

**MINUTES OF THE XXII MEETING OF COMMITTEE FOR THE PURPOSE OF CONTROL AND SUPERVISION OF EXPERIMENTS ON ANIMALS (CPCSEA) HELD ON 20.11.2007 AT 11.00 A.M. UNDER THE CHAIRMANSHIP OF SHRI B.S. PARSHEERA, CHAIRMAN, CPCSEA AND ADDITIONAL SECRETARY, MINISTRY OF ENVIRONMENT & FORESTS**

A List of Members who attended the meeting and was granted leave of absence is enclosed.

Chairman, CPCSEA, welcomed the members of the Committee and thereafter with the permission of Chairman, agenda items were taken up as follows:

**AGENDA ITEM NO.22.1 : TO CONFIRM THE MINUTES OF THE TWENTY FIRST MEETING OF CPCSEA HELD ON 18<sup>th</sup> SEPTEMBER, 2007.**

The Committee confirmed the Minutes of the XXI Meeting held on 18<sup>th</sup> September, 2007.

**AGENDA ITEM NO.22.2 : TO REVIEW THE ACTION TAKEN ON THE MINUTES OF THE XXI<sup>st</sup> MEETING AND PENDING POINTS OF PREVIOUS MEETINGS OF CPCSEA.**

**9.2-3.1.2 Review of experiments using animals in case of traditional medicine**

**9.2-3.2.5 Funding of projects on traditional system of medicine and proper scientific review with regard to the scope and purpose of research.**

The Committee felt that the presentation made by AYUSH team was not clear and lacking specific guidelines regarding animal experimentations, and it was decided that the guidelines on the use of animals should be harmonious as adopted in other organizations e.g. Ministry of Agriculture, Deptt. of Science and Technology etc. If, necessary the committee would help them to prepare the detailed guidelines on use of animals

**13.6 Deposit of the amount collected as registration/renewal fee**

The matter on the said issue was discussed by the committee and it was suggested that urgent efforts should be made to sort out this issue. A D.O reminder from Joint Secretary (AW) to Ministry of Finance for expediting the matter.

**13.7 Meeting of the Sub-Committee on Rehabilitation on Animals after their Experimentation (along with) Supplementary agenda item No.2)**

The matter was discussed by the Committee and with approval of Chairman, it was decided that a meeting of the Rehabilitation Committee would be convened by Member Secretary for finalization of the matter.

### **16.6.2 Action to be taken on the basis of Report of Consultative Group on Review of the Norms and practices for Regulation of Animal Experimentation**

The Committee discussed the issue and decided that a formal communication alongwith a copy of the approved guidelines would be sent to all the concerned authorities including ICAR/ICMR/Veterinary Universities/Agricultural Universities etc.

### **17.5 Approval of Animal House Facility by CPCSEA**

(a) In respect of Southern Regional Research Centre, Central Sheep and Wool Research Institute (CSWRI), Tamil Nadu, the committee considered the matter in depth and it was decided that a letter may be written to the Director, CSWRI to furnish the details of the animal experimentation/activities conducted in all the research centres under the institute for further consideration.

(b) In respect of Institute of Veterinary Biology Products, Department of Animal Husbandary, Pune - 411 007, Maharashtra, the Committee took serious note of non submission of the compliance report by the organizations inspite of several reminders and it was decided that a final reminder would be sent to the institute for implementation of all suggestions conveyed to them and for submission of compliance report within fifteen days on the receipt of the letter otherwise action would be initiated as per the provision of PCA Act.

### **17.6 Proposal of Forest Department, Govt. of NCT of Delhi for use of commensal monkeys being rehabilitated at their monkey shelter at Rajokari for research purposes.**

The Committee decided that a separate meeting would be convened with IGF Wildlife, and the Representative of NCT to work out this issue.

### **17.7 Sub-Committee for Selection of CPCSEA Nominees on Institutional Animal Ethics Committees.**

The issue regarding selection of new CPCSEA nominees was discussed in depth and it was decided that it should be according to the requirements and on the basis of approved guidelines for selection of nominee. It was also decided that the existing CPCSEA nominees to the present establishments should be replaced after every 3 years.

