SEA-HLM-335
Distribution: General

Policy Guidelines on Quality of Reagents for Health Laboratories

Report of an Intercountry Workshop
Jakarta, Indonesia, 8- 11 May 2001

WHO Project: ICP BCT 001

World Health Organization
Regional Office for South-East Asia
New Delhi
July 2001

CONTENTS

Page

Annexes

1. INTRODUCTION

An intercountry workshop to formulate policy guidelines on quality assurance of diagnostic kits in health laboratory services was organized at Jakarta, Indonesia from 8 to 11 May 2001. It was attended by participants from seven Member Countries of South-East Asia Region (Bangladesh, India, Indonesia, Myanmar, Nepal, Sri Lanka and Thailand) and facilitated by experts from Australia, United Kingdom, India and Indonesia. (See list of participants and the programme of work at Annexes 1 and 2).

Diagnostic kits (also known as *in-vitro* devices-IVD) are being used extensively for the screening, diagnosis and surveillance of various emerging diseases such as HIV/AIDS, hepatitis B and hepatitis C. Most of the developing countries do not have technical support and sufficient resources to develop their own infrastructure that will assure quality of both imported as well as indigenously produced diagnostic reagents and kits. In the absence of any policy guidelines and adequate infrastructure, the health laboratories may be offered sub-standard diagnostic kits, thus adversely affecting the quality of clinical care and public health activities. Accordingly, this intercountry workshop was organized to develop policy guidelines to assure quality of diagnostic reagents/kits.

2. OBJECTIVES

(1) To review the availability of policy guidelines, indigenous production, import of diagnostic kits in Member Countries, with special reference to HIV, hepatitis B and C kits;

(2) To review the regulations in practice for controlling the release of these diagnostics in the markets of Member Countries and their impact on ensuring availability of appropriate reagents/kit and identify the constraints;

(3) To discuss and finalize the draft guidelines developed by WHO to support Member Countries in assuring quality of diagnostic kits;

(4) To develop networking of laboratories in evaluation of test kits, and

(5) To identify areas needing WHO and international support.

The workshop was inaugurated on 8 May 2001 by Dr Wiadnyana on behalf of Prof Dr Ahmad Djojosugito, Director General of Medical Care, Ministry of Health and Social Welfare, Government of Indonesia. He emphasized the significant role that quality diagnostic kits can play in diagnosis, surveillance and containment of various diseases. The welcome address was delivered by Dr Gunawan Yamin, Directorate of Laboratories, Ministry of Health and Social Welfare, Government of Indonesia. The address of the Regional Director, World Health Organization, South-East Asia Regional Office, highlighting the importance of assuring quality of diagnostic kits was read out by Dr Georg Petersen, WR, Indonesia. Dr Sudarshan Kumari, Regional Adviser, BCT, WHO described the objectives of the workshop.

Professor S.P. Thyagarajan was elected the chairman, Dr Gunawan Yamin as co-chairman and Dr Sujatha Mananwatta the rapporteur for the workshop.

Dr Sudarshan Kumari gave a brief overview of the status of quality assurance of diagnostic kits in Member Countries. Most of the Member Countries had weak infrastructure and inadequate technical expertise to undertake the task of assuring the quality of diagnostic reagents. She emphasized the need of having workable guidelines to institute an effective mechanism to achieve the objective of making quality diagnostic kits available. The activities being undertaken by WHO for evaluation of kits for HIV/AIDS, hepatitis B and hepatitis C were outlined by Dr Gaby Vercauteren of the Blood Safety Team of WHO Headquarters, Geneva. She also briefed the participants about the role of WHO in global procurement of the HIV/AIDS diagnostic kits that has resulted in the availability of a large bulk of quality diagnostic kits at economic cost.

