MINUTES OF 44th MEETING OF THE TECHNICAL COMMITTEE HELD ON 05.09.2018 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. S. Venkatesh,** Director General of Health Services, Nirman Bhawan, New Delhi	Chairman
2.	**Dr. Nandini Kumar,** Former Dy. Director General Sr. Grade, Adjunct Professor, KMC, Manipal, Chennai.	Member
3.	**Dr. P.K Dalal,** Professor & Head, General Psychiatry & Drug de-addiction, King George's Medical University, Chowk, Lucknow, U.P.	Member
4.	**Dr. B.L Sherwal** Director, Rajiv Gandhi Super Speciality Hospital Tahirpur, New Delhi-110093	Member
5.	**Dr. Yash Paul** Prof.& Head, Dept of cardiology PGIMER, Chandigarh	Member
6.	**Dr Sanjay Tyagi** Prof.& Head, Dept of cardiology GB Pant Hospital, New Delhi	Member

From CDSCO:

1. Dr. S. Eswara Reddy
   Drugs Controller General (India)
2. Dr. V. G. Somani,
   Joint Drugs Controller (India)
3. Mr. A. K. Pradhan,
   Deputy Drugs Controller(India)
4. Mr. R Chandrashekar
   Deputy Drugs Controller (India)

The Chairman welcomed the committee members for the 44th Technical Committee meeting. Thereafter, total 7 proposals which were not considered for approval by the Subject Expert Committee were placed before the committee for deliberation. The committee discussed the proposals one after another. The details of the proposals and recommendation of the committee are as under:

Agenda No. 1

Proposal of M/s Emcure Pharmaceuticals Limited for grant of manufacture and marketing permission of Sucroferric Oxyhydroxide Chewable Tablets 500mg with request for waiver of local clinical trial.

Applicant: M/s Emcure Pharmaceuticals Limited

Drug Name: Sucroferric Oxyhydroxide Chewable Tablets 500mg
Sucroferric Oxyhydroxide is a non-calcium, iron-based phosphate binder used for the control of serum phosphorus levels in adult patients with chronic kidney disease (CKD) on haemodialysis (HD) or peritoneal dialysis (PD). It is used in form of chewable tablets.

Type of Application: Manufacture and market
Proposed Indication: Indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.

Regulatory Status: The drug is approved in USA, European Union, France and UK.

Recommendation of the SEC (Cardiovascular & Renal) meeting held on 05.07.2016:
The firm had presented the proposal before the committee. After detailed deliberation, the Committee was of the opinion that the proposed drug did not meet the criteria for local clinical trial waiver.
Therefore, the Committee had not recommended for grant of manufacturing and marketing permission with local clinical trial waiver.

On subsequent response of the applicant, the proposal was again deliberated in SEC (Cardiovascular & Renal) meeting held on 25.07.2017:
Recommendation of the SEC (Cardiovascular & Renal) meeting held on 25.07.2017:
The firm presented their proposal for waiver of local clinical trial. However the committee after detailed deliberation recommended that the drug did not fall under the criteria for local Phase III clinical trial waiver.
However, the firm did not agree with the recommendation of SEC and has requested to deliberate the proposal in Technical Committee for grant of manufacture and marketing permission of Sucroferric Oxyhydroxide Chewable Tablets 500mg with request for waiver of local clinical trial.

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Recommendation: - The firm presented their justification for the waiver of local clinical trial before the committee highlighting that the drug acts locally in the GI tract with no systemic absorption, metabolism and hence clinical trial in such case may not be relevant.. After detailed deliberation the committee recommended that firm should conduct bioequivalence studies of their product comparing with the innovator's products based on PD evaluation .Accordingly the firm should submit the protocol for the review by the SEC. If the results of BE study is found satisfactory, the drug may be considered for approval subject to the phase-IV clinical trial.

Agenda No. 2

Proposal of M/S Sun Pharma Laboratories Limited for grant of manufacturing and marketing permission of FDC of Cephelexin Extended release and Clavulanate Potassium Tablets (375mg + 125mg) and (750mg + 125mg).

Applicant: M/s Sun Pharma Laboratories Limited

Drug Name: Fixed dose combination of Cephelexin Extended release and Clavulanate Potassium Tablets (375mg + 125mg) and (750mg + 125mg).