It was also decided that a note for regulation of the activities of Nominees would be prepared by the Dr. D. Swaroop, Dr. P. Balakrishna Murthy and Expert Consultant.

### **18.5 Approval of Animal House Facility by CPCSEA**

(a) In the matter of Veterinary College, University Agricultural Science, Hebbal, Bangalore, the committee considered the compliance report submitted by the University and it was observed that no compliance has been made. It was decided that a final reminder would be sent to the University for Implementation of the all suggestions within 15 days otherwise action would be initiated as per the provision of the PCA Act.

(b) In the matter of PGIMER, Chandigarh. the committee considered the compliance report submitted by the institute and it was observed that the full compliance is not done in respect of the suggestions made by CPCSEA and it was decided that a reminder would be sent to the institute for complete implementation of all suggestions within 15 days in letter and spirit and submit the compliance report, otherwise action would be initiated as per the provision of the PCA Act.

### **19.3. Registration of Institutes with CPCSEA**

The issue regarding draft advertisement was discussed in the light of the comments/ views offered by the CPCSEA members and it was decided that the necessary corrections may be made as per the comments of the members and observations of the Committee. The final draft advertisement would be placed in the next meeting of CPCSEA for approval of the members. It was also decided that a meeting may be convene with Senior Law officer by the Member Secretary to discuss the issue regarding non registration of the organizations with CPCSEA and Non-compliance of the direction of CPCSEA and applicability of the provisions of the PCA Act on such organizations.

### **19.6 Approval of Animal House Facility By CPCSEA**

(a) Bharat Serum & Vaccines Limited, Road No. 27, Wagle Industrial Estate, Thane-400604, Maharashtra, the committee considered the re inspection report and agreed to grand 3 more months to complete the left over works in the Animal House Facility.

(b) In respect of Vetcare Group of Companies, IS-40, KHB Industrial Area, Yelahanka New Town, Bangalore-560064, Karnataka.

The Committee suggested that re-inspection of the Animal House Facilities of the institute to be done at the earliest by the Expert Consultant for approval of animal house facilities.

### **AGENDA ITEM NO. 21.4 : Consideration of Proposals Relating To Animal Experimentation.**

#### **AGENDA ITEM NO.21.4.1: Update regarding proposals submitted earlier-the follow up action by CPCSEA**

#### **AGENDA ITEM NO.21.4.2: CONSIDERATION OF NEW PROPOSALS Follow-Up Action by CPCSEA:**

The Committee noted the status of the proposals which were considered in the XXIst meeting of CPCSEA.

### **AGENDA ITEM NO.22.3 : REGISTRATION OF INSTITUTES WITH CPCSEA.**

The Committee noted that 1119 institutions have been registered with CPCSEA.

**AGENDA ITEM NO.22.4 : CONSIDERATION OF PROPOSALS RELATING TO ANIMAL EXPERIMENTATION.**

**AGENDA ITEM NO.22.4.1: Update regarding proposals submitted earlier.**

In the previous meetings of CPCSEA held on 19.7.2007 & 18.9.2007, the following project proposals were deferred for want of some details. The requisite details/clarifications have been received, which are as follows:

<b>S. No.</b>	<b>Name of the institute/Name of the Investigator</b>	<b>Project Title</b>	<b>Decision of the XXII CPCSEA meeting</b>
1.	Advinus Therapeutics Private Limited. Plot Nos. 21&22, Phase-II, Peenya Industrial Area, Bangalore – 560 058/ Dr. S.M. Sulaiman  Received on : 19.11.2007	Subchronic (90 day) feeding study in Goats <b>Project Code : SCG-1/07</b> Species : Goats Number to be used : As per the regulatory /guideline requirements (OECD and DBT, Government of India). The number of animals required for the study is 60 (30 M + 30 F)	The Committee did <b>not approve</b> the proposal and decided that the approval of Biosafety committee also to be furnished.

