X.19029/5/2011-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi
Dated the 31st March, 2011

ORDER

Subject: Constitution of New Drug Advisory Committee (NDAC) to advise Drugs Controller General (India) {DCG(I)} in matters for Review of Applications of New Drugs & Clinical Trials – regarding.

It has been decided to constitute a **New Drug Advisory Committee (NDAC) – Reproductive & Urology** to advise DCG(I) in matters related to review and regulatory approval of Clinical Trials & New Drugs {except for Investigational New Drugs(INDs)} of Reproductive & Urology and related categories. The committee is hereby constituted with the following composition with immediate effect:

1.	Dr. A.K.Mandal, Prof & Head, Dept. of Urology, Post Graduate Institute of Medical Education & Research, Chandigarh
2.	Dr. Santosh Kumar, Prof & Head, Dept. of Urology, Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
3.	Dr. N.K. Mohanty, Prof & Head, Dept. of Urology, Vardhman Mahavir Medical College & Safdurjung Hospital, Delhi
4.	Dr. Anup Kumar Kundu, Prof & Head, Dept. of Urology, IPGMER & SSKM, Kolkata
5.	Dr. Pushpa Singh, Prof & Head, Dept. of Obstetrics and Gynecology, Ram Manohar Lohia Hospital, Delhi
6.	Dr. S. Habeebullah, Prof & Head, Dept. of Obstetrics and Gynecology, Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
7.	Dr. Lakhbir Dhaliwal, Prof & Head, Dept. of Obstetrics and Gynecology Post Graduate Institute of Medical Education & Research, Chandigarh
8.	Dr. Suneeta Mittal , Prof & Head, Dept. of Obstetrics and Gynecology All India Institute of Medical Sciences, New Delhi
9.	Dr. Y.K.Gupta, Prof. & Head, Dept. of Pharmacology, All India Institute of Medical Sciences, New Delhi
10.	Dr. Zahid Gillani, Prof. & Head, Dept. of Pharmacology, Government Medical College, Jammu

1. **Terms of Reference**:

The committee will advise DCG(I) in the following matters:

i. To undertake 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 to be introduced for the first time in the country including vaccines & r-DNA derived products.
   - Global clinical trials.
   - Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

ii. Preparing Guidelines for clinical research 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 cases of new drugs the committee will examine 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

2. Applications for new drugs and Global clinical trials will be evaluated by the committee either through meetings or by circulation of the applications.

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 from CDSCO budget.

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, an alternative member from the same institute or from some other institute will be nominated as member for the committee.

8. Office of DCG(I) will initially examine such applications, if any particular data is lacking same will be informed to the applicant within 45 working days or else the data will be forwarded to the members of the committee.

9. The members of the committee should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.

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

11. This issues with the approval of IFD vide their Diary No. 5714 dated 28.02.2011.

Sudhir

(Sudhir Kumar)
Under Secretary to Government of India
Telefax: 23062292

Copy to:

1. Office of DCG(I) to inform all members of NDAC -. **Reproductive & Urology**
2. Secretary(H&FW)/DG Dte.GHS/SS&FA
3. Cash(Health) Section/IFD

DCG(I)

FTS 22408/2011
6 April

X.19029/5/2011-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi
Dated the 31st March, 2011

ORDER

Subject: Constitution of New Drug Advisory Committee (NDAC) to advise Drugs Controller General (India) {DCG(I)} in matters for Review of Applications of New Drugs & Clinical Trials – regarding.

It has been decided to constitute a **New Drug Advisory Committee (NDAC) – Cardiovascular & Renal** to advise DCG(I) in matters related to review and regulatory approval of Clinical Trials & New Drugs {except for Investigational New Drugs(INDs)} of Cardiovascular & Renal and related categories. The committee is hereby constituted with the following composition with immediate effect:

1.	Dr. V.K.Bahl, Prof & Head, Dept. of Cardiology All India Institute of Medical Sciences, New Delhi
2.	Dr. K.K. Talwar, Prof & Head, Dept. of Cardiology Post Graduate Institute of Medical Education & Research, Chandigarh
3.	Dr. J. Balachander, Prof & Head, Dept. of Cardiology Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
4.	Dr. Sandeep Bansal, Prof & Head, Dept. of Cardiology Vardhman Mahavir Medical College & Safdurjung Hospital, Delhi
5.	Dr. Harsh Wardhan, Prof & Head, Dept. of Cardiology Ram Manohar Lohia Hospital, Delhi
6.	Dr. Bindu Amitabh, Prof & Head, Dept. of Nephrology Vardhman Mahavir Medical College & Safdurjung Hospital, Delhi
7.	Dr. Vinay Sakhuja, Prof & Head, Dept. of Nephrology Post Graduate Institute of Medical Education & Research, Chandigarh
8.	Dr. S.K. Agarwal, Prof & Head, Dept. of Nephrology All India Institute of Medical Sciences, New Delhi
9.	Dr. Y.K. Gupta, Prof. & Head, Dept. of Pharmacology All India Institute of Medical Sciences, New Delhi
10.	Dr. T. Rameshkumar, Prof. & Head, Dept. of Pharmacology Nizams Institute of Medical Sciences, Hyderabad