Type of Application: Manufacturing and marketing

Proposed Indication: In the treatment of Upper Respiratory Tract infections (URTI) and Dental infections.

Regulatory Status: FDC is not approved in any country.

Earlier, the firm conducted a non-comparative clinical trial and results of the study was placed before NDAC in its meeting held on 25.05.2012.

Recommendations of NDAC (Antimicrobial, Antiparasitic, Antifungal and Antiviral) meeting held on 25.05.2012;

FDC is not approved in any country and further the clinical trial data generated by the firm is not adequate to support the efficacy of the formulation. Therefore, the committee did not recommend for the FDC.

On subsequent response of the applicant, the proposal was again deliberated in NDAC (Antimicrobial, Antiparasitic, Antifungal and Antiviral) meeting held on 12.04.2013.

Recommendations of NDAC (Antimicrobial, Antiparasitic, Antifungal and Antiviral) meeting held on 12.04.2013:-

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Committee recommended that a comparative double blind trial of Cephalexin+ Clavulanate Potassium vs Cephalexin should be conducted to show the superiority of the FDC. Protocol etc. should be submitted to the committee for examination.

On subsequent response of the applicant, the proposal was again deliberated in NDAC (Antimicrobial, Antiparasitic, Antifungal and Antiviral) meeting held on 18.06.2014.

Recommendations of NDAC (Antimicrobial, Antiparasitic, Antifungal and Antiviral) meeting held on 18.06.2014:-

As per the recommendations of the NDAC previously, firm presented the protocol before the committee for conducting the clinical trial. The committee recommended for conducting the proposed trial. In terms of Risk/ Benefit, the committee opined that the FDC will have superiority over Cephalexin alone. Regarding unmet need and Innovation vis a vis current therapy, the committee opined that the proposed FDC will be useful in the said resistant patients. The committee also recommended including at least one site from North-East region of India.

However, firm vide letter dated 20.06.2014 informed that experts during NDAC meeting held on 18.06.2014 agreed that the comparative trial will not show any significant superiority of FDC over cephalexin alone on the basis of scientific explanation submitted by the firm.

The proposal was also placed before Technical committee in its meeting held on 17.11.2014. Accordingly the firm was granted permission to conduct Phase III clinical trial with FDC of Cephalexin Extended Release (375 mg) and Clavulanate Potassium (125 mg) tablets with Cephalexin Extended release (375 mg) tablets – A randomized Double-blind study on 18.12.2014.

Subsequently, the firm has submitted the clinical report to this office on 05.04.2017 and the clinical report was placed in SEC (Antimicrobial, Antiparasitic, Antifungal and Antiviral) meeting held on 22.09.2017.

Recommendations of SEC (Antimicrobial, Antiparasitic, Antifungal and Antiviral) meeting held on 22.09.2017;

"The firm presented the results of two phase III clinical trials of FDC of Cephalexin + Clavulanate Vs Cephalexin alone. Committee observed that there was no statistically significant difference of efficacy between the two groups. Hence based on these data there is no justification for this combination".

On subsequent response of the applicant, the proposal was again deliberated in SEC (Antimicrobial, Antiparasitic, Antifungal and Antiviral) meeting held on 12.12.2017.

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Recommendations of SEC (Antimicrobial, Antiparasitic, Antifungal and Antiviral) meeting held on 12.12.2017;

"The firm presented their justification for approval of the product based on clinical trial data generated. The Committee deliberated in detailed and reiterated its earlier stand that there was no statistically significant difference of efficacy between the two groups. Hence based on these data there is no justification for this combination".

However, the firm did not agree with the recommendations of SEC and has requested to deliberate the proposal in Technical Committee for considering the application for grant of manufacturing and marketing permission of the FDC of Cephalexin Extended release and Clavulanate Potassium Tablets (375mg+125mg) and (750mg+125mg). The firm has mentioned that:

1. The trial proposal was evaluated by the NDAC and approval was granted.
2. The trial was not a superiority trial and hence showing statistical significant difference of FDC was not possible. The result of the clinical trials are comparable and in lines with the approved protocol with non-inferiority design.
3. Various guidance documents of United States Food and Drug Administration (USFDA) and European Medicine Agency (EMA) recommend non-inferiority design for conducting clinical trials with antimicrobials.
4. Antimicrobials are also approved internationally based on non-inferiority clinical trial.
5. CDSCO guideline on FDC product also recommends non-inferiority clinical trial design in case of combination with clavulanic acid.
6. In-vitro study proved that the combinations shows MIC >4 fold fall as compared to Cephalaxin at MIC50 and MIC90 in both combination ratio6:1 and 3:1 against Beta-Lactmase producing eighty two strains of clinical isolates taken in the study.

