

Meeting Report

Second Workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region



Manila, Philippines
12–14 March 2013



Participants of the Second Workshop for National Regulatory Authorities
for Vaccines in the Western Pacific Region
12–14 March 2013, Manila, Philippines

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REPORT

**SECOND WORKSHOP FOR
NATIONAL REGULATORY AUTHORITIES FOR VACCINES
IN THE WESTERN PACIFIC REGION**

Convened by:

**WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC**

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NOTE

The views expressed in this report are those of the participants in the Second Workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region and do not necessarily reflect the policies of the World Health Organization.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for the participants in the Second Workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region, which was held in Manila, Philippines, from 12 to 14 March 2013.

SUMMARY

The Second Workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region was held in Manila, Philippines, from 12 to 14 March 2013.

The objectives of the workshop were:

- (1) to finalize and endorse the concept paper for the Regional Alliance of National Regulatory Authorities (NRAs) for Vaccines in the Western Pacific; and
- (2) to assist countries to conduct NRA self-assessment using the WHO NRA tool and to develop or update their institutional development plans (IDPs).

The three-day extensive workshop was organized by the WHO Regional Office for the Western Pacific. Dr John Patrick Ehrenberg, Director of Combating Communicable Diseases, delivered the opening remarks on behalf of Dr Shin Young-soo, WHO Regional Director for the Western Pacific. A total of 21 participants from 15 Member States and five temporary advisers from three countries participated in the workshop.

The workshop was designed in four working sessions. Global and regional updates and detailed discussion on the Regional Alliance concept paper and road map took place in working session one. NRA self-assessment was carried out by 11 countries in working session two. Capacity-building and the Regional Alliance workplan were discussed in working sessions three and four, respectively. The 11 countries who conducted self-assessments presented a summary of their IDPs in plenary session on day three.

The participants who attended the Second Workshop for National Regulatory Authorities for Vaccines in the Western Pacific reviewed all the related documents for the Regional Alliance for NRAs for Vaccines in the Western Pacific and agreed upon the following conclusions:

- (1) The Regional Alliance concept paper, including the formation and terms of reference of the Regional Alliance Steering Committee (RASC) and the Regional Alliance Working Groups (RAWG), has been reviewed, finalized and endorsed. The Secretariat will incorporate the changes into the concept paper as discussed in the workshop.
- (2) The Taskforce involved in development of the concept paper, road map and workplan should be acknowledged and thanked for their work, and for achieving their outcomes.
- (3) The Regional Alliance for NRAs for Vaccines in the Western Pacific is now launched as a collaborative platform to promote and support strategies and programmes to develop and strengthen NRAs to ensure that all vaccines, especially those in national immunization programmes, are of assured quality.
- (4) Member States who attended the workshop will finalize their IDPs and send them to the Secretariat by 30 April 2013.
- (5) The draft Regional Alliance workplan has been reviewed and endorsed. Member States request the Secretariat to further review the IDPs from countries, and update the Regional Alliance workplan accordingly. The workplan will then be sent to the RASC for review and agreement.
- (6) Member States request the Secretariat to convene an RASC meeting in the last quarter of 2013.
- (7) Member States request the Secretariat and the RASC to explore possible funding sources for the activities of the Regional Alliance.

LIST OF ACRONYMS

CC	Collaborating Centre
ECBS	Expert Committee on Biological Standardization
EPI	Expanded Programme on Immunization
GLO	Global Learning Opportunity
GRP	Good Regulatory Practices
GRP-RC	Good Regulatory Practices – Resource Centre
GTN	Global Training Network
ICDRA	International Conference of Drug Regulatory Authorities
IDP	Institutional Development Plan
KFDA	Korea Food and Drug Administration
MAPREC	Mutant Analysis by PCR and Restriction Enzyme Cleavage
NRA	National Regulatory Authority
OPV	Oral Polio Vaccine
RA	Regional Alliance
RASC	Regional Alliance Steering Committee
RAWG	Regional Alliance Working Group
TAG	Technical Advisory Group
UN	United Nations
WHO	World Health Organization
WPRO	Western Pacific Regional Office

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Keywords:

Vaccines - Standards/ Immunization activities/ Health personnel – education

1. INTRODUCTION

The Second Workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region was held in Manila, Philippines, from 12 to 14 March 2013. A total of 21 participants from 15 Member States and five temporary advisers from three countries participated in the meeting.