1. **Terms of Reference**:

The committee will advise DCG(I) in the following matters:

i. To undertake 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 to be introduced for the first time in the country including vaccines & r-DNA derived products.
- Global clinical trials.
- Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

DD(I) TC(M)

ii. Preparing Guidelines for clinical research 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 cases of new drugs the committee will examine 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

2. Applications for new drugs and Global clinical trials will be evaluated by the committee either through meetings or by circulation of the applications.

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 from CDSCO budget.

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, an alternative member from the same institute or from some other institute will be nominated as member for the committee.

8. Office of DCG(I) will initially examine such applications, if any particular data is lacking same will be informed to the applicant within 45 working days or else the data will be forwarded to the members of the committee.

9. The members of the committee should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.

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

11. This issues with the approval of IFD vide their Diary No. 5714 dated 28.02.2011.

(Sudhir Kumar)
Under Secretary to Government of India
Telefax: 23062292

Copy to:

1. Office of DCG(I) to inform all members of NDAC - **Cardiovascular & Renal**
2. Secretary(H&FW)/DG, Dte.GHS/SS&FA
3. Cash(Health) Section/IFD

Draft

X.19029/5/2011-DFQC
Government of India
Ministry of Health & Family Welfare

FTS 2241 | 2011
6 April 2011

Nirman Bhavan, New Delhi
Dated the 31st March, 2011

ORDER

Subject: Constitution of New Drug Advisory Committee (NDAC) to advise Drugs Controller General (India) {DCG(I)} in matters for Review of Applications of New Drugs & Clinical Trials – regarding.

It has been decided to constitute a **New Drug Advisory Committee (NDAC) – Ophthalmology** to advise DCG(I) in matters related to review and regulatory approval of Clinical Trials & New Drugs {except for Investigational New Drugs(INDs)} of Ophthalmology and related categories. The committee is hereby constituted with the following composition with immediate effect:

1.	Dr. Arun Ahuja, Prof & Head, Dept of Opthalmology, Seth GS Medical College & KEM Hospital
2.	Dr. Supriyo Ghose, Chief and Prof, Dept of Opthalmology, All India Institute of Medical Sciences, New Delhi
3.	Dr. Vasudev Anand Rao, Prof & Head, Dept of Opthalmology, Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
4.	Dr. Amod Gupta, Prof & Head, Dept of Opthalmology, Post Graduate Institute of Medical Education & Research, Chandigarh
5.	Dr. Vinita Singh, Prof & Head, Dept of Opthalmology, King Gorge Medical College, Lucknow
6.	Dr. B.S. Gupta, Prof & Head, Dept. of Opthalmology, Vardhman Mahavir Medical College & Safdurjung Hospital, Delhi
7.	Dr. Sankar Kumar Pal, Prof & Head, Dept of Opthalmology, IPGME & R & SSKM Hospital, Kolkatta-20.
8.	Dr. V. P. Gupta, Prof & Head, Dept of Opthalmology, University College of Medical Sciences, New Delhi
9.	Dr. Promila Pandhi, Prof. & Head, Dept. of Pharmacology Post Graduate Institute of Medical Education & Research, Chandigarh
10.	Dr.R.Nandini, Prof. & Head, Dept. of Pharmacology, Madras Medical College, Madras

1. **Terms of Reference**:

The committee will advise DCG(I) in the following matters:

i. To undertake 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 to be introduced for the first time in the country including vaccines & r-DNA derived products.
- Global clinical trials.

Prof (Dr) TDL Gupta

- Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

ii. Preparing Guidelines for clinical research 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 cases of new drugs the committee will examine 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

2. Applications for new drugs and Global clinical trials will be evaluated by the committee either through meetings or by circulation of the applications.

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 from CDSCO budget.

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, an alternative member from the same institute or from some other institute will be nominated as member for the committee.

8. Office of DCG(I) will initially examine such applications, if any particular data is lacking same will be informed to the applicant within 45 working days or else the data will be forwarded to the members of the committee.

9. The members of the committee should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.

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

11. This issues with the approval of IFD vide their Diary No. 5714 dated 28.02.2011.

(Sudhir Kumar)
Under Secretary to Government of India
Telefax: 23062292

Copy to:

1. Office of DCG(I) to inform all members of NDAC - **Ophthalmology**
2. Secretary(H&FW)/DG Dte.GHS/AS&FA
3. Cash(Health) Section/IFD

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X.19029/5/2011-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi
Dated the 31st March, 2011

ORDER

Subject: Constitution of New Drug Advisory Committee (NDAC) to advise Drugs Controller General (India) {DCG(I)} in matters for Review of Applications of New Drugs & Clinical Trials – regarding.

