X.19029/4/2012-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi

Date: 7th March, 2014

ORDER

Subject: Constitution of In-Vitro Diagnostic Device Advisory Committee (IVDAC) to advice Drugs Controller General (India) to ensure essentiality, desirability and effectiveness of the new In-Vitro Diagnostic Devices and issues related to identified critical In-Vitro Diagnostic Devices – regarding

It has been decided to constitute a **In-Vitro Diagnostic Devices Advisory Committee (IVDAC) for Tuberculosis diagnostic devices and Reagents** to advise DCG (I) in matters related to review and regulatory approval of the said products. The committee is hereby constituted with the following composition with immediate effect:

1. Head ,

   Epidemiology and Communicable Diseases

   Indian Council of Medical Research (ICMR)

   (DEPARTMENT OF HEALTH RESEARCH) & DIRECTOR GENERAL

   Indian Council of Medical Research Post Box No. 4911, Ansari Nagar

   New Delhi

2. Head ,

   Department of Microbiology All India Institute of Medical sciences,

   Ansari Nagar, New Delhi-110029

3. Director ,

   National Institute for Research in Tuberculosis, Mayor Sathiyamoorthy Road,

   Chetpet, Chennai - 600 031,

4. Director ,

   National Jalma Institute of Leprosy and Other Mycobacterial Disease, P.O. Box 101, Dr.

   M. Miyazaki marg,

   Tajganj, Agra-282001.

5. Director ,

DDC (AS) 14/3 DE (ST)

International Centre for Genetic Engineering and Biotechnology, Aruna Asaf Ali Marg, New Delhi-110067.

6. Additional Director & Head ,
(Microbiology), Division of Microbiology
National Center for Disease Control (NCDC), Directorate General of Health Services, 22, Sham Nath Marg, New Delhi-110 054

1. Terms of Reference :

These committees will advise DCG(I) in the following matters:

I. To prescribe standards for Diagnostic Devices.

II. To identify the laboratories for testing of Diagnostic Devices to evaluate quality.

III. To prepare common testing protocol for each of the above mentioned Diagnostic Devices.

IV. To ensure availability of panel for evaluation / testing of the Diagnostic Devices.

V. To undertake in-depth evaluation of trial data, etc. furnished by the applicant for approval of:

- New Diagnostic Device
- Global trials.

VI. Preparing Guidance for clinical research industry in evolving acceptance criteria for marketing approval of new Diagnostic Device.

VII. Defining roadmap for research industry for appropriate development of new Diagnostic Device relevant to Indian population.

VIII. While considering for approval of new Diagnostic Device the committees will examine the essentiality , desirability and effectiveness of new Diagnostic Device in terms of:

- Sensitivity, Specificity, Quality , Safety and performance of the devices
- Assessment of Risk versus Benefit to the patient
- Innovation vis-à-vis existing option
- Unmet medical need in India

D(CC)

IX. The Committee will have the freedom to co-opt 2-3 eminent scientists who can make contribution in this field.

X. The committee may also invite anybody as a Special Invitee.

XI. The Committee will also take into consideration reports of Committees set up earlier if any.

XII. The Committee would also examine the best international practices which could be comparable to India.

2. Applications for new Diagnostic Device and Global trials can be evaluated by these committees either through meeting 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 meeting as well as honorarium will be paid from IPC budget.
5. The experts nominated as a member for these committees should not have any conflict of interest as per the declaration given as per the declaration given at **Annexure-A**
6. These committees 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. 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.
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 proposals.
9. The members of these committees should follow the Principle of Confidentiality with respect to the documents submitted by the applicants.
10. The members of the committee should submit their Bio-data as per the format annexed at **Annexure-B**
11. This issues with the approval of Ministry of Health & Family Welfare.

