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Report of Second Regional National Control Laboratory Network Meeting

*Barog, Dist. Solan, Himachal Pradesh, India
14-16 November 2005*



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Organization**

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Executive summary

The World Health Organization (WHO) provides international reference standards (IRS) for vaccines and other biologicals. These preparations are the primary standards against which regional or national standards, considered as secondary standards, are calibrated. The concept of using these well-characterized preparations as references against which batches of biological products are assessed for quality and consistency of production by both manufacturers and the National Control Laboratories (NCLs) remains the fundamental principle. IRS is not always available in sufficient quantities for use on an assay by assay basis. Hence, the development of regional working reference standards (RWRS) for vaccines is a new activity initiated by the regional network of NCLs of three vaccine-producing countries, namely India, Indonesia and Thailand.

The second Regional NCL Network Meeting on preparation of reference standards for vaccines was held at Barog, Himachal Pradesh, India on 14-16 November 2005 with the support of WHO.

The objectives of the meeting were to:

- (1) Review progress made on identified projects since the last meeting held in Bangkok, Thailand in 2004.
- (2) RWRS amongst the vaccine-producing countries in the South-East Asia Region as and when these are available.
- (3) Initiate collaborative studies for developing RWRS for pertussis and Japanese Encephalitis (JE) vaccines,
- (4) Develop plans of action for 2006 and 2007 on the two projects.
- (5) Decide venue of third Regional NCL Network meeting to be held in 2006.

The meeting was attended by 12 participants representing the three NCLs of the network and four observers nominated by Ministry of Health & Family Welfare, New Delhi, India. There were five resource persons from WHO's Headquarter and the South-East Regional Office (SEARO), National Institute of Infectious Diseases (NIID), Japan, and National Institute for Biological Standards and Control (NIBSC), London, to facilitate the proceedings.

1. Background

The first regional meeting of staff from National Control Laboratories (NCL) in three vaccine-producing Member countries in the WHO South-East Asia Region (SEAR) was held in Bangkok, Thailand, from 3 to 5 November 2004 to establish a regional NCL network to develop reference standards for vaccine. Eight participants representing the NCLs and national regulatory authorities (NRAs) in India, Indonesia and Thailand and 10 local observers had attended the meeting. NRA staff were invited so that they could be involved from an early stage and were aware of this important activity of NCLs. The meeting agreed to establish a NCL network to develop regional vaccine working reference standards. Two projects, based on public health needs in the Region, were identified under the workplan for 2004-2005. It was agreed that the Central Drugs Laboratory (CDL), Kasauli, India, would lead the project on pertussis and NCL, Thailand, would lead the project on Japanese encephalitis (JE).

It was also decided that the next meeting of the network will be held at CDL, Kasauli, in 2005 to launch the collaborative studies. WHO consultant would visit the three NCLs to assess their capacity to prepare, establish and distribute regional biological reference standards and submit assessment reports to WHO-HQ and WHO-SEARO prior to the second regional NCL network meeting in Kasauli.

2. Objectives

The second regional NCL network meeting to develop working reference standards for pertussis and JE vaccines was held at Barog, Himachal Pradesh, India, from 14 to 16 November 2005. The following were the objectives of the meeting:

- (1) Review progress made on identified projects since the last meeting in 2004;
- (2) Devise mechanisms for transportation, distribution and use of regional working reference standards (RWRS) among vaccine-producing countries in the Region as and when these were available;

- (3) Initiate collaborative studies for developing RWRS for pertussis and JE vaccines;
- (4) Develop plans of action for 2006 and 2007 on the two projects; and
- (5) Decide the venue of the third regional NCL network meeting to be held in 2006.

3. Proceedings of the meeting

Twelve participants from the three NCLs of the network and four observers nominated by the Ministry of Health and Family Welfare, New Delhi, India, attended the meeting. There were five resource persons from WHO/HQ and WHO/SEARO, the National Institute of Infectious Diseases (NIID), Japan, and the National Institute for Biological Standards and Control (NIBSC), London, to facilitate the proceedings.