It has been decided to constitute a **New Drug Advisory Committee (NDAC) – Vaccines** to advise DCG(I) in matters related to review and regulatory approval of Clinical Trials & New Drugs {except for Investigational New Drugs(INDs)} in respect of Vaccines. The committee is hereby constituted with the following composition with immediate effect:

1.	Dr. J.C. Samantray, Prof & Head, Dept of Microbiology, All India Institute of Medical Sciences, New Delhi
2.	Dr. Meera Sharma, Prof & Head, Dept of Medical Microbiology, Post Graduate Institute of Medical Education & Research, Chandigarh
3.	Dr. Iqbal Kaur, Prof & Head, Dept of Microbiology University College of Medical Sciences, New Delhi
4.	Dr. V.K. Paul, Prof & Head, Dept of Pediatrics, All India Institute of Medical Sciences, New Delhi
5.	Dr. A.P. Dubey, Prof & Head, Dept of Paediatrics Maulana Azad Medical College & LNJP Hospital, Delhi
6.	Dr. Swati Chakraborty, Prof & Head, Dept of Pediatrics, IPGME & R & SSKM Hospital, Kolkatta-20
7.	Dr. T.K. Dutta, Prof & Head, Dept. of Medicine, Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
8.	Dr. Amar Pazare, Prof & Head, Dept. of Medicine, Seth GS Medical College & KEM Hospital
9.	Dr. Y.K.Gupta, Prof. & Head, Dept. of Pharmacology, All India Institute of Medical Sciences, New Delhi
10.	Dr. R.K.Goel, Prof. & Head, Dept. of Pharmacology Institute of Medical Sciences, BHU, Varanasi

1. Terms of Reference:

The committee will advise DCG(I) in the following matters:

i. To undertake 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 to be introduced for the first time in the country including vaccines & r-DNA derived products.
   - Global clinical trials.
   - Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

ii. Preparing Guidelines for clinical research 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 cases of new drugs the committee will examine 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

2. Applications for new drugs and Global clinical trials will be evaluated by the committee either through meetings or by circulation of the applications.

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 from CDSCO budget.

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, an alternative member from the same institute or from some other institute will be nominated as member for the committee.

8. Office of DCG(I) will initially examine such applications, if any particular data is lacking same will be informed to the applicant within 45 working days or else the data will be forwarded to the members of the committee.

9. The members of the committee should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.

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

11. This issues with the approval of IFD vide their Diary No. 5714 dated 28.02.2011.

(Sudhir Kumar)
Under Secretary to Government of India
Telefax: 23062292

Copy to:

1. Office of DCG(I) to inform all members of NDAC - **Vaccines**
2. Secretary(H&FW)/DG Dte.GHS/SS&FA
3. Cash(Health) Section/IFD

X.19029/5/2011-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi
Dated the 31st March, 2011

ORDER

Subject: Constitution of New Drug Advisory Committee (NDAC) to advise Drugs Controller General (India) {DCG(I)} in matters for Review of Applications of New Drugs & Clinical Trials – regarding.

It has been decided to constitute a **New Drug Advisory Committee (NDAC) – Dermatology & Allergy** to advise DCG(I) in matters related to review and regulatory approval of Clinical Trials & New Drugs {except for Investigational New Drugs(INDs)} of Dermatology & Allergy and related categories. The committee is hereby constituted with the following composition with immediate effect:

1.	V.K. Sharma, Prof & Head, Dept. of Dermatology All India Institute of Medical Sciences, New Delhi
2.	Dr. D.M. Thappa, Prof & Head, Dept. of Dermatology Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
3.	Dr. Vijay Kumar, Prof & Head, Dept. of Dermatology Maulana Azad Medical College & LNJP Hospital, Delhi
4.	Dr. V.Ramesh, Prof & Head, Dept. of Dermatology Vardhman Mahavir Medical College & Safdurjung Hospital, Delhi
5.	Dr. H.K.KAR, Prof & Head, Dept. of Dermatology Ram Manohar Lohia Hospital, Delhi
6.	Dr. Amrinder Jit Kanwar, Prof & Head, Dept. of Dermatology, Venerology and Leprology, Post Graduate Institute of Medical Education & Research, Chandigarh
7.	Dr. S. N. Bhattacharya, Prof & Head, Dept. of Dermatology University College of Medical Sciences, New Delhi
8.	Dr. Gobinda Chatterjee, Prof & Head, Dept. of Dermatology IPGME & R & SSKM Hospital, Kolkatta-20.
9.	Dr. C. Adithan, Prof. & Head, Dept. of Pharmacology Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
10.	Dr. H.S.Rehan, Prof. & Head, Dept. of Pharmacology Lady Harding Medical College, New Delhi

1. **Terms of Reference**:

The committee will advise DCG(I) in the following matters:

i. To undertake 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 to be introduced for the first time in the country including vaccines & r-DNA derived products.
- Global clinical trials.
- Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

ii. Preparing Guidelines for clinical research 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 cases of new drugs the committee will examine 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

2. Applications for new drugs and Global clinical trials will be evaluated by the committee either through meetings or by circulation of the applications.