1.1 Objectives

- (1) to finalize and endorse the concept paper for the Regional Alliance of National Regulatory Authorities (NRAs) for Vaccines in the Western Pacific; and
- (2) to assist countries to conduct NRA self-assessment using the WHO NRA tool and develop or update their institutional development plans (IDPs).

1.2 Opening remarks

Dr John Patrick Ehrenberg, Director, Division of Combating Communicable Diseases, WHO Regional Office for the Western Pacific, delivered the opening remarks on behalf of Dr Shin Young-soo, WHO Regional Director for the Western Pacific. Dr Ehrenberg welcomed everyone to the workshop. Highlighting the importance of vaccine regulation, he mentioned that independent, competent and effective regulatory systems are very important to oversee the supply of vaccines of assured quality in countries.

Describing the situation analysis of regulatory status in the Region, he stated that, as of February 2013, only seven countries in the Region, including China, in 2011, have been rated as having a functional regulatory system as per the internationally recognized national regulatory authority vaccine indicators. Four are vaccine-producing countries and three are vaccine-procuring countries.

Dr Ehrenberg then shared the history of the formation of the Regional Alliance for NRAs for Vaccines in the Western Pacific. He expressed his gratitude to all members of Taskforce countries for drafting the concept paper, including the road map and workplan. He hoped that all those documents would be finalized and endorsed by Member States, as well as launching of the Regional Alliance for NRAs for Vaccines in the Western Pacific during the workshop.

He further emphasized that the Regional Alliance for NRAs for Vaccines in the Western Pacific would be a platform to address the many challenges presently faced by NRAs in countries. The Alliance would also provide support in encouraging convergence in regulatory standards, enhancing the mechanism for the exchange of regulatory information, promoting collaborative exchange programmes and building NRA capacities across the Region.

Finally, he concluded his remarks by hoping for very successful deliberations and thanking all participants for attending the workshop.

2. PROCEEDINGS

2.1 Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific

The working session on the Regional Alliance for NRAs for Vaccines in the Western Pacific was chaired by Dr Chung Keel Lee, Special Adviser to the Commissioner, Korea Food and Drug Administration (KFDA).

2.1.1 WHO NRA strategic forum

Mr Lahouari Belgharbi, Scientist, Essential Medicines and Pharmaceutical Policies, WHO Headquarters, presented the topic "WHO NRA strategy forum". He stated that WHO NRA strengthening programmes were established in 1997, their main purpose being to accelerate capacity-building in vaccine-producing countries. Vaccine demand is increasing globally; currently, 146 manufacturers in 25 countries supply 90% of global vaccines. It will be important for competent NRAs to regulate to ensure the quality of vaccines.

He explained the recognized WHO five steps for capacity-building. To date, various activities have been implemented, including mapping and assessment for building vaccine regulatory capacity in the pre-marketing and post-marketing phases. He further stated that a lot of training sessions have been delivered through the Global Training Network (GTN), Global Learning Opportunity (GLO) and NRA strengthening programmes. Mr Belgharbi also shared the main objectives and expected outcomes of the NRA Strategic Forum, including the detailed processes to establish it.

2.1.2 Update on the formation of the Regional Alliance for NRAs for Vaccines in Western Pacific

Dr Md. Shafiqul Hossain, EPI Technical Officer, WHO Western Pacific Region, stated at the beginning of his presentation that the WHO Western Pacific Region is very diverse in many aspects. Dr Hossain highlighted that, at the request of Member States, a series of activities were conducted to develop the concept paper, road map and workplan. The Technical Advisory Group (TAG) for immunization and vaccine-preventable diseases in the WHO Regional Office for the Western Pacific already support the initiative and will request its endorsement by the Regional Committee for the Western Pacific.