Recommendation:- The firm presented the clinical trial data as well as some in vitro data in support of efficacy of the FDC' in resistant strain of MSSA (Methicillin-Susceptible Staphylococcus aureus) before the committee. After detailed deliberation the committee recommended that firm should conduct an in vitro study to assess the efficacy of the FDC in resistant strain of MSSA in community setup with statistically justified sample size. Accordingly, the firm should submit a protocol for the in-vitro study with statistical justification on sample size along with Phase-IV clinical trial protocol for review by the Technical Committee. If the results in-vitro study is found satisfactory, the FDC may be considered for approval subject to the phase-IV clinical trial.

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Agenda No. 3

Proposal of M/s Meril Life sciences Pvt. Ltd. for grant of manufacturing and marketing permission of MYVAL™ Transcatheter aortic valve replacement system.

Applicant: M/s Meril Life sciences Pvt. Ltd.

Device Name: MYVAL™ Transcatheter aortic valve replacement system.

Proposed device consists of a ballon – expandable radiopaque,nickel-cobalt alloy frame, A gluterldehyde terephthalate (PET) fabric, PET commissure support, Biocompatible, 4/0 white, 5/0 white & green and 6/0 white polyster suture.

Type of Application: Manufacturing and marketing

Proposed Indication:- The MYVAL™ Transcatheter aortic valve Replacement system including components is indicated for relief of aortic stenosis in patients with symptomatic heart disease due to severe native calcific aortic stenosis who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy.

Regulatory Status: : The below mentioned similar products are approved in India, Europe, and USA.

- Edwards SAPIEN transcather heart manufactured by M/s. Edward life sciences LLC, Irvine , CA,9261 and
- Medtronic core valve system manufactured by M/s Medtronic core valve LIC, 3576 Unocal place, Santa Rosa, CA 95403e approved in India, Europe and USA.

Earlier, the firm was granted permission to conduct clinical study entitled, "A Prospective, multicentric, single arm, open label study of MyVal™ Aortic Transcatheter Aortic Valve Replacement system in the treatment of severe symptomatic native aortic valve stenosis" on 20.07.2016.

Recommendations of SEC (Cardiovascular & Renal) meeting held on 26.04.2018:-

The firm presented the clinical trial data of 30 patients with one month follow up before the committee. The committee noted that the data were encouraging in terms of safety and efficacy of the product. After detailed deliberation, the committee recommended that the firm should submit one year follow-up data as per protocol for further review by the said committee.

The firm submitted 06 months follow up data and requested this office to grant permission to manufacture and market of the proposed product. The proposal was deliberated in SEC (Cardiovascular & Renal) in its meeting dated 26.06.2018.

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Recommendations of SEC (Cardiovascular & Renal) meeting held on 26.06.2018:- The firm presented their proposal before the committee. After detailed deliberation and examination of international trial practices for follow up period with regards to Trans-catheter aortic valve replacement system, the committee recommended that the firm should continue the trial up to 12 months and submit the report for evaluation for approval of the product and further conduct the trial as per the approved protocol.

Now, the firm has again requested to grant the permission to manufacture and market based on the 06 months follow up data generated upon conduct of the said clinical trial.

Recommendation:- The firm presented the clinical trial data on 30 patients out of which 20 patients have completed follow-up of more than 12 month. After detailed deliberation the committee recommended for grant of permission to manufacture and market the product based on the data presented by the firm.

Agenda No. 4

Proposal of M/s Ordain Healthcare Global Pvt. Ltd for grant of import and marketing permission of Rituximab 100 mg/mL and 500 mg/mL concentration for solution for infusion.

Applicant: M/s Ordain Healthcare Global Pvt. Ltd, Chennai, India

Drug Name- Rituximab 100 mg/mL and 500 mg/mL concentration for solution for infusion

Type of application- Import and Marketing

Proposed Indication- Diffuse Large B-Cell Lymphoma (DLBCL)

Regulatory Status- Drug is approved in USA, EU, UK, Australia and Germany Etc.