The list of participants and facilitators is given at Annex 1. The agenda is given at Annex 2.

Dr David Wood, Coordinator, Quality Assurance and Safety, IVB/WHO/HQ welcomed the participants. Dr J.Sokhey, Short-term Professional, IVD/SEARO outlined the purpose and scope of the meeting. She stated that the project leaders would: (a) share their plans for the identified projects; (b) develop plans of action for 2006-2007 to initiate collaborative studies with vaccine manufacturers for the projects; and (c) decide the venue and the time of the next meeting in 2006.

Dr David Wood was elected as the Chairman and Rapporteur: Mrs Teeranart Jivapaisarnpong (Thailand) was elected as the Rapporteur for discussions on the JE vaccine project, and Dr A.K. Tahlan (India) was elected as the Rapporteur for discussions on the pertussis vaccine project.

3.1 Development of RWRS on JE vaccine

The findings and recommendations of Dr Derek Calam, WHO Short-term consultant after his visits to the three NCLs, which had been submitted to WHO/SEARO, were presented by Dr J.Sokhey.

Dr Derek Calam had been assigned by WHO in July 2005 to visit the NCLs in India, Indonesia and Thailand to assess their capacity to prepare, establish and distribute regional biological reference materials.

He had reported that all laboratories were competent, well-equipped and staffed for their current responsibilities. All NCLs operated under international quality assurance systems and maintained comprehensive documentation of their activities. The regulatory approach to vaccine control, including lot release of all batches of vaccines intended for use, was similar in all countries. Different levels of testing for lot release were in place. Many of the products were of similar importance in all three countries and employed similar test methods. This meant that provision of reference standards on a regional basis would avoid duplication and make a more efficient use of existing resources. All three laboratories had programmes for the preparation of national reference standards for vaccines but there were some aspects of calibration and stability that needed improvement. All laboratories had adequate storage facilities with emergency power supply at different temperatures appropriate for storage of reference materials. All laboratories had good stock-control systems in place manually operated in India and Indonesia and computerized in Thailand. Computerization was very sophisticated since it allowed multiple interrogation of the database and provided not only information on stocks, including their location, storage temperature and numbers issued but also reasons for issue and results obtained. This facilitated monitoring of performance and provided alerts on any change. The laboratory in Thailand had a good traceability system for chemicals, reagents and media used.

All three NCLs recognized the need for training in the design and analysis of collaborative studies, including statistical analysis and testing of newer vaccines. Dr Sokhey said that Dr Calam had strongly recommended accelerated degradation studies to be performed for the reference materials and information leaflets sent out alongwith supply of each reference material.

3.2 Preparation of international reference materials

Dr D. Wood made a presentation on the preparation of WHO international reference materials for quality control of biological products. He said that WHO's role in assuring the quality, safety and efficacy of biological products was covered under the following three main areas of work:

By setting :

- (1) Global written standards approved by the Expert Committee on Biological Standardization (ECBS) and then published in Technical Report Series (TRS);
- (2) Global measurement standards prepared jointly with WHO collaborating centres; and
- (3) Promote regulatory convergence.

One of the core functions was setting and validating norms and standards as well as promoting and monitoring their proper implementation. This was planned as short-term, medium-term and long-term activities. It was planned that, by 2015, all countries will use vaccines of assured quality. There had been many developments in this regard such as transferring the preparation of reference materials for antibiotics from NIBSC to European Department for Quality of Medicines (EDQM), establishment of reference material standardization working group, initiation of regional reference materials, activities on capacity-building as well as development of standards in new areas like genetic testing and cell therapy development.

WHO had set up a system for priority setting to develop reference materials to address global public health needs. The prioritization process was published in WHO-TRS 932. In addition, the list of priorities will be reviewed by the Advisory Expert Panel on Biological Standardization. WHO was recruiting more experts for this panel to have appropriate gender and regional balance. There were many reference materials in the pipeline, including those to replace old ones and develop new materials. Currently WHO works with WHO Collaborating Centres on a one-on-one basis with plans to develop more networking systems.