2.	<p>Wockhardt Research Centre D-4, MIDC Area, Chikalhana, Aurangabad – 431 210 / Dr. M.B. Nandanwar</p> <p>Received on : 8.10.2007</p>	<p>Pharmacokinetics &amp; Toxicokinetic study of <b>NCE (WCK 4086)</b> in Beagle Dog</p> <p>Species : Dog Strain : Beagle</p> <p>2-4 years</p> <p><u>No. to be used :</u></p> <p>(i) Pharmacokinetic Study : 8Male &amp; 8 Female</p> <p>(ii) Toxicokinetic Study : 8 Male &amp; 8 Female</p> <p>Objective : To assess the Pharmacokinetics &amp; Toxicokinetics of <b>NCE (WCK 4086)</b> for finalizing in vivo efficacy and long-term toxicity dose regimen</p>	Approved
3.	<p>M/s. Sun Pharma Advanced Research Center (SPARC), Tandalji Vadodara – 390 020 (Gujarat)/ Dr. M. R. Marathe Received on 3.10.2007</p>	<p>14 days DRF and repeated dose regulatory toxicity study in Beagle Dogs - (Project code: 10711133)</p> <p>Species: Beagle Dogs</p> <p>Male 4 – 6 months, 30nos.</p> <p>Female 4 – 6 months, 30nos.</p> <p>Objectives : To Characterize the toxicity profile of test item after repeated exposure to Beagle Dogs.</p>	<p>The Committee considered the proposal and the following suggestions were made</p> <p>1. 14 days DRF (Dose Range Finding) study should be one mid dose.</p> <p>2. Repeated dose (GLP) 30 days study should be 2 Males and 2 Females.</p> <p>The Revised proposal may be approved by Chairman, CPCSEA and committee be informed in the next meeting.</p>

**AGENDA ITEM NO.22.4.2: CONSIDERATION OF NEW PROPOSALS:**

S. No	Name of the institute/Name of the Investigator	Project Title	Decision of the XXII CPCSEA meeting
1.	M/s. Sun Pharma Advanced Research Center (SPARC), Tandalji Vadodara – 390 020 (Gujarat)/ Dr. Vinod Burade	Evaluation of efficacy of ophthalmic formulations/NCEs in dog.  Species: Beagle Dogs  Gender : Male/Female Numbers to be used: 24 nos.	The proposal discussed by the committee and believes that Beagle Dogs is not a appropriate model in such type of studies and testing may be done at the level of the lower phylogenic model like Rabbit and Guinea Pigs.
2.	Sree Chitra Tirunal Institute for Medical Science and Technology, Biomedical Technology Wing (BMT Wing), Poojapura, Thiruvananthapuram-695 012, Kerala /Dr. Lissy K. Krishnan  Received on 26.10.2007	Preparation of New Born Calf Serum for use as supplement in cell culture experiments.  Species: Bovine  Gender : Male (a) Numbers to be used (Year-wise breakups and total figures needed to be given)  Period of experimentation: 1 days  Total number of animals : 12  <b>28</b> Number of days animal will be housed: 7 days.	The Committee considered the proposal and it was approved with the conditions that records of the rehabilitation of the experimental animals should be maintained in the institute and to be made available to CPCSEA.
3.	Jai Research Foundation (JRF) Valvada – 396 108 Dist. Valsad, Gujarat./Dr. Virendrasinh. M. Zala  Received on 5.11.2007	28 Days Sub-acute Toxicity Study of metformin Lapoate in Dogs.  Species : Beagle Dog Gender/Sex : Male and Female No. to be used : Main Study : M12+12 F Range Finding: : M8+8F	The Committee considered the proposal and took a view that the results of toxicity studies done on the lower animals should be provided. The detailed minutes of IAEC of the Institution should be attached along with the proposal.

4.	<p>National Institute of Virology 20-A, Dr. Ambedkar Road, Pune 411 001 Dr. K.S. Lole</p> <p>Received on 14.11.2007</p>	<p>Construction of genotype 1 (human)/ genotype 4 (swine) hepatitis E virus chimeras and their characterization in-vivo and in-vitro</p> <p>Species: Pigs Gender: Either but only one gender No. to be used: 4 animals in 2007, and 10 animals in 2008 Total 14.</p>	<p>The proposal discussed by the committee and the committee found that there is discrepancy in the proposal regarding date of initiation of experiment and IAEC approval Hence, the proposal was not approved. It was also decided that the IAEC minutes should be attached alongwith proposal.</p>
5.	<p>National Institute of Virology 20-A, Dr. Ambedkar Road, Pune 411 001 Dr. K.S. Lole</p> <p>Received on 14.11.2007</p>	<p>Construction of genotype 1 (human)/ genotype 4 (swine) hepatitis E virus chimeras and their characterization in-vivo and in-vitro</p> <p>Species: Rhesus monkey Gender: Preferably females No. to be used: 2 monkeys in the year 2007.</p>	<p>The proposal discussed by the committee and the committee found that there was discrepancy in the proposal regarding date of initiation of experiment and IAEC approval Hence, the proposal was not approved. It was also decided that the IAEC minutes should be attached alongwith proposal.</p>

