File No.12-01/14-DC (Pt-20)
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
(Expert Committee Coordination Cell)

FDA Bhawan,
Kotla Road,
New Delhi
Dated: 21/11/2017

NOTICE

Subject: Invitation for inclusion of professionals in the expert panels / subject expert committees under CDSCO.

Inorder to evaluate applications related to approval of New Drugs including Biological, Medical Devices and Clinical Trials and other related issues, CDSCO maintains panels of medical experts of various therapeutic areas, who advise DCG(I) in evaluation of such applications.

CDSCO is in the process of expanding the list of experts from various Govt.Hospitals /Institutions/ National Laboratories / Research Institutes for inclusion in the following panels:

PULMONARY	GYNACOLOGY	ORTHOPEDIC
ANALGESIC	ONCOLOGY	GASTROENTEROLOGY
A NAESTHETIC	HEMATOLOGY	RADIODIAGNOSIS
VACCINE	CARDIOLOGY	OPTHALMOLOGY
HEPATOLOGY	UROLOGY	DERMATOLOGY
DENTISTRY	NEPHROLOGY	ENDOCRINOLOGY
NEUROLOGY	ANTIVIRAL	PHARMACOLOGY
PSYCHIATRIC	ANTIMICROBIAL	BIO— MEDICAL ENGINEERING
PEDIATRIC	RHEUMATOLOGY	VETERINARY SCIENCES
BIOSTATISTICIAN	TOXICOLOGY	PHYTOPHARMACEUTICALS
CELL AND CELL BASED THERAPY	GENE THERAPY	OTHER RELATED AREAS

For evaluation of the applications of New Drugs, Medical Devices, Clinical Trials. Subject Experts Committees (SECs) are constituted by including experts from these panels.

1. SEC's advise DCG **(1)** in matters relating to:

i. In-depth evaluation of non-clinical data including pharmacological toxicological data, clinical trial data (Phase **1, 11,** 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 advise.

ii. Preparing Guidelines for clinical trial industry in evolving acceptance criteria 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 SEC's will examine essentiality and desirability of new drugs in terms of:

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

iv. Any other issues where expert advice is needed by CDSCO.

The Terms of Reference for members of the SEC's are as under:

2. Applications for new drugs and Global clinical trials will be evaluated by the experts through meetings in person or through video conference.

3. For review of each proposal, each expert attending the meeting will be paid fee of Rs. 2500/-whose upper limit would be Rs.10000 on a single day.

4. TA/DA for attending the meetings as well as sitting charges will be paid from 1PC budget.

5. The expert nominated as a member for the SEC should not have any conflict of interest as per the declaration given in the Annexure.

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. 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.

8. The committee shall evaluate the proposals of new drugs and clinical trials keeping in view the requirements as prescribed in the regulatory framework.

9. The expert committees will review the proposal and give their recommendations in a composite manner as far as practical.

10. 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.

11. The members should follow the Principle of Confidentiality with respect to the documents submitted by the applicants.

12. 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.

The interested experts from various Govt.Hospitals/ Institutions / National Laboratories Research Institutes having relevant expertise who can dedicate time for the above activities and agree to the terms of references as mentioned above may submit declaration of Conflict of Interests and Bio-Data as per the formats enclosed within six weeks of issuing of this letter to CDSCO, FDA Bhavan, Kotla Road, New Delhi — 110002 or email to dci@nic.in with a copy marked to seccdsco@gmail.com for considering their inclusion in the list of expert panels.

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

Copy to-

1. Notice Board, FDA Bhawan
2. Guard File

ANNEXURE-A

DECLARATION OF INTERESTS FOR EXPERTS FOR CDSCO

CDSCO work on drug regulatory issues requires the assistance of external experts who **may have interests** related to their expertise. To ensure the highest integrity and public confidence in its activities, CDSCO requires that experts serving in an advisory role disclose any circumstances that could give rise to a potential conflict of interest related to the subject of the activity in which they will be involved.