3.3 Preparation of international and secondary standards

*presented by Dr M. Ferguson, Principal Scientist,
NIBSC, London*

Dr Ferguson said that to prepare the international standards (IS), the candidate material was filled with great precision to meet all stringent conditions in quality-control testing. IS must be prepared in a freeze-dried form. Appropriate freeze-drying cycle and all critical parameters that will

impact product characteristics and quality needed to be determined. Stability studies of the candidate standards must be done and predicted and loss of standards activity should be calculated at various temperatures such as -20 °C, +4 °C and +20 °C.

WHO recommendations for the preparation, characterization and establishment of international and other biological reference standards (revised 2004) would be published as a WHO TRS in 2006.

3.4 **Preparation of JE antibody standard**

presented by Dr M.Ferguson

She said that the JE antibody standard had been prepared using sera of six persons in the USA, who were vaccinated with the JE vaccine. The antibody was calibrated by neutralizing with three JE virus antigens: Nakayama, Beijing and JE virus natural strain. The antibody from the vaccine immunized by JE Nakayama showed a higher Neutralization Test (NT) titer against the Nakayama strain than that against the Beijing and natural strains. The antibody from vaccine immunized by JE Beijing also showed a higher NT titer against Beijing than that against the Nakayama and the natural strains. Therefore, it was not possible to use one JE antibody standard for the determination of antibody titer in the vaccine. However, this preparation may be used as a positive serum for the standardization of plaque reduction neutralization test (PRNT) assay of mouse serum.

3.5 **JE vaccine reference preparation in Japan**

*presented by Dr Ichiro Kurane, Department of Virology,
National Institute of Infectious Diseases, Japan*

JE vaccine reference standard was prepared in Japan using the same method of production and formulation as the vaccine prepared routinely by the manufacturer. JE vaccine reference standards using both the Nakayama and Beijing JE virus strains were prepared. Calibration of the candidate reference was done against the current reference material. The lot that showed potency close to the current one was chosen and used as the new reference. Stability studies of the reference materials were not performed. However, data for the last five years showed no loss in PRNT50 of the reference material. Therefore, the expiry date of the reference standard was assigned at five years.

3.6 Production and QC of JE vaccine in Japan

Dr Ichiro Kurane informed that the JE vaccine currently produced and used in Japan is freeze-dried inactivated mouse brain using Beijing virus strain. Some manufacturers also produce the vaccine from Nakayama virus strain for export purposes only. Previously, the potency assay was done using single dilution immunization of mice and chick embryo (CE) cell culture was used for PRNT. Due to statistical reasons and difficulties faced in preparation of CE cell culture the method of testing had been changed to four dilution immunization of mice and the use of Vero cells for PRNT. The results of PRNT using Vero cells and CE cell culture showed good correlation.

3.7 Additional information and comments

- If Vero cell-based JE vaccine is licensed in Japan, there will be a need to develop a new reference standard specific to this vaccine.
- Vero cell line with complete historical record is available with NIBSC, London, as WHO stock and can be provided to all NCLs. However, it will be necessary to validate and standardize the test method PRNT using Vero cells.
- NIID, Japan, should provide the rationale of using pooled sera in PRNT instead of individual mouse serum.
- If the candidate vaccine has PRNT50 value close to the current reference vaccine it could be used as a new reference vaccine. However, in Japan there are no defined criteria for setting up the potency value of the new reference vaccine. In case results show a significant difference between potency values of the new and current reference vaccines. NIID will hold discussions with the manufacturer to finally assign the acceptable potency value.