All the documents related to the Regional Alliance had been prepared for presentation and review in the workshop for Member States' endorsement. Dr Hossain further mentioned that a website for the Regional Alliance has been developed, where the documents will be posted.

2.1.3 Reports of the Regional Alliance Taskforce committee meetings

Dr Elisabeth Kerr from the Therapeutic Goods Administration, Australia, presented reports of the two Regional Alliance Taskforce meetings held in Canberra, Australia, and Manila, Philippines, in 2012 and 2013.

The main objectives of the Taskforce meeting held in Canberra from 31 May to 1 June 2012 were to finalize the draft concept paper for formation of the Regional Alliance for NRAs and to discuss possible support for the Regional Alliance from Taskforce

member countries. The WHO Regional Office for the Western Pacific shared the developed documents among Member States for comment.

The main objectives of the Taskforce meeting held in Manila on 11 March 2013 were to undertake a final review of the draft concept paper, to develop a membership proposal for the Regional Alliance Steering Committee (RASC) and to develop the Regional Alliance workplan for Member States' review and endorsement.

2.1.4 Concept paper for the Regional Alliance for NRAs for Vaccines

Dr Kerr shared the main part of the concept paper with all workshop participants, reviewing it sentence by sentence. Multiple questions were raised, which were answered and clarified by the presenter, Taskforce member countries and the Secretariat. The Secretariat also agreed to revise or add to further clarify in some definitions.

2.1.5 Formation of and terms of references for the Regional Alliance Steering Committee, the Regional Alliance Working Groups and the Secretariat

Mr Seog-Youn Kang from KFDA gave a presentation on the formation and terms of references of the Regional Alliance Steering Committee, the Regional Alliance Working Groups and the Secretariat. The participants reviewed the document sentence by sentence and raised some questions for further clarification.

The criteria used for selection of countries in the RASC is based on vaccine-producing countries with functional NRAs (four countries), one vaccine-procuring country with a functional NRA and two United Nations vaccine-procuring countries. Along with the four vaccine-producing countries with functional NRAs (Australia, China, Japan and the Republic of Korea), it was proposed that Malaysia, the Philippines and Viet Nam also be included as members of the RASC.

The participants agreed that the Regional Director for the WHO Western Pacific Region should officially propose the nomination of the four vaccine-producing countries and the three other countries (Malaysia, the Philippines and Viet Nam) for membership of the RASC. Membership will be for four years. Regarding the question on chairing of the RASC, the Secretariat answered that the chairperson of the RASC would be selected by the Regional Director each year. It was agreed that Regional Alliance Working Groups (RAWGs) would be developed after completion of the Regional Alliance workplan.

2.2 NRA self-assessment

The working session on NRA self-assessment was chaired by Ms Yasuko Inokuma, Ministry of Health, Labour and Welfare, Japan.

2.2.1 Introduction to the NRA assessment process

Mr Belgharbi introduced the WHO vaccine NRA assessment tool to the participants, assisted by Mr Samir M.A. Abdel Wahab El Hemsy, Information Technology and Telecommunication Technical Officer, WHO Eastern Mediterranean Region. He then shared the NRA assessment procedures: (1) self-assessment by county to identify gaps and strengths, and develop an IDP; and (2) assessment and reassessment.

The assessment tool includes the following components: system, marketing authorization, post-marketing surveillance, laboratory access, lot release, regulatory inspection, and oversight of clinical trials. Countries with functional NRAs provide the

technical support in the assessment process for other countries. However, experts from non-functional NRAs are not excluded if the specific function is already functional and if they possess related expertise.

The presenter shared the NRA assessment statistics, with more than 101 countries assessed globally using the WHO NRA assessment tool. He also shared, in detail, the importance of assessment for establishing/strengthening NRAs in countries.

