F.No. 12-01/14-DC (Pt. 20)

Central Drugs Standard Control Organization

Directorate General of Health Services

Ministry of Health and Family Welfare

Govt. of India

FDA Bhawan, New Delhi

Dated: 5th Jan 2015

Order

Subject: Panels of experts for Subject Expert Committees (SECs).

Ministry of Health and Family Welfare, Government of India has approved 25 panels of experts of various therapeutic areas for evaluation of various categories of applications of (a) clinical trials, (b) new drugs and (c) new medical devices. Subject Expert Committee (SEC), comprising 8 medical experts (01 Pharmacologist and 07 medical specialists) shall be constituted drawing the names of the experts from the respective panels approved by the Ministry. In case any of the experts fail to attend the SEC meeting, another from the same panel will be invited to attend the meeting. DCG (I) on the request of any SEC, may invite a suitable expert having experience in the particular area of specialization as required by SEC, pertaining to the specified application. DCG (I) may add names of experts from Govt. Medical Colleges/Hospitals or persons of eminence in the panels wherever considered necessary. However, a standard procedure will be formulated for induction of experts in the panels.

The details of 25 approved panels of experts are enclosed at Annexure A

Terms of References:

The following are the terms of reference for the subject expert committee.

1. To advise DCG (I) in the following matters:
   (i) In-depth evaluation of non-clinical data including pharmacological toxicological data, clinical trial data (Phase I, II, III, and IV) etc. furnished by the applicant for approval of following:

- New drug substance of chemical and biological origin and new medical device to be introduced for the first time in the country including vaccines & r-DNA derived products.
- Subsequent approval of biological products including vaccines & r-DNA derived products already approved in the country.
- Global clinical trials.
- Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.
- Causality analysis, safety of drugs or any other technical matter in the opinion of Ministry of Health and Family Welfare or DCGI which requires expert advice.

(ii) Preparation of Guidelines for clinical research industry in evolving criteria for acceptance for marketing approval of new drugs of different therapeutic categories.

(iii) Defining roadmap for research industry for appropriate development of new drugs relevant to Indian population.

While considering approval of new drugs and clinical trial of NCEs/GCTs the Committees will examine the essentiality and desirability of new drugs in terms of:

- Assessment of Risk versus Benefit to the patient
- Innovation vis-à-vis existing therapeutic option
- Unmet medical need in India

(iv) Any other issues refered to the committee by CDSCO for advice.

2. Applications for new drugs and global clinical trials shall be evaluated by the experts through meetings or through video conferencing.
3. Each expert attending the meeting shall be paid an honorarium of Rs. 2500/- subject to a maximum of Rs 10000/- per meeting.
4. The expenditure on account of TA/DA for attending the meetings and honorarium to the experts shall be met from IPC budget.
5. The expert nominated as a member of the SEC should not have any conflict of interest as per the declaration given at Annexure B.

6. The members of the committee shall hold office for a period of three years but shall be eligible for re-nomination provided that the persons nominated continue to hold their offices in their respective organization by virtue of which they are nominated.
7. In case any expert from the panel retires from his Institute/Organization, subject expert from the same Institute/ organization may be included in the panel.
8. The members of these committees shall give their expert comments in writing after evaluating the proposal within a period of 6 weeks from the receipt of such proposal even if they fail to attend the meeting.
9. The committee shall evaluate the proposals of new drugs and clinical trials keeping in view the requirements as prescribed in the regulatory framework.
10. The expert committees will review the proposal and give their recommendations in a composite manner as far as practical.
11. In case of query/suggestion for modification /revision in the proposal, recommended by any SEC after initial review of the proposal, in the subsequent meetings the committee shall deliberate the matter keeping in view the earlier decision /suggestion.
12. The members shall maintain confidentiality of documents submitted by the applicants.

(Dr G. N Singh)
Drugs Controller General (India)

To

All members of the panel.

Copy to:

1. PPS to Secretary
2. PS to DGHS
3. PPS to AS & DG
4. PS to JS (R)
5. Indian Pharmacopoeia Commission, Sector-23, Raj Nagar, Ghaziabad with copies of approval of the Ministry alongwith approved Terms of References of SECs.