3.8 JE vaccine reference standard preparation in South Korea

Dr D Wood presented the report on behalf of Dr Jin-Ho-Shin. He informed that JE inactivated vaccine (Nakayama strain) was first licensed in the 1970s. Homologous Japanese reference standard vaccine was used in the potency assay of the vaccine. Korean Food & Drug Administration (KFDA) initiated in 2001 the National Biological Standardization Programme for

preparing vaccine reference standards. Thirteen national reference standards were established in 2004 including that for JE vaccine. Six laboratories, including KFDA, and vaccine manufacturers had participated in the collaborative study. In the collaborative study NIID189 - the reference standard & X004 - the candidate reference standard materials included were freeze-dried inactivated mouse brain JE vaccines of the Nakayama virus strain. The potency assay was done by the single dilution immunization of 12 ICR mice and PRNT method using CE cell culture. The statistically evaluated data has shown comparable potency values of the two standard materials included in the study.

Comments

Some information was not clear, such as how many tests were performed in each laboratory and why there were 12 data for each sample studied. Dr Wood said he would convey these questions to Dr Jin Ho Shin for clarification.

4. Country presentations in quality control testing of JE vaccines using JE reference standards

These were presented by Mr D.K. Sood, Joint Director, CDL Kasauli, India; Dr Supaporn Phumiamorn, Medical Scientist, Division of Biological Products, Ministry of Public Health, Thailand and Ms Elizabeth Ika Prawahju Arisetianingsih of National Quality Control Laboratory of Drug and Food (NQCL DF), Jakarta, Indonesia.

NCLs India and Thailand have been performing the lot release of JE vaccines that are produced locally and imported. There is one manufacturer of JE inactivated mouse brain-based vaccine in each country.

CRI, Kasauli manufactures freeze-dried inactivated JE vaccine using the Nakayama virus strain.

Currently, the single dilution immunization of mice and PRNT in CE cell culture method for potency testing is used for the lot release of JE vaccine by CDL using the Nakayama strain. However, this lab has also developed the NT method using CPE of JE virus in Vero cells. It was informed that this newly developed NT method will be proposed as an

additional method of potency assay for the lot release of JE vaccine. The reference vaccine standard received from NIID, Japan, is used as working reference standard and a national reference standard (NRS) has not been prepared. CDL performs 2-3 potency assays a year of JE vaccine using Nakayama strain. So far, it has not received any JE vaccine of the Beijing strain.

In Thailand, Government Pharmaceutical Organization (GPO) produces inactivated mouse brain based-liquid JE vaccine using Beijing virus strain. Approximately 60-100 vaccine batches are produced in a year. The division of Biological Products (DBP) NCL-Thailand, performs the lot release of JE vaccines that are produced locally from Beijing virus strain and imported vaccines prepared using the Nakayama and Beijing virus strains.

Potency assay of JE vaccine is performed by using three dilution immunizations of mice and PRNT in Vero cells. The working reference standard used has been received from NIID Japan. The current reference vaccine standard used is Lot 184A. DBP plans to replace it with the national reference vaccine standard which will be prepared and calibrated against the new NIID Japan reference vaccine standard Lot 197P.

In 2006, DBP plans to receive the concentrated JE bulk from GPO. The candidate reference vaccine will be freeze-dried in 10 doses per vial. The two laboratories of DBP and QC laboratory of GPO will participate in the collaborative study. Approximately 6,000 vials of JE reference vaccine standard will be available for use and supply for three years.

In Indonesia, currently, JE vaccine is neither used nor is licensed. NQCL has no experience about the potency assay of the vaccine. However, surveillance data shows that in 2004 & 2005 JE cases have been reported in some areas of the country. Therefore there is a likelihood that JE vaccine will be used in the future in endemic areas. It was also mentioned during the discussions that NQCL staff needed training in potency assay of JE vaccine in future and it became clear that prequalified JE vaccine will be imported and licensed as and when available.

Comments and recommendations

- Dr Kurane recommended that CDL perform PRNT in Vero cells. However, if comparable potency results are shown using CE cell

culture and CPE in Vero cells then this laboratory can use CPE method in Vero cells for the collaborative study on regional reference JE vaccine project.

