

**F.No.12-01/12-DC (Pt-77)**  
**Central Drugs Standard Control Organization**  
**Directorate General of Health Services**  
**Office of Drugs Control General (India)**

FDA Bhavan, Kotla Road  
New Delhi-110 002

Date: **28 AUG 2012**

**NOTICE**

**Subject: Expansion of panel of experts for evaluation of applications of New Drugs, Clinical Trials & Medical Devices – regarding.**

Under the provisions of Drugs & Cosmetics rules, Central Drugs Standard Control Organisation (CDSCO) is responsible for grant of statutory approvals for manufacture / import of new drugs, medical devices and clinical trials.

Presently, 12 New Drug Advisory Committees (NDACs) & 6 Medical Device Advisory Committees (MDACs) of various medical specialties are advising CDSCO in the process of such regulatory approvals of New Drugs, New Medical Devices & clinical trials.

In order to bring more transparency, consistency and accountability in the approval process and to have wider representation of experts of various disciplines from across the country, CDSCO is in process of expanding the pool of such experts in the areas of Oncology, Hematology, Ophthalmology, Immunology, Cardiology, Nephrology, Gastroenterology, Hepatology, Gynecology & Obstetrics, Pulmonology, Neurology, Psychiatry, Urology, Pediatrics, Rheumatology, Microbiology, Pharmacology, Medicine, Anesthesiology, Vaccines, Dermatology, Radio Diagnostics and Dentistry.

The experts will evaluate the proposals under the following Terms of Reference (TOR):

1. The **Terms of Reference** will be as follows:
  - To advise DCG(I) in the matters related to regulatory approval of new drugs, Global clinical trials, Fixed Dose Combinations, Medical Devices.
  - Preparing Guidelines for clinical research industry in evolving acceptance criteria for marketing approval of new drugs of different therapeutic categories.
  - Defining roadmap for research industry for appropriate development of new drugs relevant to Indian population.
2. Applications will be evaluated by either through meetings or by circulation.

3. For review of each proposal experts will be paid an honorarium of Rs. 1000/-
4. TA/DA for attending the meetings as well as honorarium will be paid as per the government rules.
5. The expert nominated as a member for the committee should not have any conflict of interest as per the declaration given as per 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. In case a member retires during the terms of validity a suitable alternative member probably from the same institute or from some other institute will be nominated as member for the committee.
8. The members of these committees should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.
9. The members of these committee should follow the Principle of Confidentiality with respect to the documents submitted by the applicants.

Interested experts having experience in the relevant fields working in government medical colleges / institutions and having no conflict of interest may please send their Curriculum Vitae and Conflict of Interest duly filled via e-mail [ndac@cdsco.nic.in](mailto:ndac@cdsco.nic.in) or by post to **Drugs Controller general (India), CDSCO, FDA Bhavan, Kotla Road, New Delhi – 110002** within 30 days of this notice.

  
(Dr. G.N. Singh)

**Drugs Controller General (India)**

**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:-

**Date and title of meeting:- Meeting of expert Committee to examine issue of restricting or prohibiting marketing of sibutramine on 12-11-10 at FDA Bhawan, Kotla Road, New Delhi**

*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 you received any payments (other than 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. 1 - 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)
<b>Nos.4-5: Describe the subject, specific circumstances, parties involved, time frame</b>				

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 honour 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 the 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 \_\_\_\_\_