Sudhir Kumar
(Under Secretary to Government of India)

Copy to:

1. All members of (IVDAC) - Tuberculosis diagnostic devices and Reagents
2. Secretary(H&FW)/DG Dte.GHS/AS&FA
3. DCG(I)
4. IPC

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X.19029/4/2012-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi

Date: 7th March, 2014

ORDER

Subject: Constitution of In-Vitro Diagnostic Device Advisory Committee (IVDAC) to advice Drugs Controller General (India) to ensure essentiality, desirability and effectiveness of the new In-Vitro Diagnostic Devices and issues related to identified critical In-Vitro Diagnostic Devices – regarding

It has been decided to constitute a **In-Vitro Diagnostic Devices Advisory Committee (IVDAC) for Cancer diagnostic devices and Reagents** to advise DCG (I) in matters related to review and regulatory approval of the said products. The committee is hereby constituted with the following composition with immediate effect:

1. Head ,

   Non-Communicable Diseases

   Indian Council of Medical Research (ICMR)

   (DEPARTMENT OF HEALTH RESEARCH) & DIRECTOR GENERAL

   Indian Council of Medical Research Post Box No. 4911, Ansari Nagar

   New Delhi

2. Professor & Head ,

   BRA-IRCH (Dr. B.R.A Institute-Rotary Cancer Hospital) All India Institute of Medical sciences, Ansari Nagar, New Delhi-110029

3. Director ,

   INSTITUTE OF CYTOLOGY AND PREVENTIVE ONCOLOGY

   I-7, Sector-39, P.O.Box.No.544 near Degree College Opposite City Centre, Noida - 201301

4. Additional Director & Head ,

   (Microbiology), Division of Microbiology

   National Center for Disease Control (NCDC), Directorate General of Health Services, 22, Sham Nath Marg, New Delhi-110 054

5. Director ,

DDC (AS) 14/3

DD(SD) 14.3.14

Delhi State Cancer Institute (GNCT of Delhi)

Dilshad Garden, Delhi 110 095 (India)

6. Director ,

The Gujarat Cancer & Research Institute
The Gujarat Cancer Society
Civil Hospital Campus, Asarwa,

Ahmedabad-380 016.

Gujarat, INDIA

1. Terms of Reference :

These committees will advise DCG(I) in the following matters:

I. To prescribe standards for Diagnostic Devices.

II. To identify the laboratories for testing of Diagnostic Devices to evaluate quality.

III. To prepare common testing protocol for each of the above mentioned Diagnostic Devices.

IV. To ensure availability of panel for evaluation / testing of the Diagnostic Devices.

V. To undertake in-depth evaluation of trial data, etc. furnished by the applicant for approval of:

- New Diagnostic Device
- Global trials.

VI. Preparing Guidance for clinical research industry in evolving acceptance criteria for marketing approval of new Diagnostic Device.

VII. Defining roadmap for research industry for appropriate development of new Diagnostic Device relevant to Indian population.

VIII. While considering for approval of new Diagnostic Device the committees will examine the essentiality , desirability and effectiveness of new Diagnostic Device in terms of:

- Sensitivity, Specificity, Quality , Safety and performance of the devices
- Assessment of Risk versus Benefit to the patient
- Innovation vis-à-vis existing option

- Unmet medical need in India

IX. The Committee will have the freedom to co-opt 2-3 eminent scientists who can make contribution in this field.

X. The committee may also invite anybody as a Special Invitee.

XI. The Committee will also take into consideration reports of Committees set up earlier if any.

XII. The Committee would also examine the best international practices which could be comparable to India.

2. Applications for new Diagnostic Device and Global trials can be evaluated by these committees either through meeting 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 meeting as well as honorarium will be paid from IPC budget.
5. The experts nominated as a member for these committees should not have any conflict of interest as per the declaration given as per the declaration given at **Annexure-A**
6. These committees 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. 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.
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 proposals.
9. The members of these committees should follow the Principle of Confidentiality with respect to the documents submitted by the applicants.
10. The members of the committee should submit their Bio-data as per the format annexed at **Annexure-B**
11. This issues with the approval of Ministry of Health & Family Welfare.

Sudhir Kumar
(Under Secretary to Government of India)

Copy to:

1. All members of (IVDAC) - Cancer diagnostic devices and Reagents
2. Secretary(H&FW)/DG Dte.GHS/AS&FA
3. DCG(I)
4. IPC

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X.19029/4/2012-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi

Date: 7th March, 2014

ORDER

Subject: Constitution of In-Vitro Diagnostic Device Advisory Committee (IVDAC) to advice Drugs Controller General (India) to ensure essentiality, desirability and effectiveness of the new In-Vitro Diagnostic Devices and issues related to identified critical In-Vitro Diagnostic Devices – regarding

It has been decided to constitute a **In-Vitro Diagnostic Devices Advisory Committee (IVDAC) for Blood grouping sears, Human Leukocyte Antigen (HLA), Blood Glucose Diagnostic Devices and Reagents** to advise DCG (I) in matters related to review and regulatory approval of the said products. The committee is hereby constituted with the following composition with immediate effect:

1. Director ,
   National Institute of Biologicals (NIB),
   Plot No. A-32, Sector-62
   Institutional Area,
   NOIDA-201 307 (U.P.)
2. Head ,
   Non-Communicable Diseases
   Indian Council of Medical Research (ICMR)
   (DEPARTMENT OF HEALTH RESEARCH) & DIRECTOR GENERAL
   Indian Council of Medical Research Post Box No. 4911, Ansari Nagar
   New Delhi
3. Director ,
   National Institute of Immunohaematology
   13th floor, New Multistoreyed Bldg
   KEM Hospital Campus
   Parel, Mumbai 400012
4. Head ,

Department of Transplant Immunology & immunogenetics, All India Institute of Medical sciences,
Ansari Nagar, New Delhi-110029

5. Head ,
   Department of Hematology, All India Institute of Medical sciences,
   Ansari Nagar, New Delhi-110029
6. Additional Director & Head ,
   (Microbiology), Division of Microbiology
   National Center for Disease Control (NCDC), Directorate General of Health Services, 22, Sham Nath Marg, New Delhi-110 054

1. Terms of Reference :

These committees will advise DCG(I) in the following matters:

I. To prescribe standards for Diagnostic Devices.

II. To identify the laboratories for testing of Diagnostic Devices to evaluate quality.

III. To prepare common testing protocol for each of the above mentioned Diagnostic Devices.

IV. To ensure availability of panel for evaluation / testing of the Diagnostic Devices.

V. To undertake in-depth evaluation of trial data, etc. furnished by the applicant for approval of:

- New Diagnostic Device
- Global trials.

VI. Preparing Guidance for clinical research industry in evolving acceptance criteria for marketing approval of new Diagnostic Device.

VII. Defining roadmap for research industry for appropriate development of new Diagnostic Device relevant to Indian population.

VIII. While considering for approval of new Diagnostic Device the committees will examine the essentiality , desirability and effectiveness of new Diagnostic Device in terms of:

- Sensitivity, Specificity, Quality , Safety and performance of the devices

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

IX. The Committee will have the freedom to co-opt 2-3 eminent scientists who can make contribution in this field.

X. The committee may also invite anybody as a Special Invitee.

XI. The Committee will also take into consideration reports of Committees set up earlier if any.

XII. The Committee would also examine the best international practices which could be comparable to India.

2. Applications for new Diagnostic Device and Global trials can be evaluated by these committees either through meeting 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 meeting as well as honorarium will be paid from IPC budget.
5. The experts nominated as a member for these committees should not have any conflict of interest as per the declaration given as per the declaration given at **Annexure-A**
6. These committees 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. 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.
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 proposals.
9. The members of these committees should follow the Principle of Confidentiality with respect to the documents submitted by the applicants.
10. The members of the committee should submit their Bio-data as per the format annexed at **Annexure-B**
11. This issues with the approval of Ministry of Health & Family Welfare.

