p>smoke, dry atmosphere, air-conditioning extended computer screen use or contact lens wear on 21/06/2005.</p> <p><b>Regulatory status in other countries:</b> European Union.</p>	<p>established, the proposal to market the product cannot be considered. Firm has submitted published clinical studies and requested for re-examination.</p> <p><b>Recommendation of the NDAC (Ophthalmology) held on 24.02.2014:-</b></p> <p>The proposal was again deliberated for the 2nd time in NDAC held on 24/02/2014. The committee opined that proposed strength 0.2% is superior to 0.18% strength. Duration of action is prolonged due to higher viscosity. The committee recommended that firm has to conduct Phase II clinical trial and accordingly submit the clinical trial protocol.</p> <p>The firm has requested for CT waiver. Quoting the viscosity as the major factor and published literature. The firm vide letter dated 10/05/2017– requested waiver based on the recommendation of Prof. Ranjit Roy Choudary Committee report.</p> <p><b>Recommendation of the SEC (Ophthalmology) held on 26.07.2017:-</b></p> <p>The committee stated that, earlier the proposal has been deliberated in NDAC ophthalmology meetings held on 27/04/2013 &amp; 24/02/2014 and the committee had asked for conduct of phase III clinical trial. After detailed deliberation, the committee reiterated the need for phase III clinical trial as the firm has not presented any data supporting superiority of 0.2% over 0.18% of sodium hyaluronate eye drops.</p> <p><b>SEC Expert List:</b></p> <ol style="list-style-type: none"> <li>1. Dr. V.P. Gupta, Director, Professor &amp; Head, UCMS, New Delhi.</li> </ol>
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