6.	<p>National Institute of Virology 20-A, Dr. Ambedkar Road, Pune 411 001 Dr. V.A. Arankalle</p> <p>Received on 14.11.2007</p>	<p>Attempts to identify and characterize Hepatitis E virus from domestic animals.</p> <p>Species: 1. Cattle (Cows and Buffalos) 2. Canine (Dogs and Cats) 3. Ovine (Sheep &amp; Goat)</p> <p>Gender: Both genders No. to be used: Year 1 : Bovine (Cows and Buffaloes) Exp I: 100 calves each of cows and buffaloes Exp II: Four each young adult cows and buffaloes (anti HEV negative)</p> <p>Year 2: Canine (Dogs and Cats) Exp I: 100 puppies each of dogs and cats Exp II: Four each young adult dogs and cats (anti HEV negative)</p> <p>Year 3: Ovine (Sheep and Goat) Exp II: four each young adult sheep and goat (Anti HEV negative)</p>	<p>The proposal discussed by the committee and the committee found that there was discrepancy in the proposal regarding date of initiation of experiment and IAEC approval Hence, the proposal was not approved. It was also decided that the IAEC minutes should be attached alongwith proposal.</p>
7.	<p>Central Drug Research Institute, Chattar Manzil, P.O. Box 173, Lucknow – 226 001/Dr. S.K. Puri</p> <p>Received on 14.11.2007</p>	<p>Antimalarial efficacy evaluation of combinations of candidate antimalarial compounds (CDRI 97/78 and CDRI 99/411 with Piperaquine and Lumefantrine.</p> <p>Species : Rhesus monkey Gender : Either No. to be used : 20 monkeys</p>	<p>Approved</p>

**AGENDA ITEM NO.22.5 : REHABILITATION OF MONKEYS FROM CENTRAL ANIMAL FACILITY, AIIMS TO ASOLA BHATTI WILD LIFE THROUGH A TRAUMA-FREE EXERCISE – REGARDING PERMISSION OF CPCSEA.**

Dr. P.K. Yadav, SVO, AIIMS, New Delhi has requested for a permission of this Committee regarding Rehabilitation of 17 nos. monkeys kept in Central Animal Facility, AIIMS. The Wild Life Officer, Government of N.C.T. of Delhi has already granted the permission for translocation of monkeys from AIIMS to Asola Bhatti Wildlife Sanctuary.

The committee considered the request made by Dr. Yadav, SVO, AIIMS regarding the rehabilitation of the 17 numbers of monkeys. It was observed that this issue has been dealt earlier also and therefore earlier references be seen to examine the case.

**AGENDA ITEM NO. 22.6: APPROVAL OF ANIMAL HOUSE FACILITY BY CPCSEA**

The Animal House Facilities of the following institutions have been inspected and brief details are given below for consideration/approval by CPCSEA

**(a) Bio-Med Pvt. Ltd., Bulandshahr Road, Indl. Area, Ghaziabad-201 009, U.P.**

The Committee decided that the suggestions/observations made by the Inspection team for construction of New Primate Facility may be sent to the organization and it was decided that a complete report of the Primate Facility as per Guidelines may be sent to the CPCSEA for its further inspection.

- (i) Create proper primate facility as per CPCSEA norms.
- (ii) Animal should be procured from the legal source / registered breeders with CPCSEA.
- (iii) Proper record of the animals should be maintained.
- (iv) The people who will handle the animals should be trained etc.
- (v) Proposal should be submitted to CPCSEA only after the due consideration and approval of IAEC.