Recommendation of SEC (Oncology & Haematology) meeting on 07.02.2018:-

The firm presented the Phase III Global Clinical Trial study report conducted on 239 patients including 73 Indian patients before the committee. After detailed deliberation, the committee opined the following;

1. The firm should complete the study by recruiting at least 110 evaluable subjects from India as was proposed in the earlier approved protocol.
2. The firm needs to present the entire data with proper consort diagram, accounting for all the randomized patients.
3. The firm should also present the India specific data in comparison with Global data.

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4. The details of serious adverse events (SAEs) need to be specified.

Recommendation of SEC (Oncology & Haematology) meeting held on 23.05.2018:-

In pursuance of the recommendation of SEC meeting held on 07.02.2018, the firm again presented the India specific data of 73 patients included in global clinical trial conducted on 239 patients in comparison with the global data on 23.05.2018. However, after detailed deliberation the committee recommended that the firm should generate data on additional at least 37 patients so that the data is generated on at least 110 evaluable Indian subjects under the clinical trial protocol already approved, for further consideration.

However, the firm did not agree with the recommendations of SEC and has requested to deliberate the proposal in Technical Committee for grant of import and marketing permission of Rituximab 100 mg/mL and 500 mg/mL concentration for solution for infusion.

Recommendation:- The firm presented their justification for approval of the product based on the India specific global clinical trial conducted on 239 patients including 73 Indian patients before the committee. After detailed deliberation the committee recommended that the firm should generate data on additional at least 37 patients so that the data is generated on at least 110 evaluable Indian subjects as recommended by the SEC.

Agenda No. 5

Proposal of M/s Novartis Pharmaceuticals Ltd. for grant of Manufacturing & Marketing permission of Vildagliptin MR tablet 100 mg (Additional Dosage form & Add. Indication) with request for waiver of local clinical trial & BE study.

Applicant:- M/s. Novartis Pharmaceuticals Ltd.

Drug Name:- Vildagliptin Modified Release (MR) Tablet 100mg.

Type of Application: Import & Marketing.

Proposed Indication: As an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus (T2DM).

- **As monotherapy**
- **In dual combination**
  - With metformin, when diet, exercise and metformin alone do not result in adequate glycemic control.
  - With a sulfonylurea (SU), when diet, exercise and a SU alone do not result in adequate gylcemic control.
  - With a thiazolidinedione (TZD) when diet, exercise and a TZD do not result in adequate glycemic control.

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- **In Triple combination**
  - With a sulfonylurea and metformin when diet and exercise plus dual therapy with these agents do not provide adequate glycemic control.
    Vidagliptin is also indicated in combination with insulin (with or without metformin) when diet, exercise and a stable dose of insulin do not result in adequate gylcemic control.
    Vidagliptin is also indicated as initial combination therapy with metformin in patients with T2DM whose diabetes is not adequately controlled by diet and exercise alone.

Regulatory status

1. **Vildagliptin Tablets 50mg/100mg**,
   Indication: As an adjunct to diet and exercise to improve glycemic control in patients with type-II diabetes mellitus, approved on 18.01.08 (M/s Novartis Pharmaceuticals Ltd)
2. **Vildagliptin 50mg/50mg/50mg + Metformin Hcl 500mg +850mg +1000mg tablets,**
   Indicated :
   (i) For the treatment of Type 2 diabetes mellitus when single drug therapy alongwith diet, exercise do not result in adequate glycemic control, approved on 21.07.08
   (ii) Indicated for the treatment of Type 2 diabetes mellitus having HbA1c> 8% where diabetes is not adequately controlled by diet and exercise alone, approved on 22.10.2013.

International approval status:

Galvus 50 mg tablets:-
Therapeutic indications Vildagliptin is indicated in the treatment of Type 2 diabetes mellitus in adults:

As monotherapy - in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

As dual oral therapy in combination with - metformin, in patients with insufficient glycaemic control despite maximal tolerated dose of monotherapy with metformin, - a sulphonylurea, in patients with insufficient glycaemic control despite maximal tolerated dose of a sulphonylurea and for whom metformin is inappropriate due to contraindications or intolerance, - a thiazolidinedione, in patients with insufficient glycaemic control and for whom the use of a thiazolidinedione is appropriate.