2.2.2 Demonstration of the NRA self-assessment tool

Mr Belgharbi demonstrated the step-by-step procedure to conduct self-assessment, gave examples and entertained questions from participants. At the end of the session, he requested the selected 11 countries to go to their designated group work table for self-assessment of their NRAs. Facilitators from WHO and Taskforce countries were assigned to each group to support the assessment activity.

2.2.3 NRA self-assessment and development and presentation of IDPs

The country participants continued to conduct assessment until the afternoon of 13 March and then started to develop their IDPs on the basis of their assessment findings.

In the morning session of 14 March, participants from 11 countries (Brunei Darussalam, Cambodia, Fiji, the Lao People's Democratic Republic, Malaysia, Mongolia, New Zealand, the Philippines, Papua New Guinea, Singapore and Viet Nam) presented their IDPs in the plenary session.

During the discussion, the Secretariat mentioned that, while IDPs are mainly for country use, they would also be helpful to the Regional Alliance in facilitating collaboration and support, e.g. capacity-building. Once the IDPs are available, WHO and highly-capacitated NRA countries, like Australia, China, Japan and the Republic of Korea, may plan their support for the activities in these countries.

The participants presented their IDPs and commented that the assessment had identified weakness and strengths in their NRA systems, as well as management issues among institutions. The presenters urged country participants to continue their self-assessments and to involve all relevant institutions in the process, including reviewing documents on their return to their respective countries. It was discussed that the NRAs of these countries should identify focal points for each function, finalize their self-assessments and upload the results into the sharepoint. The Secretariat, with the support of countries with functional NRAs, will validate the self-assessments and follow up on IDPs. These countries also expressed the need for continuing support from the Secretariat.

During the presentation in the plenary session, Brunei Darussalam, Cambodia, Fiji, the Lao People's Democratic Republic, Malaysia, Mongolia, New Zealand, Papua New Guinea, Singapore and Viet Nam all requested the building of capacity in the lot release function. The Secretariat mentioned that the proposed procedures should check the mandate and define the approach of lot release, and then develop the decision-making process. Capacity-building in the lot release function may not be possible in the short term.

It was discussed that countries may need one month to complete their self-assessments and develop their IDPs, involving all related departments/institutions/sections.

2.3 Capacity-building

The working session on capacity-building was chaired by Dr Wang Junzhi from the National Institutes for Food and Drug Control, China.

2.3.1 Regulatory science

Dr David Wood, Coordinator of Quality, Safety and Standard, WHO Headquarters, gave a presentation on the regulatory science agenda. He covered the Global Vaccine Action Plan, the vaccine regulatory science agenda, examples of vaccine regulatory science, and strategies and actions to support vaccine regulatory sciences.

Dr Wood said that the Global Vaccine Action Plan was a catalyst and offered a unique opportunity for regulators worldwide to develop and propose a global regulatory science agenda for vaccines. He then described the definition of regulatory science as follows:

- (1) Regulatory science consists of the areas of science that are used in the assessment of the quality, safety and efficacy of human and veterinary medicines throughout their lifespan, as well as the scientific areas used in regulatory decision-making.
- (2) Regulatory science includes basic and applied biomedical sciences, including genetics, pharmacology, biostatistics, clinical trial methodology and epidemiology, as well as social sciences, such as decision sciences, risk assessment and communication sciences. It aims to contribute towards the development of standards and tools to be used in the regulation of medicines.
- (3) Regulatory science is the science of developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of regulated products.

The presenter also shared the expected outcome of regulatory science and provided some examples that have contributed to improvement in the assessment of vaccines as follows:

- (1) MAPREC and transgenic mouse tests for evaluation of OPV.
- (2) Development and use of alternative potency evaluations for pandemic H1N1 vaccines.
- (3) Defining international consensus values for serological correlates of immunity for pneumococcal conjugate vaccines.