**(b) Ranbaxy Laboratories Ltd., Satbari, New Delhi.**

The Animal House Facilities (Old Kennel Facility) of is approved for the purpose of Breeding and Experimentation which need not require for operative/invasive procedure and techniques for Beagle Dogs.

**(c) Veterinary Preventive Medicine, Ranipet – 632 401, Tamil Nadu**

The Committee decided that the suggestions/observations made by the Inspection team for improvement of the Animal House Facilities may be sent to the institution for its compliance within six months.

### Small Animal Facility

1. Foot bath should be maintained at the entrance of the each room.
2. Fan and exhaust should be repaired in each room.
3. Maximum-minimum thermometer and hygrometer should be placed in each animal room for maintenance of the temperature and humidity.
4. Proper labeling should be made available in all cages and name board should be placed in all the room.
5. All the rusted cages should be painted / replaced.
6. Overcrowding should be avoided in the mice/rat cages.
7. Germinated Bengal gram to be fed to Guinea Pigs.
8. Pellet feed should be given for Mice, Rat and Rabbits.
9. Filtered water should be provided to all animals.

### Large Animal Facility

1. SOP should be placed in each animal shed.
2. Animal health should be checked and health record should be maintained as per the standard.
3. The rusted door should be repaired / replaced.
4. Green grass should be soaked in 10 %  $\text{KMnO}_4$  solution in water.
5. Experiment and stock facility should be made separate.

### Poultry

1. Fan and exhaust should be repaired in each room.
2. Rusted cages should be repaired / replaced.
3. Overcrowding should be avoided.

### Overall suggestions

1. All the animal house staff should be trained.
2. For disposal of carcass, in addition to the existing incinerator facility, deep burial with appropriate disinfectant should be established.

**(d) Mediclone Biotech Pvt. Ltd., Block – B, 36-37, Millennium House,, M.K. Srinivasan Nagar Main Road, No.144, Old Mahabalipuram Road, Perungudi, Chennai – 600 096, Tamil Nadu.**

The Animal House Facilities is **approved** for the purpose of Experimentation of the animals namely: **Rat, Mice, Horse, Ponies, Mule and Sheep.**

**(e) Amrita Institute of Medical Sciences, Elamakkara - PO, Kochi, Kerala 682 026.**

The Animal House Facilities is **approved** for the purpose of **Breeding and Experimentation of the animals namely: Rat, Mice and Rabbit.**

**(f) Sri Venkateswara Veterinary University, College of Veterinary Science, Rajendra Nagar - 500 030, Hyderabad.**

The Animal House Facilities is **approved** for the purpose of **Breeding and Experimentation of the animals namely: Goat, Sheep, and Cattle.**

**(g) Advy Chemicals, 52, Mital Chambers, Nariman Point, Mumbai – 400 021**

The Animal House Facilities is **approved** for the purpose of **Experimentation of the animals namely: Goat.**

**(h) National Institute for Research in Reproductive Health, Jehangir Merwanji Street, Parel, Mumbai – 400 012, Maharashtra.**

The Animal House Facilities is **approved** for the purpose of **Breeding and Experimentation of the animals namely: Rat, Mice, Rabbit and Non-human Primates (Marmoset and Bonnet Monkey).**

**(i) Bombay Veterinary College, Parel, Mumbai - 400 012.**

The Committee decided that the inspection report of the Animal House Facility is to be sent to the Vice Chancellor, Maharashtra Animals and Fisheries University, Nagpur, and a copy of the letter be endorsed to the Veterinary Council of India (VCI) and Indian Council of Agricultural Research (ICAR). It was also decided that the condition of the Animal House Facilities should be improved within 3 months otherwise action would be initiated as per the PCA Act.

**(j) Intervet India Private Limited, Brianagar, Off Pune – Nagar Road, Wagholi – 412 207, Pune Maharashtra.**

The Animal House Facilities is **approved** for the purpose **Breeding and Experimentation of the animals namely: Mice, Guinea Pig.**

**Experimentation of the animals namely: Cattle, Sheep, and Dog.**

**(k) Raj Biotech Private Limited, Talekar Vasti, Opp. Suessen Asia, P.O. Village Wing, Taluk Khandala, Dist. Satara – 412 801, Maharashtra**

The Committee considered the inspection report in depth and it was decided that the suggestions/observations made by the Inspection team for improvement of the Animal House Facilities may be sent to the institution for its compliance within six months.