- DBP should expand the collaborative study on national reference JE vaccine to the collaborative study for regional reference JE vaccine.
- There is the possibility that in Indonesia live attenuated JE vaccine would be used as it is likely to be prequalified in the near future. Therefore, it is important for NQCL to know and confirm the kind of JE vaccine that will be used in the country before taking part in the collaborative study and get its staff trained in potency testing of the vaccine.

5. Group discussion on plan of action 2006-2007 for developing JE vaccine regional working reference standard

It was agreed that the candidate reference vaccine for the JE regional working reference standard should be freeze-dried inactivated mouse brain vaccine using the Beijing virus strain. Since very few potency tests are done in a year for JE vaccine prepared from Nakayama virus strain, there is no need to develop a regional working reference standard for it.

Department of Biological Products (DBP) Thailand will lead the JE project on preparation of RWRS. The five laboratories participating in the collaborative study are NIID Japan, CDL Kasauli, two laboratories in DBP and GPO-QC laboratory in Thailand.

NQCL Indonesia could make use of the RWRS for JE vaccine and the collaborative studies experience if inactivated JE vaccine is used in the country. NQCL will investigate the country situation prior to deciding whether to participate in this collaborative study or not. Beijing JE virus strain is available with CDL Kasauli. It is recommended that positive JE antibody serum should be included in each PRNT. The human JE antiserum is also available with NIBSC London for this purpose.

Since GPO in Thailand has no experience in producing freeze-dried JE vaccine, DBP recommended seeking support in supply of freeze-dried candidate material from Biken, Japan, or going in for a contract with NIBSC London, for filling and freeze-drying of the bulk received from GPO in Thailand.

DBP is due to prepare a collaborative study draft protocol and send it to WHO-SEARO and HQ, NIBSC, London, NIID, Japan, CDL, Kasauli and NQCL, Indonesia for comments prior to the start of the collaborative study in 2006.

The plan of action for 2006-2007 to initiate the collaborative study for developing JE vaccine RWRS was presented by NCL Thailand, responsible for leading the JE vaccine project (Annex 4). Constraints like filling, freeze drying and distribution of materials which had no easy solution were stated. In 2006, the two participating laboratories - CDL and NCL Thailand will standardize the potency assay of JE vaccine using Vero cells. A draft of collaborative study protocol will be prepared by NCL Thailand and sent to WHO & NIBSC for comments.

6. Presentations and discussions

6.1 Discussions on development of RWRS on pertussis vaccine

The session began with country presentations on preparation of reference standards for pertussis component of DTwP vaccine. Dr A.K. Tahlan, Head, CDL narrated the Indian experience in preparation of NRS for vaccines. He discussed briefly about the organization and structure of the laboratory, its functions, number of samples tested for lot release of vaccines, role in supply of NRS for bacterial & viral vaccines and antisera to various Indian manufacturers and testing of samples in AEFI reported cases. Different research projects undertaken by the laboratory in the recent past, including on stability study of pertussis challenge strain with 10% DMSO as stabilizer, efficacy of thiomersal as preservative and its effectiveness under different conditions, and studies on adsorption, interference and bio-equivalence in combined vaccines were presented.

Studies undertaken in respect of pertussis reference standard such as assay validation, harmonization of potency testing procedures, details about stock inventory of the proposed RWRS and progress made on the ongoing collaborative study with the manufacturers on the new candidate reference vaccine standard were presented. Stability of proposed reference standard, manufacturers' willingness to use the same and annual requirement within the country was also discussed. It was explained that presently only real-time stability data with respect to biological reference standards is available with CDL.

CDL suggested that the details available regarding unitage, methodology used in assigning it and stability data may be exchanged between NCLs of the region for review & statistical analysis. It was also suggested that since the present stock of pertussis reference standard available with CDL is insufficient, it should have a bigger batch of candidate reference vaccine which could suffice for at least five years as RWRS.