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 from CDSCO budget.

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, an alternative member from the same institute or from some other institute will be nominated as member for the committee.

8. Office of DCG(I) will initially examine such applications, if any particular data is lacking same will be informed to the applicant within 45 working days or else the data will be forwarded to the members of the committee.

9. The members of the committee should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.

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

11. This issues with the approval of IFD vide their Diary No. 5714 dated 28.02.2011.

Sudhir

(Sudhir Kumar)
Under Secretary to Government of India
Telefax: 23062292

Copy to:

1. Office of DCG(I) to inform all members of NDAC - **Dermatology & Allergy**
2. Secretary(H&FW)/DG Dte.GHS/SS&FA
3. Cash(Health) Section/IFD

DCGI

X.19029/5/2011-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi
Dated the 31st March, 2011

FR 22404/2011 (Appl)

ORDER

Subject: Constitution of New Drug Advisory Committee (NDAC) to advise Drugs Controller General (India) {DCG(I)} in matters for Review of Applications of New Drugs & Clinical Trials – regarding.

It has been decided to constitute a **New Drug Advisory Committee (NDAC) – Analgesics, Anesthetics & Rheumatology** to advise DCG(I) in matters related to review and regulatory approval of Clinical Trials & New Drugs {except for Investigational New Drugs(INDs)} of Analgesics, Anesthetics & Rheumatology and related categories. The committee is hereby constituted with the following composition with immediate effect:

1.	Dr. Chandralekha, Prof & Head, Dept. of Anesthesiology, All India Institute of Medical Sciences, New Delhi
2.	Dr. Madhu Garasi, Prof & Head, Dept. of Anesthesiology, Seth GS Medical College & KEM Hospital
3.	Dr. D.K. Patro, Prof & Head, Dept of Orthopaedics, Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
4.	Dr.P.P.Kotwal, Prof & Head, Dept of Orthopaedics All India Institute of Medical Sciences, New Delhi
5.	Dr S.K. Das, Prof & Head, Dept of Rheumatology King Gorge Medical College, Lucknow
6.	Dr. R.K. Arya, Prof & Head, Dept of Orthopaedics Ram Manohar Lohia Hospital, Delhi
7.	Dr. Subhash C. Varma, Prof & Head, Dept. of Internal Medicine Post Graduate Institute of Medical Education & Research, Chandigarh
8.	Dr. Richa Dewan, Prof & Head, Dept. of Medicine Maulana Azad Medical College & LNJP Hospital, Delhi
9.	Dr. Y.K.Gupta, Prof. & Head, Dept. of Pharmacology All India Institute of Medical Sciences, New Delhi
10.	Dr.(Mrs)Manjula Bhargava, Prof. & Head, Dept. of Pharmacology Sawai Man Singh Medical College, Jaipur

1. **Terms of Reference**:

The committee will advise DCG(I) in the following matters:

i. To undertake 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 to be introduced for the first time in the country including vaccines & r-DNA derived products.
   - Global clinical trials.

DDC(P)

- Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

ii. Preparing Guidelines for clinical research 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 cases of new drugs the committee will examine 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

2. Applications for new drugs and Global clinical trials will be evaluated by the committee either through meetings or by circulation of the applications.

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 from CDSCO budget.

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, an alternative member from the same institute or from some other institute will be nominated as member for the committee.

8. Office of DCG(I) will initially examine such applications, if any particular data is lacking same will be informed to the applicant within 45 working days or else the data will be forwarded to the members of the committee.

9. The members of the committee should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.

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

11. This issues with the approval of IFD vide their Diary No. 5714 dated 28.02.2011.

S. K.

(Sudhir Kumar)
Under Secretary to Government of India
Telefax: 23062292

Copy to:

1. Office of DCG(I) to inform all members of NDAC - Analgesics, Anesthetics & Rheumatology
2. Secretary(H&FW)/DG Dte.GHS/SS&FA
3. Cash(Health) Section/IFD

DCG(I)

FTS 22402/2011
8 April 2011

X.19029/5/2011-DFQC
Government of India
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi
Dated the 31st March, 2011

ORDER

Subject: Constitution of New Drug Advisory Committee (NDAC) to advise Drugs Controller General (India) {DCG(I)} in matters for Review of Applications of New Drugs & Clinical Trials – regarding.