As triple oral therapy in combination with - a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control. Vildagliptin is also indicated for use in combination with insulin (with

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or without metformin) when diet and exercise plus a stable dose of insulin do not provide adequate glycaemic control.
Novartis Europharm Limited Vista Building Elm Park, Merrion Road Dublin 4 Ireland
Date of first authorisation: 26 September 2007.

Recommendation of SEC (Metabolism & Endocrinology) meeting dated 17.07.2018:-

The firm presented their proposal for Vildagliptin MR Tablets 100mg (Additional dosage form and additional indication) before the committee. After detailed deliberation, the committee, did not recommend for waiver of BE study as well as clinical trial".
However, the firm did not agree with the recommendations of SEC and had stated that they would be conducting a Bioequivalence study and do not agree with conducting of Clinical trial with the formulation. The firm has submitted the following justification:-

1. Vildagliptin is presently approved in India as Vildagliptin 50mg BID for more than 10 years.
2. Vildagliptin tablet 50mg is currently approved in more than 132 countries worldwide.
3. Vildagliptin has an estimated post marketing exposure of 8855442 PTYs. The safety of product is continuously monitored and reported to Health authorities including India via PSURs.
4. A modified release formulations of Vildagliptin (100mg) with one daily dosing can provide an additional treatment option in Type 2 Diabetes Mellitus patients, which has the potential of achieving similar efficacy with lower dosing and exposure than the current Vildagliptin IR formulation (50mg) twice daily dosing. This could be beneficial for patients with type 2 diabetes.
5. Vildagliptin 100mg MR OD is likely to provide similar effects as that for 50mg BID IR.
6. Vildagliptin 100mg MR OD and Vildagliptin 50mg BID showed comparable inhibition effect on DPP-4 activity.
7. Vildagliptin 100mg MR OD and Vildagliptin 50mg BID showed comparable inhibition effect on glucose reduction and were safe and well tolerated in subjects with type 2 diabetes.

Firm has submitted (PK/PD) Clinical study data of study CLAF237A2351: A randomized, open-label, three period, cross-over study to evaluate the pharmacokinetics, pharmacodynamics, safety, and tolerability of two new LAF237 100mg and 150mg modified release formulations in patients with type 2 diabetes.

The firm has now proposed for single dose as well as multiple dose steady state bio-equivalence studies with 1.Vildagliptin MR Tablets OD versus Vildagliptin Tablets BD.

Recommendation: - The firm presented the rationale for the Vildagliptin 100 mg MR tablets (OD) along with hepato-toxicity profile of the drug and proposed for single dose as well as multiple dose steady state BA/BE studies before the committee. The committee. after detailed deliberation recommended that firm should conduct single

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dose as well as multiple dose BA/BE studies of Vildagliptin 100mg MR OD Vs Vildagliptin 50mg BID. If the results of the single dose and multiple dose BA/BE studies are found satisfactory, the MR tablets may be considered for approval . Accordingly the firm should submit and present the single dose and the multiple dose BA/BA study protocols before the SEC for review.

Agenda No. 6

Permission for use of Ivermectin (3mg) tablets in Triple Drug Therapy for co-administration with Albendazole and Diethylcarbamazine (DEC) for elimination of Lymphatic Filariasis- regarding

This office has received a request from Directorate of National Vector Borne Disease Control Programme (NVBDCP) for NOC for use of Ivermectin (3mg) tablets in Triple Drug Therapy for co- administration with Albendazole and Diethylcarbamazine (DEC) for elimination of Lymphatic Filariasis.

DEC and Albendazole are already in use under NVBDCP for Mass Drug Administration for elimination of Lymphatic Filariasis. Ministry of Health and Family Welfare has approved a pilot on IDA (triple drug therapy) in 5 districts viz, Nagpur (Maharashtra), Varanasi (Uttar Pradesh). Arwal (Bihar), Simdaga (Jharkhand) and Yadgir (Karnataka). Ivermectin (3mg) tablets for elimination of Lymphatic Filariasis will be made available through WHO on donation basis.

The NVBDCP has proposed to use of Ivermectin (3mg) tablets in different doses based on age/body weight as Triple Drug Therapy to be co-administered with Albendazole and Diethylcarbamazine (DEC) for elimination of Lymphatic Filariasis under National Vector Borne Disease Control Programme.