3. STATUS OF QUALITY ASSURANCE OF DIAGNOSTIC KITS IN SEAR

The status of quality assurance of diagnostic kits in Member Countries of the South-East Asia Region, as presented by country representatives on the basis of a questionnaire sent by the Regional Office has been summarized in the table below:

***Table**: Status of quality assurance of diagnostic kits in SEAR countries.*

Sl. No.	Parameter for quality assurance of diagnostic kits	Bhutan	Bangladesh	DPR Korea	Indonesia	India	Myanmar	Nepal	Sri Lanka	Thailand
1	National policy and guidelines for quality assurance of diagnostic kits	-	-	-	-	-	-	-	-	+
2	National Regulatory Authority for pharmaceutical products	+	+	+	+	+	+	+	+	+
3	National Regulatory Authority assuring quality of kits	-	-	+	+	+	-	-	-	+
4	National Regulatory Laboratory for pharmaceutical products	-	+	+	+	+	+	+	+	+
5	National Regulatory Laboratory for diagnostic kits	-	-	-	-	+	-	-	-	+
6	Availability of legal framework for kits	-	-	+	+	-	-	-	-	+
7	Networking of laboratories for quality assurance	-	-	-	-	-	-	-	-	+
8	Organization of NEQAS	-	-	-	-	-	-	-	-	+

In brief, except Thailand, none of the remaining countries of the Region has adequate infrastructure, expertise and mechanism to assure quality of diagnostic kits.

Dr Elizabeth Dax, Director, National Serology Reference Laboratory of Australia, described in detail the mechanism that was in operation in Australia for assuring the quality of diagnostic kits. She also explained the linkages between the regulatory authority and the reference laboratory along with the details of the role other laboratories play in providing post-marketing surveillance data. Similarly, proposed guidelines of European Community that will be in operation in the near future were briefly discussed by Dr John V Parry, Deputy Director, Public Health Laboratory Services, London. He described the intricacies of accurate evaluation of diagnostic kits in the laboratory and the expertise and infrastructure required.

4. POLICY GUIDELINES FOR QUALITY ASSURANCE OF DIAGNOSTIC KITS

Dr Rajesh Bhatia, WHO/SEARO and Professor S.P. Thyagarajan introduced to the participants various elements that are required to implement an effective mechanism. These included development of national policy, establishment of infrastructure with adequate resources and skilled personnel, establishment of criteria for laboratory proficiency, international collaboration and movement of diagnostic kits across the countries. The draft guidelines prepared by the Regional Office were finalized after discussion by the participants.

5. COUNTRY-SPECIFIC ACTION PLANS

Representatives from all the countries, with the help of the facilitators, developed country-specific action plans to initiate a formal mechanism of quality assurance of diagnostic kits in their respective countries.

6. RECOMMENDATIONS

The need for making available quality diagnostic kits for screening, diagnosis and surveillance of diseases was recognized, especially in developing countries where infections such as HIV/AIDS, hepatitis B and hepatitis C have emerged as diseases of great public health significance. Realizing that currently many shortcomings exist in the regulatory mechanism for diagnostic kits, the participants made the following recommendations

6.1 To Member Countries

(1) The Member Countries should adapt generic policy guidelines for assuring the quality of diagnostic reagents/devices in consonance with their local laws governing the quality of other drugs and devices to support diagnostic services and thereby facilitate quality of care. The guidelines will be implemented through National Drug/Devices Control Authority in whom all the legal powers will be vested.

(2) As far as possible, an independent laboratory should be recognized as the National Reference Laboratory for diagnostic kits. If this is not feasible, more than one laboratory may be designated as National Reference Laboratory for a specific category of diagnostic kits. These laboratories must have quality management system, meet international standards, get themselves accredited to an international agency and provide technical support to the National Regulatory Authority in all matters pertaining to diagnostic kits.

(3) The Member Countries should constitute Advisory Committees for National Regulatory Authority (NRA) and the National Reference Laboratories (NRL) that will undertake evaluation of diagnostic kits.

(4) NRA, on the advice of the national committee, should develop guidelines based on international criteria for manufacturers/importers to get the quality of diagnostic kits assessed for certification, licensing and registration.

(5) The Member Countries should provide adequate infrastructure, human resources and financial inputs to ensure that an efficient national regulatory mechanism becomes operational and is sustained.