It has been decided to constitute a **New Drug Advisory Committee (NDAC) – Neurology & Psychiatry** to advise DCG(I) in matters related to review and regulatory approval of Clinical Trials & New Drugs {except for Investigational New Drugs(INDs)} of Neurology & Psychiatry and related categories. The committee is hereby constituted with the following composition with immediate effect:

1.	Dr. Madhuri Behari, Prof & Head, Dept. of Neurology, All India Institute of Medical Sciences, New Delhi
2.	Dr. Sudesh Prabhakar, Prof & Head, Dept. of Neurology, Post Graduate Institute of Medical Education & Research, Chandigarh
3.	Dr. Sunil K. Narayan, Prof & Head, Dept. of Neurology, Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
4.	Dr.Subhash Kaul, Prof & Head, Dept. of Neurology, Nizams Institute of Medical Sciences, Hyderabad
5.	Dr.S.R.Parkar, Prof & Head, Dept. of Psychiatry, Seth GS Medical College & KEM Hospital
6.	Dr.Rajat Ray, Prof & Head, Dept. of Psychiatry, All India Institute of Medical Sciences, New Delhi
7.	Dr. P.Kulhara , Prof & Head, Dept. of Psychiatry, Post Graduate Institute of Medical Education & Research, Chandigarh
8.	Dr. Smita N. Deshpande, Associate Prof & Head, Dept. of Psychiatry, Ram Manohar Lohia Hospital, Delhi
9.	Dr. Urmila Thatte, Prof. & Head, Dept. of Clinical Pharmacology, Seth GS Medical College & KEM Hospital, Mumbai
10.	Dr. C. Adithan, Prof. & Head, Dept. of Pharmacology, Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry

1. **Terms of Reference**:

The committee will advise DCG(I) in the following matters:

i. To undertake 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 to be introduced for the first time in the country including vaccines & r-DNA derived products.
   - Global clinical trials.

ADC(P)

- Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

ii. Preparing Guidelines for clinical research 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 cases of new drugs the committee will examine 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

2. Applications for new drugs and Global clinical trials will be evaluated by the committee either through meetings or by circulation of the applications.

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 from CDSCO budget.

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, an alternative member from the same institute or from some other institute will be nominated as member for the committee.

8. Office of DCG(I) will initially examine such applications, if any particular data is lacking same will be informed to the applicant within 45 working days or else the data will be forwarded to the members of the committee.

9. The members of the committee should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.

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

11. This issues with the approval of IFD vide their Diary No. 5714 dated 28.02.2011.

(Sudhir Kumar)
Under Secretary to Government of India
Telefax: 23062292

Copy to:

1. Office of DCG(I) to inform all members of NDAC - **Neurology & Psychiatry**
2. Secretary(H&FW)/DG Dte.GHS/SS&FA
3. Cash(Health) Section/IFD

X.19029/5/2011-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi
Dated the 31st March, 2011

ORDER

Subject: Constitution of New Drug Advisory Committee (NDAC) to advise Drugs Controller General (India) {DCG(I)} in matters for Review of Applications of New Drugs & Clinical Trials – regarding.

It has been decided to constitute a **New Drug Advisory Committee (NDAC) – Pulmonary** to advise DCG(I) in matters related to review and regulatory approval of Clinical Trials & New Drugs {except for Investigational New Drugs(INDs)} of Pulmonary and related categories. The committee is hereby constituted with the following composition with immediate effect:

1	Dr. S. Vinod Kumar, Prof. & Head, Dept. of T.B. & Chest Diseases, Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
2	Dr. J. C. Suri, Prof. & Head, Dept. of Pulmonary Medicine, Vardhman Mahavir Medical College & Safdurjung Hospital, Delhi
3	Dr.Rajendra Prasad, Prof. & Head, Dept. of Pulmonary Medicine, King Gorge Medical College, Lucknow
4	Prof. S.K.Jindal, Prof. & Head, Dept. of Pulmonary Medicine, Post Graduate Institute of Medical Education & Research, Chandigarh
5	Prof. A.Sampath Kumar, Chief, Cardio-Thoraic Centre, All India Institute of Medical Sciences, New Delhi
6	Dr. A.U. Athavale , Professor & Head of Chest Medicine & Chief of E.P.R.C, Seth GS Medical College & KEM Hospital
7	Dr. Tapan Das, Prof. & Head, Dept. of Respiratory Medicine, IPGME & R & SSKM Hospital, Kolkatta-20.
8	Dr. Mukal. P. Agarwal, Prof & Head, Dept. of Medicine, University College of Medical Sciences, Delhi
9	Dr. C.D. Tripathi, Prof. & Head, Dept. of Pharmacology, All India Institute of Medical Sciences, New Delhi
10	Dr. Uma Tekur, Prof. & Head, Dept. of Pharmacology, Maulana Azad Medical College & LNJP Hospital, Delhi

1. **Terms of Reference**:

The committee will advise DCG(I) in the following matters:

i. To undertake 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 to be introduced for the first time in the country including vaccines & r-DNA derived products.
- Global clinical trials.

- Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

ii. Preparing Guidelines for clinical research 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 cases of new drugs the committee will examine 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

2. Applications for new drugs and Global clinical trials will be evaluated by the committee either through meetings or by circulation of the applications.

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 from CDSCO budget.

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, an alternative member from the same institute or from some other institute will be nominated as member for the committee.

8. Office of DCG(I) will initially examine such applications, if any particular data is lacking same will be informed to the applicant within 45 working days or else the data will be forwarded to the members of the committee.

9. The members of the committee should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.

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

11. This issues with the approval of IFD vide their Diary No. 5714 dated 28.02.2011.

(Sudhir Kumar)
Under Secretary to Government of India
Telefax: 23062292

Copy to:

1. Office of DCG(I) to inform all members of NDAC - **Pulmonary**
2. Secretary(H&FW)/DG Dte.GHS/SS&FA
3. Cash(Health) Section/IFD

X.19029/5/2011-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi
Dated the 31st March, 2011

ORDER

Subject: Constitution of New Drug Advisory Committee (NDAC) to advise Drugs Controller General (India) {DCG(I)} in matters for Review of Applications of New Drugs & Clinical Trials – regarding.

It has been decided to constitute a **New Drug Advisory Committee (NDAC) – Oncology & Hematology** to advise DCG(I) in matters related to review and regulatory approval of Clinical Trials & New Drugs {except for Investigational New Drugs(INDs)} of Oncology & Hematology and related categories. The committee is hereby constituted with the following composition with immediate effect:

1.	Dr. T. S. Sagar, Chairman & Prof. Dept. of Medical Oncology, Cancer Institute, Adyar Chennai.
2.	Dr. Geeta Narayanan, Prof. & HOD, Dept. of Medical Oncology, Regional Cancer Centre, Trivandrum
3.	Dr. S.D.Banavalli, Prof. & Head, Dept. of Medical Oncology, Tata Memorial Hospital, Parel, Mumbai-12.
4.	Prof. G.K. Rath, Chief- Rotary, Cancer (IRC), All India Institute of Medical Sciences, New Delhi
5.	Dr. Renu Saxena, Prof. & Head, Dept. of Hematology, All India Institute of Medical Sciences, New Delhi
6.	Dr. Neelam Verma, Prof. & Head, Dept. of Hematology, Post Graduate Institute of Medical Education & Research, Chandigarh
7.	Dr. D.K.Gupta, Prof. & Head, Dept. of Hematology, Vardhman Mahavir Medical College & Safdurjung Hospital, Delhi
8.	Dr. Alok Srivastava, Prof. & Head, Dept. of Hematology, Christian Medical College, Vellore
9.	Dr. Promila Pandhi, Prof. & Head, Dept. of Pharmacology, Post Graduate Institute of Medical Education & Research, Chandigarh
10.	Dr. Urmila Thatte, Prof. & Head, Dept. of Clinical Pharmacology, SGS Medical College & KEM Hospital, Mumbai

1. **Terms of Reference**:

The committee will advise DCG(I) in the following matters:

i. To undertake 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 to be introduced for the first time in the country including vaccines & r-DNA derived products.
   - Global clinical trials.

- Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

ii. Preparing Guidelines for clinical research 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 cases of new drugs the committee will examine 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

2. Applications for new drugs and Global clinical trials will be evaluated by the committee either through meetings or by circulation of the applications.

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 from CDSCO budget.

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, an alternative member from the same institute or from some other institute will be nominated as member for the committee.

8. Office of DCG(I) will initially examine such applications, if any particular data is lacking same will be informed to the applicant within 45 working days or else the data will be forwarded to the members of the committee.

9. The members of the committee should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.

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

11. This issues with the approval of IFD vide their Diary No. 5714 dated 28.02.2011.

(Sudhir Kumar)
Under Secretary to Government of India
Telefax: 23062292

Copy to:

1. Office of DCG(I) to inform all members of NDAC - **Oncology & Hematology**
2. Secretary(H&FW)/DG Dte.GHS/SS&FA
3. Cash(Health) Section/IFD

DCG(I)

FTS 22330/2011 6 April 2011

X.19029/5/2011-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi
Dated the 31st March, 2011

ORDER

Subject: Constitution of New Drug Advisory Committee (NDAC) to advise Drugs Controller General (India) {DCG(I)} in matters for Review of Applications of New Drugs & Clinical Trials – regarding.