Ms Kusmiaty, Head, Vaccine Section, NQCL Indonesia made a presentation on the preparation of reference standard for pertussis component of DTwP vaccine. She presented the method of preparation of pertussis vaccine component and various tests conducted for its evaluation. The first NRS was prepared in 1993, the second in 1997 and third in 2000. The main problem faced in the preparation was the lyophilization of the material because of limited capacity of the freeze drier, resulting in frequent preparation of NRS.

Ms Sakalin Trisiriwanich, Medical Scientist, Department of Medical Sciences, Ministry of Public Health representing NCL Thailand presented the laboratory's experience in preparation and standardization of pertussis NRS. She elaborated the method of preparation of pertussis vaccine standard, testing methodology and analysis of results. It was stated that the existing reference vaccine standard used might be discontinued if the RWRS is made available. Annual requirement of pertussis reference standard in Thailand was also discussed.

Dr Dorothy Xing, Principal Scientist, Bacteriology Division, NIBSC London discussed in detail the development of various pertussis international reference standards. For the proposed RWRS for pertussis vaccine, she elaborated the methodology of preparation and characterization of the candidate material, type of data that need to be

generated and the importance of statistical evaluation. It was agreed that though the Kendrick test shows inter-as-well-as intra-laboratory variability, it is still the gold standard for the potency estimation of pertussis vaccine. It was also emphasized that moisture and oxygen content greatly influence the stability of the reference standard in the long run. Accelerated degradation studies need not be done before distribution of candidate reference material but may be done in tandem with routine testing on a continuous basis.

Key issues for the proposed RWRS collaborative study

- Number of vials required for proposed RWRS;
- Minimum number of assays required to be done by each participating laboratory;
- Preparation of draft study protocol;
- Number of ampoules/vials of IRS required for study;
- Modalities for transportation of material/ref. std to the participating NCLs. It was agreed that the receiver should be responsible for the transportation fee;
- Role of WHO/SEARO as facilitator in the proposed study;
- Study design was discussed and it was decided that in-house methodology would be used;
- CDL Kasauli will distribute adequate quantity of the proposed working reference standard for pertussis vaccine to NCLs Indonesia and Thailand for the collaborative study and also ensure subsequent distribution of RWRS on regular basis;
- Correspondence with collaborating laboratories and international laboratories to coordinate the study;
- It was agreed that before the initiation of the proposed study the participants would have to take the permission of their respective Governments.

6.2 Site visit to CDL Kasauli

On 16 November 2005, a site visit to CDL Kasauli was made in the forenoon by all participants and facilitators. It was a very useful opportunity

for them to get first-hand information about the laboratory, its functioning, testing and lot release vaccines performed and the like.

6.3 Plan of action for reference standard on JE vaccine

In the afternoon, Ms Teeranart Jivapaisarnpong, Director, NCL Thailand, presented the plan of action for 2006-2007 developed on JE vaccine reference standard collaborative study as follows:

In 2006

- DBP Thailand will prepare and send JE positive mouse serum sample to CDL Kasauli and NIID Japan for determination of PRNT50 (draft protocol will be prepared and sent to WHO & NIBSC for comments and the finalized protocol will be sent to CDL Kasauli with the serum sample. At this point it was agreed that there was no need for NCL, Thailand to send the JE positive mouse serum sample and the protocol to the other laboratories. Each lab should use its own JE positive mouse serum or may request NIBSC for supplies.
- DBP Thailand and CDL Kasauli will standardize the potency assay of JE vaccine using Vero cells.
- DBP Thailand will prepare the candidate reference vaccine in freeze dried form (as study pilot material) or seek possibility to procure the freeze dried candidate reference vaccine from Biken, Japan.
- DBP will perform the accelerated degradation testing of the candidate reference vaccine.
- DBP will prepare draft protocol for the collaborative study and it will be sent to WHO & NIBSC for comments.

In 2007

- DBP will send the candidate NIID reference vaccine Lot 197A to the participating laboratories of the collaborative study. Each laboratory will perform three tests by using their own method of potency testing.