Dr Wood also shared the proposed strategies and actions to support vaccine regulatory science.

2.3.2 Good Regulatory Practices - Resource Centre (GRP-RC)

Mr Belgharbi, in his presentation on Good Regulatory Practices Resources Centre (GRP-RC), started with the definition and terminology of good regulatory practices. He also shared the common understanding on regulatory principles and best practices of the United States – European Union High-Level Regulatory Cooperation Forum.

He stated that regulatory measures should be proposed through an open and transparent process to the extent that is feasible. Accountability and participation of citizens and

stakeholders should be promoted, with adequate time, opportunity and tools (including the Internet) for stakeholder input and public comment at appropriate stages of the policy preparation process in advance of final adoption.

Mr Belgharbi then shared the definition of “capacity-building” from different sources. He discussed the International Conference of Drug Regulatory Authorities (ICDRA) recommendation to WHO on capacity-building and shared WHO activities in capacity-building.

Regarding the GRP-RC, the presenter also described how it can work in building capacities.

- (1) The GRP-RC should be located within the NRA or an affiliated institution as part of the official regulatory system.
- (2) GRP-RC status does not conflict with WHO collaborating centre status.
- (3) The GRP-RC should have been assessed against the WHO NRA published indicators as a functional NRA or as an institution that is part of the system.
- (4) The GRP-RC should have at least minimal resources to devote to GRP-RC functions, such as:
 - (a) institutional funding devoted to knowledge management, staff development and collaboration with other NRAs;
 - (b) technical expertise that is qualified to be invested in capacity-building activities;
 - (c) a strategic planning and monitoring process that is linked to the national system and is consistent with the WHO Strategic Plan (Regional Alliance); and
 - (d) a GRP policy in place that is promoted and documented.
- (5) The GRP-RC is selected by WHO based on the above criteria (which can be updated), with input from the Regional Alliance(s).

2.3.3a WHO Collaborating Centres for Biologicals

Dr Ivana Knezevic, Team Leader, Essential Medicines and Pharmaceutical Policies, WHO Headquarters, gave a presentation on WHO Collaborating Centres for Biologicals.

At the beginning of her presentation, she described the WHO norms and standards programme, including statistics on the development of written standards from 2010 to March 2013. She shared the outcome of the 2012 Expert Committee on Biological Sciences (ECBS) with the participants and discussed the regulatory risk assessment, standardization of bioterapeutics and implementation workshops.

Regarding WHO collaborating centres, Dr Knezevic said that there are more than 800 such centres in about 80 countries. She described the collaborating centre concept as follows:

- (1) Institutions are designated as WHO collaborating centres to help WHO implement its mandated work.

- (2) Designation is on the basis of existing collaboration as well as plans for the future.
- (3) Designation is not a lifelong agreement but should be reviewed regularly in the light of WHO needs.
- (4) No financial assistance is received from WHO.
- (5) Experience shows that the best results are achieved when collaborating centres work together as a network.
- (6) Successful operation needs frequent communication, interaction and flexibility to meet changing public health needs.

She stated that there is some misconception about collaborating centres that needs to be cleared up, and she shared the terms of reference of collaborating centres in biological standardization. She described the initiatives of the network of WHO collaborating centres for standardization and evaluation of vaccines. Finally, she shared the strategic issues facing collaborating centres.

2.3.3b Technical assistance to countries in the Region.

There are seven WHO collaborating centres for standardization and evaluation of vaccine globally, of which four are located in the WHO Western Pacific Region. There are no "regional" or "global" WHO collaborating centres. The WHO mission is global and therefore the input from collaborating centres should improve health worldwide.

Australia, China, Japan and the Republic of Korea gave a presentation on technical assistance to countries in the Western Pacific Region. At the beginning of the presentation, the presenters expressed their appreciation to WHO for establishment of the Regional Alliance as a collaborative platform. In their presentation, they described the organogram, terms of reference, activities performed by their collaborating centres and their current workplans. They also shared their available expertise and expressed their commitment to providing support to the Regional Alliance for NRAs for Vaccines in the Western Pacific. The Republic of Korea also proposed the establishment of a Western Pacific regional laboratory network.