(6) The National Reference Laboratory should also act as the National Focal Point for the Member Country for all international technical issues.

(7) The training of professional staff employed in the National Regulatory Authority and Laboratory may be arranged in those countries where the regulatory mechanisms are fully functional. Assistance from WHO may be sought for capacity-building as well as for the procurement of international standards and reference materials.

(8) Member Countries will initiate National External Quality Assessment Schemes in HIV/AIDS, hepatitis B and hepatitis C. The results of these NEQAS shall be made available to the National Reference Laboratories to monitor their competence and also to indicate the performance of various kits that have been used.

6.2 To WHO

(1) WHO should continue advocacy at the highest level in Member Countries for assuring the quality of diagnostic kits.

(2) WHO should facilitate capacity-building, training of personnel from regulatory agencies and procurement of international standards and reference materials to support development of efficient infrastructure in Member Countries.

(3) WHO should coordinate the development of an electronic network between various regulatory agencies to facilitate rapid exchange of information, data and technical advances.

(4) WHO should organize an intercountry workshop for laboratories undertaking evaluation of diagnostic kits to harmonize the specifications for quality assessment of diagnostic kits and to avoid intercountry variations in certification and licensing of these diagnostic kits.

7. CONCLUDING SESSION

In conclusion, the participants were requested to initiate activities listed in their respective action plans in their countries upon return. Technical support from the experts who facilitated this workshop and WHO would be forthcoming and countries could seek the same as and when required. WHO would continuously monitor the progress made, so as to facilitate achievement of targets set in the country-specific action plans.

Annex 1

LIST OF PARTICIPANTS

Bangladesh

Mr A.K.M. Animul Islam Superintendent, I.V. Fluid Plant
Institute of Public Health
Mohakali
Dhaka

Mr Muhammad Kamaluddin
Deputy Director
Drug Administration
Dhaka
e-mail: sheehale@bangla.net

India

Dr Sopai Tawsik
Pathologist
General Hospital
Naharlagun – 791110
Arunachal Pradesh

Mr Rakh Vishwanath K.
Chief Bacteriologist
State Public Health Laboratory
Stavely Road, Pune-411001
Maharashtra
e-mail: sphlpn@vsnl.com

Indonesia

Dr July Kumalawati, DMM, SpPk
Cipto Mangunkusumo Hospital
Jakarta
e-mail: july@cbn.net.id

Dr Ria Syafitri, E.G.
Central for Blood Transfusion
Indonesian Red Cross
Jakarta

Dra Anggraini Armyn, MM
Directorate of Drug and
Health-Equipment Control
Jakarta

Myanmar

Professor Kyi Kyi Thin
Head, Microbiology Division
Institute of Medicine (1)
Department of Medical Sciences
Yangon

Dr Myint Myint
Assistant Director
Food and Drug Administration
Department of Health
Yangon
e-mail: jda@mptmail.net.mm

Nepal

Mr Din Dayal Bhattarai
Senior Drug Administrator
Department of Drug Administration
Kathmandu

Dr Sarala Malla
Pathologist
Bir Hospital
Kathmandu
e-mail: harimal@wlink.com.np

Sri Lanka

Dr (Mrs) S. Mananwatta
Senior Microbiologist
National STD/AIDS Control Programme
Colombo
e-mail: sujam@itmin.com

Dr U.A. Mendis
Deputy Director General (LS)
Department of Health Services
Colombo

Thailand

Mrs Wilai Chalermchan
Medical Technologist
National Institute of Health
Department of Medical Services
Nonthaburi
e-mail: wilai@dmsc.moph.go.th

Ms Siriphan Eamrungroj
Senior Pharmacist
Division of Medical Devices Control
Food and Drug Administration
Nonthaburi
e-mail: hiri@health.moph.go.th

Temporary Advisers

Dr S.P. Thyagarajan
Head, Microbiology
Dr. ALM Postgraduate Institute of
Basic Medical Sciences
University of Madras
Taramani
Chennai-600 0113
e-mail: sptrajan@md4.vsnl.net.in

Dr S.P. Das
Deputy Drug Controller of India
Directorate-General of Health Services
Ministry of Health and Family Welfare
Nirman Bhawan
New Delhi 110011

Dr Elizabeth M. Dax
Director
National Serology Reference Laboratory
41 Victoria Parade
Fitzroy 3065
Australia
e-mail: liz@nrl.go.au

Dr John V Parry
Deputy Director
PHLS Sexually Transmitted &
Blood-Borne Virus Laboratory
Virus Reference Division
Central Public Health Laboratory
61 Colindale Avenue
London NW95HT, UK
e-mail: JohnVParry@appleonline.net

Dr Gunawan Yamin
Manager
National External QA in Microbiology &
Investigation of Noscomial Infections
Ministry of Health and Social Welfare
Jakarta

Observers

Dr Fonny J. Silfanus, M.Kes
Directorate of Direct
Transmittable Diseases Control
Directorate-General of Communicable Diseases
Control and Environmental Health
Ministry of Health and Social Welfare
Jakarta

Dr Tony Soetanto, SpPK
Infectious Diseases Hospital
Jakarta, Indonesia
Dr Swispen Masda, Apt
Provincial Health Laboratory
Jakarta

WHO Secretariat

Dr Gaby Vercauteren
BCT
WHO/HQ, Geneva
e-mail: vercautereng@who.ch

Dr Sudarshan Kumari
BCT
WHO/SEARO, New Delhi
e-mail: kumari@whosea.org

Dr Rajesh Bhatia
STP, BCT
WHO/SEARO, New Delhi
e-mail: bhatiaraj@whosea.org

Dr Amaya Maw-Naing
WHO Medical Officer (STD/AIDS)
WR Indonesia
Jakarta

Dr Bing Wibisono
WHO National Professional
WR Indonesia
Jakarta

Annex 2

PROGRAMME

Tuesday, 8 May 2001

0900 hrs	Registration and inauguration	
1000 hrs	Status of diagnostic kits in SEAR and need for quality assurance	Dr S Kumari
1030 hrs	Methodology of global evaluation of diagnostic kits and recent experiences	Dr Gaby Vercauteren
1130 hrs	Country status reports: Bangladesh Indonesia India	Country Representatives
1400 hrs	Country status reports contd: Myanmar Nepal	Country Representatives
1515 hrs	Country status reports contd: Sri Lanka Thailand	Country Representatives
1630 hrs	Wrap up for the day	Chairman

Wednesday, 9 May 2001

0900 hrs	Quality Assurance of diagnostic kits in Australia. – Feasibility of its application in SEAR countries	Dr Elizabeth Dax
1015 hrs	Quality Assurance of diagnostic kits in Europe – Feasibility of its application in SEAR countries	Dr John V Parry
1115 hrs	Strategies for quality assurance of diagnostic kits in SEAR countries – Organizational set-up – Infrastructure and methodology	Dr Rajesh Bhatia and Prof S.P. Thyagarajan

	– Monitoring and evaluation – Networking – R&D – International cooperation – Information technology	
1400 hrs	Constraints experienced in SEAR countries in quality assurance of diagnostic kits and issues for consideration	Dr S Kumari
1430 hrs	Group Work: – National policy on quality assurance of diagnostic kits – International movement of devices – Role of National Control Laboratory in quality assurance of diagnostic kits – Methodology for evaluation of kits and development of acceptance criteria	

Thursday, 10 May 2001

0930 to 1300 hrs	Group Work contd..	
1400 hrs	Presentation of group work by the chairpersons/rapporteurs Discussion	
1530 hrs	Presentations contd	
1630 hrs	Finalization of draft guidelines	

Friday, 11 May 2001

0930 hrs	Preparation of country-specific action plan for quality assurance of diagnostic kits	
1130 hrs	Preparation of action plan contd….	
1400 hrs	Presentation of action plan	
1600 hrs	Recommendation Valedictory session and closing	