- DBP will collect all results with raw data and do the statistical analysis as well as assign potency value to the reference vaccine.

The following constraints were highlighted:

- Supply of bulk JE vaccine by GPO needs to be confirmed. It depends on the policy of the new Director General of GPO.
- DBP has no experience and knowledge in freeze drying of JE vaccine.
- Filling and freeze drying of the vaccine has not yet been committed by joint venture facility.

6.4 Plan of action for reference standard on pertussis vaccine

Dr A.K.Tahlan presented the plan of action 2006-2007 for developing RWRS for pertussis vaccine and to initiate the collaborative study:

In 2006

- CDL will prepare and send questionnaire to DBP Thailand and NQCL Indonesia to know their requirements of RWRS (January).
- CDL will develop documents related with the study design, study protocol, instruction leaflets, safety data sheets, handling instructions, label content and storage and shipment procedures (February).
- CDL will get back the information from DBP Thailand and NQCL Indonesia regarding their requirements of RWRS (February).
- CDL to get back comments, if any, from DBP and NQCL on specifications of candidate reference material to be ultimately used as RWRS (March).
- CDL will assess the cumulative requirements and send proposal to the manufacturer for sourcing of candidate reference material (March).
- CDL will send study draft protocol and instruction leaflet to NIBSC for comments (March).
- CDL will send the study protocol, Instruction leaflet and Indian NRS of pertussis vaccine to DBP and NQCL and receive vaccine samples from them (May, pending government clearance).

- CDL to have the candidate reference vaccine ready (June).
- CDL to conduct pilot study with participating labs with currently available NRS (October).
- CDL to collect data and results of participating labs and statistically analyze the results of pilot study (October).
- CDL to present the pilot study results at the network meeting which will be held at NQCL Indonesia in the last quarter of 2006.

In 2007

- Commencement of the collaborative study with participating laboratories, including the vaccine manufacturers (January).

The meeting closed with a vote of thanks for all participants, facilitators and organizers. It was agreed that the third regional NCL meeting will be held at NQCL Indonesia in the last quarter of 2006.

Annex 1

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Annex 2

PROGRAMME

Monday, 14 November 2005

JE MEETING

09:30	Opening of the meeting	
	Welcome Address	Dr David Wood
	Administrative Announcements	Dr Jaspal Sokhey
	Introduction of participants and faculty members	
09:45	Discussions on Prof. Derek Calam's report	
11:00	Presentations by the three Laboratories on JE standards	
	CDL, Kasauli	
	NCL, Thailand	
	NQCL, Indonesia	
11:30	Presentation on JE reference standard preparation	Dr Kurane
12:00	Presentation on JE reference standard preparation	Dr Morag Ferguson
12:30	Discussions	
14:00	Presentation on JE reference standard preparation by HQ	Dr Jin-Ho Shin
15:30	Discussions and preparation of protocols etc to initiate JE collaborative study	

Tuesday, 15 November 2005

PERTUSSIS MEETING

09:30	Preparation and characterization of reference standards for Biologicals	Dr David Wood
10:00	Preparation, characterization and standardization of Pertussis ref standard	Dr Mike Cobel
11:00	Preparation and standardization of pertussis national ref standard	Dr A K Tahlan, CDL,K
11.30	Preparation and standardization of pertussis national ref standard	Ms Teeranart, NCL-THA

- 12:00 Preparation and standardization of pertussis national ref standard NQCL-INO
- 12:30 Discussions on how to proceed and initiate the collaborative study on preparation of regional working ref standard on pertussis vaccine
- 14:00 Discussion continued
- 15:30 Preparation of draft protocol for the collaborative study

Wednesday, 16 November 2005

- 09:30 Visit to CDL, Kasauli
- 11:00 Discussions and finalization of protocols developed for collaborative study on JE vaccine
- 14:00 Discussions and finalization of protocols developed for collaborative study on Pertussis vaccine
- 15:30 Discussion continue
- 16:00 Wrap-up