**AGENDA ITEM NO. 22.7: ANNUAL ACCOUNTS FOR THE FINANCIAL YEARS 2006-07 IN RESPECT OF CPCSEA.**

It was observed that annual accounts are not required to be put-up in the committee. Accordingly, the item is withdrawn.

**AGENDA ITEM NO. 22.8: STATE WISE LIST OF THE APPLICANTS ALONGWITH THEIR DETAILS TO BECOME CPCSEA NOMINEES - FOR CONSIDERATION AND APPROVAL OF CPCSEA.**

The committee considered the issue the regarding the selection of new nominees and it was decided that the Expert Consultant would prepare detailed information of the existing nominees and allotted institutions. It was also decided that this matter will be discussed in the next meeting.

**AGENDA ITEM NO. 22.9: ANY OTHER ITEM WITH PERMISSION OF CHAIRMAN**

The members of the Committee appreciate the smooth functioning of CPCSEA work. Further Committee members were of the opinion that the existing staff in CPCSEA office is not sufficient to undertake the day to day activities of CPCSEA, some more supporting staff and accountant should be appointed on contractual basis. The member also expressed that sitting fee for the meeting should be increased as it is payable in the other ministries. The Chairman, CPCSEA informed the members that the suggestions would be examined.

\*\*\*

**The following Members were present for the meeting on 20.11.2007**

1. Shri. B.S. Parsheera, Chairman  
Additional Secretary,  
Ministry of Environment & Forests,  
Paryavaran Bhawan, CGO Complex,  
Lodhi Road, New Delhi - 110 003.
2. Shri. G. Balachandhran Vice Chairman  
Joint Secretary (Animal Welfare),  
Ministry of Environment & Forests,  
Paryavaran Bhawan, CGO Complex,  
Lodhi Road, New Delhi - 110 003.
3. Shri. Anjani Kumar, Member-Secretary  
Deputy Secretary (AW)  
Ministry of Environment & Forests  
8<sup>th</sup> Floor, Jeevan Prakash Bldg.,  
25, Kasturba Gandhi marg,  
New Delhi – 110001.
4. Dr. P. Balakrishnamurthy,  
Director,  
International Institute of Biotechnology & toxicology (IIBAT),  
12, Harleys Road, Kilpauk,  
Chennai - 600 010.
5. Dr. Shashi Motilal,  
Professor (Philosophy),  
University of Delhi,  
7, Vaishali Apartments, IIT/Delhi, Hauz Khas,  
New Delhi-110 016.
7. Dr. D. Swaroop  
Head, Division of Medicine,  
IVRI, Izatnagar – 243122  
Uttar Pradesh
8. Dr. Kondavalla Venkaiah,  
Head & Addl. Director,  
Bio-Statistics Department,  
National Institute of Nutrition,  
Hyderabad-500 007.

**Leave of absence was granted to following:**

1. Dr. K. Nachimuthu,  
Director of Research,  
Tamilnadu Veterinary and Animal Sciences University (TANUVAS),  
No.4, Dhamodara Street, Panchvadi, Chetpet,  
Chennai-600 031.
2. Prof. A. J. Rao ( Retd),  
Department of Biochemistry,  
Indian Institute of Science,  
Bangalore – 560012.
3. Dr. V.K. Vinayak,  
(Retd.) Senior Advisor),  
Department of Biotechnology,  
B-1, E-12, Mohan Co-Operative Industrial  
Estate, Mathura Road, New Delhi-110 044.
4. Dr. Vasantha Muthuswamy,  
Sr. Dy. Director General &  
Chief, Division of BMS, Traditional Medicines & Bioethics,  
Indian Council of Medical Research,  
Ansari Nagar, New Delhi-110 029.
5. Prof. Anup Kumar Nayak,  
Wildlife Institute of India,  
Post Bag #18, Chandrabani,  
Dehradun – 248 001, Uttaranchal.
6. Dr. T.P.R. Bhardwaj,  
Senior Consultant, Haematologist,  
Apollo Hospitals, 21, Greams Lane,  
Off. Greams Road, Chennai-600 006.

\*\*\*