Please complete this form and submit it to CDSCO (HQ)

If you are unable or unwilling to disclose the details of an interest that may pose a real or perceived conflict, you must disclose that a conflict of interest may exist and the CDSCO may decide that you be totally recused from the meeting or work concerned, after consulting with you.

Name of expert:
Institution:
Email:
Contact No:-

Please answer each of the questions below. If the answer to any of the questions is "Yes", briefly describe the circumstances on the last page of the form.

1. EMPLOYMENT AND CONSULTING

Within the past 2 years, have you received remuneration from a commercial entity or other organization with an interest related to the subject of the meeting of work?

I a	Employment	Yes	No
I b	Consulting, including service as a technical or other advisor	Yes	No

2. RESEARCH SUPPORT

Within the past 2 years, have you or has your research unit received support from a commercial entity or other organization with an interest related to the subject of the meeting or work?

2a Research support, including grants, collaborations, sponsorships, and other funding Yes No

2b Non-monetary support valued at more than Rs. 20,000/- overall (include equipment, facilities, research assistants, paid travel to meetings, etc.)
Yes No

Support (including honoraria) for being on a speakers bureau, giving speeches or training for a commercial entity or other organization with an interest related to the subject of the meeting or work?

3. INVESTMENT INTERESTS

Do you have current investments (valued at more than Rs. 200000/- overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified and on which you exercise no control.

3a Stocks, bonds, stock options, other securities (e.g., short sales)

Yes No

3b Commercial business interests (e.g., proprietorships, partnerships, joint ventures, board memberships, controlling interest in a company)

Yes No

4. PUBLIC STATEMENTS AND POSITIONS (during the past 2 years)

4a As part of a regulatory, legislative or judicial process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization?
Yes No

5. ADDITIONAL INFORMATION

5a If not already disclosed above, have you worked for the competitor of a product that is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a personal, professional, financial or business competitive advantage?

Yes No

5b To your knowledge, would the outcome of the meeting or work benefit adversely affect interests of others with whom you have substantial common personal, professional, financial or business interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)?

Yes No

5d Have your received any payments (other then for travel costs) or honoraria for speaking publicly on the subject of this meeting or work?
Yes No

5e Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence?

Yes No

Within the past 4 years, have you had employment or received research support or other funding from or had any other professional relationship with, an entity directly involved in the production, manufacture, distribution or sale of tobacco products or representing the interests of any such entity?

Yes No

EXPLANATION OF "YES" RESPONSES: if the answer to any above questions is "yes", check above and briefly describe the circumstances on this page.

Nos. I - 3 Type of interest, question number and category and basic descriptive details.	**Name of company, organization, or institution**	**Belongs to you, a family member employer, research unit or other?**	**Amount of income or value of interest is assumed to be significant)**	**Current Interest (or year ceased)**
Nos.4-5: Describe the subject, specific circumstances, **parties** involved, time frame and other relevant **details**				

CONSENT TO DISCLOSURE. By completing and signing this form, you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report *or* work product

DECLARATION: I hereby declare on my honor that the disclosed information is true and complete to the best of my knowledge.

Should there be any change to the above information, I will promptly notify to CDSCO and complete a new declaration of interest form that describes the changes. This includes any change that occurs before or during the meeting or work itself and through the period up to the publication of the Final results or completion of the activity concerned

Date: _____ Signature_____

CURRICULUM VITAE

NAME:

DATE OF BIRTH:

MARITAL STATUS:

CONTACT DETAILS:

ACADEMIC DETAILS/ QUALIFICATION:

Sr. No.	COURSE	INSTITUTION	UNIVERSITY/ BOARD	YEAR OF PASSING

AREAS OF SPECIALISATION:

DETAILS OF PRESENT AND PREVIOUS POSITIONS:

PROFESSIONAL EXPERIENCE:

Sr. No.	POST	DURATION	INSTITUTION/ COMAPNY

SCIENTIFIC PUBLICATIONS AND PRESENTATIONS:

ANY OTHER ACHIEVEMENTS: