

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(CAS)  14/3
DEK(ST)
Jawar
14/03/14

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

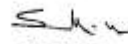
6. Additional Director & Head,
(Microbiology), Division of Microbiology
National Center for Disease Control (NCDC), Directorate General of Health Services, 22,
Sham Nath Marg, New Delhi-110 054

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 (44)
- 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

GOVERNMENT OF INDIA

CDSCO (I)

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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 advise 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
14/3/14
14/3/14
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

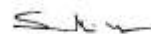
1. Terms of Reference :

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

GOVERNMENT OF INDIA

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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 ,

DDC (PS) 14/3

DI/CSS
Jain
14/3/14

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

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- IX. The Committee will have the freedom to co-opt 2-3 eminent scientists who can make contribution in this field.
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- 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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11. This issues with the approval of Ministry of Health & Family Welfare.

S. K. U.
(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) *dgf*
4. IPC

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GOVERNMENT OF INDIA

CDSCO (HQ)

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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 advise 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 (AS) *[Signature]* 14/3
DDC (SJ)
[Signature] 14/3/14

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

I. 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.

- 9/11/14
- 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.
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 9. The members of these committees should follow the Principle of Confidentiality with respect to the documents submitted by the applicants.
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 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

GOVERNMENT OF INDIA

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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 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)

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 _____

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:

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Ministry of Health & Family Welfare

Nirman Bhavan, New Delhi

Date: 7th March, 2014

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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)

14/3

DI/CSJ

14/3/14

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

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- I. To prescribe standards for Diagnostic Devices.
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- 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.
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11. This issues with the approval of Ministry of Health & Family Welfare.

S.K.

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

GOVERNMENT OF INDIA

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14/02/14

Minutes of the Meeting of need for regulatory check for issuing commercial Licence to manufactures of Malaria Rapid Diagnostic Tests held on 18-12-2013 at 3 pm in the Committee Room, A- Wing, 4th Floor, Room No. 445, Directorate General of Health Services, Nirman Bhawan, New Delhi-110001

Chairman:

Dr. (Prof.) Jagdish Prasad,
Director General Health Services (D.G.H.S),
Ministry of Health & Family Welfare,
Nirman Bhawan, C-Wing, New Delhi-110009

Name of the invitees attended the meeting:

1. Dr. A. C. Dhartiwal Director,
NVBDCP, 22 ShamnathMarg, Delhi 110054
2. Dr. Neena Valecha
Scientist G & Director, National Institute of Malaria Research, Sec-8, Dwarka,
Delhi-110077.
3. Dr. Rashmi Arora
SC.G & Head Division of ECD, ICMR, New Delhi.
4. Dr. Neeru Singh
Director Regional Medical Research Centre for Tribals (RMRCT), Jabalpur
5. Dr. Reba Chhabra,
National Institute of Biologicals (NIB), Noida
6. Dr. Shashi Khare
Additional Director & Head, (Microbiology), A Division of Microbiology, National
Centre for Disease Control (NCDC), 22 Sham NathMarg, New Delhi-110054
7. Dr. Suman Lata Wattal
Dy. Director, NVBDCP.22-Sham Nath Marg.
8. Dr. G.S. Sonal
Additional Director, Head of Malaria Devision, NVBDCP, 22 ShamnathMarg,
Delhi 110054
9. Mr S, Kishore Kumar
Scientist-F and Head,
Bureau of Indian Standards (BIS), ManakBhavan, 9 Bahadur Shah ZafarMarg,
New Delhi-110002.

10. Dr. Arti Kapil
Prof. Microbiology, AIIMS, New Delhi
11. Dr. Charu M Kamal
SG-III, NIB, Noida
12. Dr. Praveen K Bhatt
Scientist 'C', RMRCT, Jabalpur, M.P. India.
13. Dr. Anup Anvikar
Scientist E, NIMR, Sector 8 Dwarka.

Officers from CDSCO (HQ):

1. Dr. S. Eswara Reddy, Deputy Drugs Controller (I), CDSCO HQ, New Delhi
2. Dr. Ravi Kant Sharma, Assistant Drugs Controller (I), CDSCO HQ, New Delhi
3. Sh. Sella Senthil, Drugs Inspector, CDSCO (HQ), New Delhi.
4. Mr. Saurabh Jain, Drugs Inspector, CDSCO (HQ), New Delhi.

DG, DGHS welcomed the invitees of meeting and briefed the agenda and objective of the meeting.

Dr. Neeru Singh, Director, RMRCT, Jabalpur, explained her study of Comparative evaluation of Bivalent Malaria Rapid Diagnostic Tests versus traditional methods in field with special reference to heat stability testing in Central India. The results reveal that few kits show low sensitivity and specificity that may cause severe hazards on public health and indicate that not all commercially available bivalent kits are suitable for the programme. In this regard Secretary, Deptt of Health Research, MOH& FW & Director General, ICMR requested the Director, NVBDCP; some kind of regulatory check is required while issuing commercial licence to the manufacturers. In this connection Director, NVBDCP has requested Drugs controller General of India to organize a meeting under the chairmanship of Director General of Health Services and ICMR to deliberate the matter in detail and to discuss the followings in respect of In-Vitro Diagnostic kit for malaria.

- I. To prescribe minimum standards
- II. To identify the laboratories for testing
- III. To prepare common testing protocol
- IV. To ensure availability of panel for evaluation / testing

In response to question raised by the DG, DGHS regarding required sensitivity of the kits, Dr. Neena Valecha, Director, NIMR explained that the kits procured by the programme are based on the specifications developed by expert committee of NVBDCP and there are standard guidelines for pre-dispatch batch testing as well as post-dispatch Quality Assurance being carried out by NIMR since 2009. This is done as per standard WHO/NVBDCP protocols / SOPs which are in place. She further informed that although field evaluation is ideal, but it is time consuming and not cost effective. Further, the results are variable and not reproducible.

After deliberations, the member recommends following action points:

1. As the study is field base, the laboratory based evaluation shall be carried out at national level government institutes and the result shall be compared.
 2. Batch testing by using standard procedures as per set protocol is acceptable mode of evaluation.
 3. Constitution of consortium of testing laboratories may be constituted with the following Government institutes in order to have the common testing protocol, Testing Specification, Testing Fees, Time line for testing, common testing panel, quantity required for testing etc., for the testing of In vitro diagnostic kits for Malaria (Rapid, ELISA, NAT, Etc.):
 - i. NVBDCP, 22 Sharnath Marg, Delhi 110054
 - ii. National Institute of Malaria Research, Sec-8, Dwarka, Delhi-110077.
 - iii. Regional Medical Research Centre for Tribals (RMRCT), Jabalpur
 - iv. National Institute of Biologicals (NIB), Noida
 - v. National Centre for Disease Control (NCDC), 22 Sham Nath Marg, New Delhi-110054
 - vi. AIIMS, New Delhi
- For this purpose NVBDCP, NIMR & NIB, Noida shall be responsible for providing the same within the time bound manner.
4. The samples of the In Vitro diagnostic kits for Malaria will be drawn by the officers of CDSCO and respective states and the samples will be forwarded to at least two of the above mentioned laboratories for testing purpose. If product tested at two laboratories is found to be of Not of Standard quality then action shall be taken against the manufacturer, importer, Distributors, under the provisions of Drugs and Cosmetics Act & Rules.

5. The NIB, Noida to take up the necessary steps for testing of the Malaria diagnostic kits at their laboratory, and to obtain training from NIMR and NVBDCP for panel preparation and evaluation..
6. It was proposed that prior to issue import and manufacturing license three lots of the above mentioned kits shall be tested at National Institute of Malaria Research, Sec-8, Dwarka, Delhi-110077 (or) Regional Medical Research Centre for Tribals (RMRCT), Jabalpur or NIB, Noida.
7. If samples are forwarded by the CDSCO to the above mention government laboratories for batch testing, no testing fee is required.
8. If samples are forwarded by the manufacturer/importer, for batch testing for the grant of import/manufacturing license, fees as prescribed by the concerned laboratory is applicable.

The meeting ended with the vote of thanks to the chair

Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare
(Medical Device and Diagnostic Division)

Food and Drug Administration Bhawan
Kotla Road, New Delhi-110002

F. No. 29/Misc/4/2013-DC (S3)

Dated: 9 DEC 2013

Meeting Notice

Subject: Meeting of need for regulatory check for issuing commercial Licence to manufacturers of Malaria Rapid Diagnostic Tests-Regarding

Director, RMRCT, Jabalpur has conducted Comparative evaluation of Bivalent Malaria Rapid Diagnostic Tests versus traditional methods in field with special reference to heat stability testing in Central India. The results of the evaluation indicate that not all commercially available Bivalent kits are suitable for the programme. In this regard Secretary, Deptt of Health Research, MOHS FW & Director General, ICMR requested the Director, NVBDCP; some kind of regulatory check is required while issuing commercial licence to the manufacturers. In this connection Director, NVBDCP has requested Drugs controller General of India to organize a meeting under the chairmanship of Director General of Health Services and ICMR to deliberate the matter in detail.

In the view of the above it is proposed to convene the high level meeting under chairmanship of Director General of Health Services on 18-12-2013 at 3 pm in the Committee Room, A- Wing, 4th Floor, Room No. 445, Directorate General of Health Services, Nirman Bhawan, New Delhi-110001 to discuss the followings in respect of In-Vitro Diagnostic kit for malaria.

- I. To prescribe minimum standards
- II. To identify the laboratories for testing
- III. To prepare common testing protocol
- IV. To ensure availability of panel for evaluation / testing

You are requested to make it convenient to attend the meeting along with line of acceptances and confirmation to this email id dg@nic.in and dg@nic.in (or) to fax 011-23136073.

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

To,

1. The Secretary to GOI, Deptt. Of Health Research, MOHS/FW & Director General, Indian Council of Medical Research (ICMR), Post Box No. 4811, Ansari Nagar, New Delhi
2. Dr. A. C. Dharwad Director, NVBDCP, 22 Sharnath Marg, Delhi 110064
3. Dr. Neeru Singh, Director Regional Medical Research Centre for Tribals (RMRCT), Jabalpur
4. Director, National Institute of Biologicals (NIB), Noida
5. Mr P K Bhat, Secretary-G Chief (Laboratory) Bureau of Indian Standards (BIS), Manik Bhawan, 8 Bahadur Shah Zafar Marg, New Delhi-110002.
6. Additional Director & Head, (Microbiology), A Division of Microbiology, National Centre for Disease Control (NCDC), 22 Sharnath Marg, New Delhi-110064
7. Head, Department of Microbiology, All India Institute of Medical sciences (AIIMS), Ansari Nagar, New Delhi-110029

Copy to

1. PS to Director General Health Services DGHS, Nirman Bhawan, New Delhi