(Sudhir Kumar)
Under Secretary to Government of India

Copy to:

1. All members of (IVDAC) - Blood grouping sears, Human Leukocyte Antigen (HLA), Blood Glucose Diagnostic Devices and Reagents
2. Secretary(H&FW)/DG Dte.GHS/AS&FA
3. DCG(I)
4. IPC

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X.19029/4/2012-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi

Date: 7th March, 2014

ORDER

Subject: Constitution of In-Vitro Diagnostic Device Advisory Committee (IVDAC) to advice Drugs Controller General (India) to ensure essentiality, desirability and effectiveness of the new In-Vitro Diagnostic Devices and issues related to identified critical In-Vitro Diagnostic Devices – regarding

It has been decided to constitute a **In-Vitro Diagnostic Devices Advisory Committee (IVDAC) for HIV, HBV, HCV, Influenza, Syphilis and STD diagnostic devices and Reagents** to advise DCG (I) in matters related to review and regulatory approval of the said products. The committee is hereby constituted with the following composition with immediate effect:

1. Director,
   National AIDS Research Institute (NARI),
   Address: 73, 'G'-Block, MIDC, Bhosari,
   Pune 411 026.
2. Director ,
   National Institute of Biologicals (NIB),
   Plot No. A-32, Sector-62
   Institutional Area,
   NOIDA-201 307 (U.P.)
3. Director ,
   National Institute of Virology (NIV),
   20/ A, Dr. Ambedkar Road. Post Box No. 11,
   Pune 411001
4. Head ,
   Epidemiology and Communicable Diseases
   Indian Council of Medical Research (ICMR)
   (DEPARTMENT OF HEALTH RESEARCH) & DIRECTOR GENERAL
   Indian Council of Medical Research Post Box No. 4911, Ansari Nagar
   New Delhi
5. Head ,
   Department of Microbiology, All India Institute of Medical sciences,
   Ansari Nagar, New Delhi-110029
6. Additional Director & Head ,

DDC (AB) 14/3

DZ(SJ)

(Microbiology), Division of Microbiology
National Center for Disease Control (NCDC), Directorate General of Health Services, 22, Sham Nath Marg, New Delhi-110 054

1. Terms of Reference :

These committees will advise DCG(I) in the following matters:

I. To prescribe standards for Diagnostic Devices.

II. To identify the laboratories for testing of Diagnostic Devices to evaluate quality.

III. To prepare common testing protocol for each of the above mentioned Diagnostic Devices.

IV. To ensure availability of panel for evaluation / testing of the Diagnostic Devices.

V. To undertake in-depth evaluation of trial data, etc. furnished by the applicant for approval of:

- New Diagnostic Device
- Global trials.

VI. Preparing Guidance for clinical research industry in evolving acceptance criteria for marketing approval of new Diagnostic Device.

VII. Defining roadmap for research industry for appropriate development of new Diagnostic Device relevant to Indian population.

VIII. While considering for approval of new Diagnostic Device the committees will examine the essentiality , desirability and effectiveness of new Diagnostic Device in terms of:

- Sensitivity, Specificity, Quality , Safety and performance of the devices
- Assessment of Risk versus Benefit to the patient
- Innovation vis-à-vis existing option
- Unmet medical need in India

IX. The Committee will have the freedom to co-opt 2-3 eminent scientists who can make contribution in this field.

X. The committee may also invite anybody as a Special Invitee.

XI. The Committee will also take into consideration reports of Committees set up earlier if any.

DCG(I)

XII. The Committee would also examine the best international practices which could be comparable to India.

2. Applications for new Diagnostic Device and Global trials can be evaluated by these committees either through meeting 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 meeting as well as honorarium will be paid from IPC budget.
5. The experts nominated as a member for these committees should not have any conflict of interest as per the declaration given as per the declaration given at **Annexure-A**
6. These committees 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. 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.
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 proposals.
9. The members of these committees should follow the Principle of Confidentiality with respect to the documents submitted by the applicants.
10. The members of the committee should submit their Bio-data as per the format annexed at **Annexure-B**
11. This issues with the approval of Ministry of Health & Family Welfare.

(Sudhir Kumar)
Under Secretary to Government of India

Copy to:

1. All members of (IVDAC) - HIV, HBV, HCV, Influenza, Syphilis and STD diagnostic devices and Reagents
2. Secretary(H&FW)/DG Dte.GHS/AS&FA
3. DCG(I)
4. IPC

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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:-

Date and title of meeting:- ----------

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

ANNEXURE-B

BIO-DATA

Name of the Expert:
Date of Birth:
Designations:
Office Address:
Address for Communications: **Telephone No. / Mobile:** **Email Id:**
Qualification:
Experience:
Publications: Publications in Peer reviewed Journals

(a) National (Indexed) (b) International
Peer Reviews:
Major Achievements:
Membership Details:

X.19029/4/2012-DFQC
Government of India
Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi

Date: 7th March, 2014

ORDER

Subject: Constitution of In-Vitro Diagnostic Device Advisory Committee (IVDAC) to advice Drugs Controller General (India) to ensure essentiality, desirability and effectiveness of the new In-Vitro Diagnostic Devices and issues related to identified critical In-Vitro Diagnostic Devices – regarding

It has been decided to constitute a **In-Vitro Diagnostic Devices Advisory Committee (IVDAC) for Malaria, Dengue, Chikunguniya, Typhoid and Kala-azar (Leishmaniasis) Diagnostic devices and Reagents** to advise DCG (I) in matters related to review and regulatory approval of the said products. The committee is hereby constituted with the following composition with immediate effect:

1. Head ,
   Epidemiology and Communicable Diseases
   Indian Council of Medical Research (ICMR)
   (DEPARTMENT OF HEALTH RESEARCH) & DIRECTOR GENERAL
   Indian Council of Medical Research Post Box No. 4911, Ansari Nagar
   New Delhi
2. Head ,
   Department of Microbiology , All India Institute of Medical sciences,
   Ansari Nagar, New Delhi-110029
3. Director ,
   National Institute of Biologicals (NIB) ,
   Plot No. A-32, Sector-62
   Institutional Area,
   NOIDA-201 307 (U.P.)
4. Director ,
   National Institute of Virology (NIV) ,
   20/ A, Dr. Ambedkar Road. Post Box No. 11,

DDC (AS) 15/3

DI (SI) 14/03/14

Pune 411001

5. Director ,

   National Institute of Malaria Research (NIMR)

   Sector 8, Dwarka, Delhi-110077, India

6. Additional Director & Head ,

   (Microbiology) , Division of Microbiology
   National Center for Disease Control (NCDC), Directorate General of Health Services, 22, Sham Nath Marg, New Delhi-110 054

1. Terms of Reference :

These committees will advise DCG(I) in the following matters:

I. To prescribe standards for Diagnostic Devices.

II. To identify the laboratories for testing of Diagnostic Devices to evaluate quality.

III. To prepare common testing protocol for each of the above mentioned Diagnostic Devices.

IV. To ensure availability of panel for evaluation / testing of the Diagnostic Devices.

V. To undertake in-depth evaluation of trial data, etc. furnished by the applicant for approval of:

- New Diagnostic Device
- Global trials.

VI. Preparing Guidance for clinical research industry in evolving acceptance criteria for marketing approval of new Diagnostic Device.

VII. Defining roadmap for research industry for appropriate development of new Diagnostic Device relevant to Indian population.

VIII. While considering for approval of new Diagnostic Device the committees will examine the essentiality , desirability and effectiveness of new Diagnostic Device in terms of:

- Sensitivity, Specificity, Quality , Safety and performance of the devices
- Assessment of Risk versus Benefit to the patient
- Innovation vis-à-vis existing option

DCG(I)

- Unmet medical need in India

IX. The Committee will have the freedom to co-opt 2-3 eminent scientists who can make contribution in this field.

X. The committee may also invite anybody as a Special Invitee.

XI. The Committee will also take into consideration reports of Committees set up earlier if any.

XII. The Committee would also examine the best international practices which could be comparable to India.

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3. For review of each proposal experts will be paid an honorarium of Rs. 1000/-
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5. The experts nominated as a member for these committees should not have any conflict of interest as per the declaration given as per the declaration given at **Annexure-A**
6. These committees 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.
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10. The members of the committee should submit their Bio-data as per the format annexed at **Annexure-B**
11. This issues with the approval of Ministry of Health & Family Welfare.

Sudhir Kumar
(Under Secretary to Government of India)

Copy to:

1. All members of (IVDAC) - Malaria, Dengue, Chikunguniya, Typhoid and Kala-azar (Leishmaniasis) Diagnostic devices and Reagents.
2. Secretary(H&FW)/DG Dte.GHS/AS&FA
3. DCG(I)
4. IPC

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