It is reported that approval status of the Ivermectin 3mg tablet for human use is not available in CDSCO. However certain formulations have been approved by CDSCO. FDC of Albendazole IP 400mg and Ivermectin IP 6mg was first approved on 25/04/2009 for treatment of intestinal helminthes and suppression of Microfilaremia especially with bancrofti infections.

Recommendation:- The proposal was deliberated before the committee. The committee after detailed deliberation recommended the use of Ivermectin 3 mg tables in triple drug therapy for co-administration with albendazole and Diethylcarbamazine (DEC) for elimination of lymphatic Filariasis under NVBDCP.

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Agenda No. 7

Proposal of M/s Torrent Pharmaceuticals Ltd. for grant of Permission to conduct Phase III Clinical Trial for Tapentadol nasal spray 225mg/ml.

Applicant:- M/s Torrent Pharmaceuticals Ltd.

Drug Name: Tapentadol Nasal Spray 225mg/ml

Type of Application: Application for grant of NOC to conduct Phase III clinical trial of Tapentadol Nasal Spray 225mg/ml.

Proposed Indication: For relief of moderate to severe acute pain in adults for a period not exceeding 5 days.

CDSCO approval status

Drug Name	Indication	Date of Approval
Tapentadol Extended release Tablet 50mg (Additional Strength)	For use in in-patients for dose titration under hospital settings for severe acute pain for a period not exceeding 5 days.	12-11-2013
Tapentadol Extended release tablet 100/150/200mg (Additional strength)	For use in in-patients under hospital setting for severe acute pain for a period not exceeding 5 days.	09.12.2013
Tapentadol Hydrochloride Tablets 50mg/75mg/100mg	For relief of moderate to severe acute pain in adults 18 years of age or older.	18.04.2011

International approval status:

NUCYNTA® Tapentadol Immediate release oral tablet50/75/100mg is approved by USFDA.

History of Proposal

Earlier the proposal (Manufacturing & Marketing permission of Tapentadol Nasal Spray 125mg/ml, 225mg/ml, 250mg/ml) was deliberated with 27th SEC (Analgesic) meeting held on 06-12-2016. Firm presented the Part-A (Single dose ascending study) of the CT report. After detailed deliberation, the committee approved the proposed Part-B (Multiple Ascending dose study). However the terms and conditions of the previous approval remains same (NDAC Analgesic held on 22.03.2013).

Accordingly, firm has submitted the results of Part–B of Phase I (Multiple Ascending dose study) with 38th SEC-Analgesic & Rheumatology meeting on 14.03.2018. and proposed for Phase III study protocol for Tapentadol Nasal Spray 225mg/ml.

Recommendation of SEC (Analgesic & Rheumatology) meeting held on 14.03.2018:-

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The firm presented the Part-B Phase I (Multiple ascending dose study) study report and also proposed Phase III study protocol before the committee. After detailed deliberation the committee recommended that Phase III study protocol should be revised as per the following issues-

1. Standardized the type of surgery, anaesthesia, use of intra operative analgesics.
2. Comparator drugs should be gold standard i.e. injection morphine/ fentanyl.
3. Rescue analgesia should be well defined taking in to consideration the comparator drugs.
4. Principal investigator should be an Anesthiologist/ Pain expert.
5. Exclusion criteria should be clearly defined.

After that, firm has submitted the revised protocol as per issues raised by SEC and was deliberated with 41st SEC-Analgesic & Rheumatology meeting on 12.07.2018.

Recommendation of SEC (Analgesic & Rheumatology) meeting held on 12.07.2018:-

The firm presented their revised protocol before the committee. However, the committee opined that the revised protocol was not as per the earlier recommendation of the committee made in its meeting held on 14.03.2018. Therefore, the committee recommended that the firm should revise the protocol in consultation with PIs (Anesthesiologists/Pain experts) incorporating the five points as per the recommendation and submit the same for review.

Firm did not agree with the recommendations of SEC and has requested to deliberate the proposal in Technical Committee for grant of manufacture and marketing permission of Tapentadol Nasal Spray 225mg/ml.

Recommendation:- The firm presented their justification for comparing their Tapentadol nasal spray with Tramadol injection and capsules in the proposed Phase-III clinical trial before the committee. The committee after detailed deliberation recommended that use of Tramadol injection and capsule as comparator drug in the phase-III clinical trial may be considered appropriate and recommended for grant of permission to conduct the Phase-III clinical trial as per the protocol submitted.

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