It has been decided to constitute a **New Drug Advisory Committee (NDAC) – Gastroenterology & Hepatology** to advise DCG(I) in matters related to review and regulatory approval of Clinical Trials & New Drugs {except for Investigational New Drugs(INDs)} of Gastroenterology & Hepatology and related categories. The committee is hereby constituted with the following composition with immediate effect:

1.	Prof. Kartar Singh, Prof. & Head, Dept. of Gastroenterology, Post Graduate Institute of Medical Education & Research, Chandigarh
2.	Dr. Gaurav Chaudhary, Prof. & Head, Dept. of Gastroenterology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, India.
3.	Dr. Shobhna Bhatia, Prof. & Head, Dept. of Gastroenterology, Seth GS Medical College & KEM Hospital, Mumbai
4.	Dr B.M. Singh, In-Charge, Dept. of Gastroenterology, Ram Manohar Lohia Hospital, Delhi
5.	Prof. Y.K. Chawla, Prof. & Head, Dept. of Hepatology, Post Graduate Institute of Medical Education & Research, Chandigarh
6.	Dr. S.K. Acharya, Prof. & Head, Dept. of Hepatology, All India Institute of Medical Sciences, New Delhi
7.	Dr. S.K. Sharma, Prof. & Head, Dept. of Hepatology, All India Institute of Medical Sciences, New Delhi
8.	Dr. B D Goswami, Prof. & Head, Dept. of Hepatology, Gauhati Medical College, Gauhati
9.	Dr. Promila Pandhi, Prof. & Head, Dept. of Pharmacology, Post Graduate Institute of Medical Education & Research, Chandigarh
10.	Dr. Kamlesh K. Pant, Prof. & Head, Dept. of Pharmacology, King Gorge Medical College, Lucknow

1. **Terms of Reference**:

The committee will advise DCG(I) in the following matters:

i. To undertake 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 to be introduced for the first time in the country including vaccines & r-DNA derived products.
- Global clinical trials.

ADC(P)

- Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

ii. Preparing Guidelines for clinical research 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 cases of new drugs the committee will examine 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

2. Applications for new drugs and Global clinical trials will be evaluated by the committee either through meetings or by circulation of the applications.

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 from CDSCO budget.

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, an alternative member from the same institute or from some other institute will be nominated as member for the committee.

8. Office of DCG(I) will initially examine such applications, if any particular data is lacking same will be informed to the applicant within 45 working days or else the data will be forwarded to the members of the committee.

9. The members of the committee should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.

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

11. This issues with the approval of IFD vide their Diary No. 5714 dated 28.02.2011.

(Sudhir Kumar)
Under Secretary to Government of India
Telefax: 23062292

Copy to:

1. Office of DCG(I) to inform all members of NDAC - **Gastroenterology & Hepatology**
2. Secretary(H&FW)/DG Dte.GHS/SS&FA
3. Cash(Health) Section/IFD

X.19029/5/2011-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi
Dated the 31st March, 2011

ORDER

Subject: Constitution of New Drug Advisory Committee (NDAC) to advise Drugs Controller General (India) {DCG(I)} in matters for Review of Applications of New Drugs & Clinical Trials – regarding.

It has been decided to constitute a **New Drug Advisory Committee (NDAC) – Metabolism & Endocrinology** to advise DCG(I) in matters related to review and regulatory approval of Clinical Trials & New Drugs {except for Investigational New Drugs(INDs)} of Metabolism & Endocrinology and related categories. The committee is hereby constituted with the following composition with immediate effect:

1.	Dr. A. C. Ammini, Prof. & Head , Dept. of Endocrinology, All India Institute of Medical Sciences, New Delhi
2.	Dr. Krishna Biswas, Prof. & Head, Dept. of Endocrinology, Vardhman Mahavir Medical College & Safdurjung Hospital, Delhi
3.	Dr. Anil Bansali, Addl. Prof. & Head, Dept. of Endocrinology, Post Graduate Institute of Medical Education & Research, Chandigarh
4.	Dr. Subhankar Choudhury, Prof. & Head, Dept. of Endocrinology, IPGME & R & SSKM Hospital, Kolkatta-20.
5.	Dr. A.K. Ajmani, Prof. & Head, Dept. of Endocrinology Ram Manohar Lohia Hospital, Delhi
6.	Dr. P. Roychowdhury, Prof. & Head, Dept. of Endocrinology, Medical College, Kolkata
7.	Dr. Richa Dewan, Prof. & Head, Dept. of Medicine, Maulana Azad Medical College & LNJP Hospital, Delhi
8.	Dr. P.V. Rao , Prof. & Head, Dept. of Endocrinology, Nizams Institute of Medical Sciences, Hyderabad
9.	Dr. Y.K. Gupta, Prof. & Head, Dept. of Pharmacology, All India Institute of Medical Sciences, New Delhi
10.	Dr. Urmila Thatte, Prof. & Head, Dept. of Clinical Pharmacology, Seth GS Medical College & KEM Hospital, Mumbai

1. **Terms of Reference**:

The committee will advise DCG(I) in the following matters:

i. To undertake 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 to be introduced for the first time in the country including vaccines & r-DNA derived products.
   - Global clinical trials.

- Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

ii. Preparing Guidelines for clinical research 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 cases of new drugs the committee will examine 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

2. Applications for new drugs and Global clinical trials will be evaluated by the committee either through meetings or by circulation of the applications.

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 from CDSCO budget.

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, an alternative member from the same institute or from some other institute will be nominated as member for the committee.

8. Office of DCG(I) will initially examine such applications, if any particular data is lacking same will be informed to the applicant within 45 working days or else the data will be forwarded to the members of the committee.

9. The members of the committee should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.

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

11. This issues with the approval of IFD vide their Diary No. 5714 dated 28.02.2011.

Sudhir

(Sudhir Kumar)
Under Secretary to Government of India
Telefax: 23062292

Copy to:

1. Office of DCG(I) to inform all members of NDAC - **Metabolism & Endocrinology**
2. Secretary(H&FW)/DG Dte.GHS/SS&FA
3. Cash(Health) Section/IFD

X.19029/5/2011-DFQC
Government of India
Ministry of Health & Family Welfare
Nirman Bhavan, New Delhi
Dated the 31st March, 2011

ORDER

Subject: Constitution of New Drug Advisory Committee (NDAC) to advise Drugs Controller General (India) {DCG(I)} in matters for Review of Applications of New Drugs & Clinical Trials – regarding.

It has been decided to constitute a **New Drug Advisory Committee (NDAC) – Antimicrobial, Antiparasitic & Antifungal, Antiviral** to advise DCG(I) in matters related to review and regulatory approval of Clinical Trials & New Drugs {except for Investigational New Drugs(INDs)} of Antimicrobial, Antiparasitic & Antifungal, Antiviral and related categories. The committee is hereby constituted with the following composition with immediate effect:

Sr. No.	Name of Member	Institute
1.	Dr. Subhash C. Varma, Prof & Head, Dept. of Internal Medicine	Post Graduate Institute of Medical Education & Research, Chandigarh
2.	Dr. T.K. Dutta, Prof & Head, Dept. of Medicine	Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
3.	Dr. S. K. Sharma, Prof & Head, Dept. of Medicine	All India Institute of Medical Sciences, New Delhi
4.	Dr. Prasad Matthew, Prof & Head, Medical Unit-I, Dept. of Medicine	Christian Medical College, Vellore
5.	Dr. B. Gupta, Prof & Head, Dept. of Medicine	Vardhman Mahavir Medical College & Safdurjung Hospital, Delhi
6.	Dr. Amar Pazare, Prof & Head, Dept. of Medicine	Seth GS Medical College & KEM Hospital
7.	Dr. J.C.Samantray, Dept. of Microbiology	All India Institute of Medical Sciences, New Delhi
8.	Dr. Meera Sharma, Dept. of Medical Microbiology	Post Graduate Institute of Medical Education & Research, Chandigarh
9.	Dr. Y.K. Gupta, Prof. & Head, Dept. of Pharmacology	All India Institute of Medical Sciences, New Delhi
10.	Dr. Dipankar Bhattacharyya, Prof. & Head, Dept. of Pharmacology	IPGMER & SSKM, Kolkatta
11.	Representative from NACO (for Anti-HIV drugs)	
12.	Representative from NVBDCP (for drugs for vector borne diseases)	
13.	Representative from NIMR (for Anti-Malarial drugs)	
14.	Representative from T.B. Division, DGHS (for Anti-T.B. drugs)	

1. **Terms of Reference**:

The committee will advise DCG(I) in the following matters:

i. To undertake 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 to be introduced for the first time in the country including vaccines & r-DNA derived products.
   - Global clinical trials.
   - Fixed Dose Combinations of two or more drugs to be introduced for the first time in the country.

ii. Preparing Guidelines for clinical research 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 cases of new drugs the committee will examine 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

2. Applications for new drugs and Global clinical trials will be evaluated by the committee either through meetings or by circulation of the applications.
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 from CDSCO budget.
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, an alternative member from the same institute or from some other institute will be nominated as member for the committee.
8. Office of DCG(I) will initially examine such applications, if any particular data is lacking same will be informed to the applicant within 45 working days or else the data will be forwarded to the members of the committee.
9. The members of the committee should be in a position to give their expert opinion within a period of 6 weeks from the receipt of such proposal.
10. The members of the committee should follow the Principle of Confidentiality with respect to the documents submitted by the applicants.
11. This issues with the approval of IFD vide their Diary No. 5714 dated 28.02.2011.

S.K.

(Sudhir Kumar)
Under Secretary to Government of India
Telefax: 23062292

Copy to:

1. Office of DCG(I) to inform all members of NDAC - **Antimicrobial, Antiparasitic & Antifungal, Antiviral**
2. Secretary(H&FW)/DG Dte.GHS/SS&FA
3. Cash(Health) Section/IFD