In reply to questions regarding the responsibilities of WHO collaborating centres, the Secretariat stated that the centres would continue to work according to their terms of reference. In their usual workplans, there are also activities to support the Region. At the same time, beyond their collaborating centre activities, these institutions are located in the Region and, as reputed institutions in the Region, have a responsibility to support neighbouring countries and other countries in the Region to strengthen their capacities.

The Secretariat will review the IDPs developed by countries in the workshop and will then develop a workplan and submit requests to the four institutions located in the Region to support countries according to their expertise and availability.

2.4 Regional Alliance workplan

The working session on the Regional Alliance workplan was chaired by Dr Kerr.

2.4.1 Regional Alliance draft workplan

Mr Belgharbi presented the draft Regional Alliance workplan, based on the IDPs developed by 11 countries in the workshop and IDP from China.

He mentioned that mapping was carried out by conducting self-assessment. Strengths and gaps were identified and the Regional Alliance needs to validate the self-assessments within two to three months. IDPs need to be officially endorsed, and technical assistance and support sought. He added that the Secretariat needs to coordinate priorities and identify technical/financial support to countries.

The presenter then shared the recommended activities based on the developed IDPs. He also outlined Regional Alliance activities according to six categories.

Objective 1 Develop and strengthen the medicine regulatory system in the Western Pacific Region, with a focus on vaccines.

Objective 2 Promote and advocate the concept of functional NRAs to obtain government commitment and external partners.

Objective 3 Improve the sharing of information, technical expertise, best practices and communication among NRAs.

Objective 4 Contribute to increased global and/or regional production of vaccines of assured quality through assessed functional NRAs.

Objective 5 Promote the convergence of regulatory frameworks to facilitate access to quality-assured and affordable products.

Project management: Secretariat, RASC and RAWG of the Regional Alliance for NRA for Vaccines.

2.4.2 Donor proposal

Dr Hossain gave a presentation on donor proposals, describing the background on development of such proposals.

Formation of the Regional Alliance brought hope to countries regarding development or strengthening of their regulatory systems and functions, but there are inadequate funds to conduct all the necessary activities and WHO has only limited fund-raising capacity. System development or strengthening of programmes takes a long time and needs sustainable and long-term funding.

Dr Hossain then shared the outline and estimated cost of the budget proposal for five years.

3. CONCLUSIONS

The participants attending the Second Workshop for National Regulatory Authorities for Vaccines in the Western Pacific reached agreement on the following conclusions:

- (1) The Regional Alliance concept paper, including the formation and terms of reference of the Regional Alliance Steering Committee (RASC) and the Regional Alliance Working Groups (RAWG), has been reviewed, finalized and endorsed. The Secretariat will incorporate the changes into the concept paper as discussed in the workshop.
- (2) The Taskforce involved in development of the concept paper, road map and workplan should be acknowledged and thanked for their work, and for achieving their outcomes.
- (3) The Regional Alliance for NRAs for Vaccines in the Western Pacific is now launched as a collaborative platform to promote and support strategies and programmes to develop and strengthen NRAs to ensure that all vaccines, especially those in national immunization programmes, are of assured quality.
- (4) Member States who attended the workshop will finalize their IDPs and send to them to the Secretariat by 30 April 2013.
- (5) The draft Regional Alliance workplan has been reviewed and endorsed. Member States request the Secretariat to further review the IDPs from countries, and update the Regional Alliance workplan accordingly. The workplan will then be sent to the RASC for review and agreement.
- (6) Member States request the Secretariat to convene an RASC meeting in the last quarter of 2013.
- (7) Member States request the Secretariat and the RASC to explore possible funding sources for the activities of the Regional Alliance.

MEETING OF THE REGIONAL ALLIANCE TASKFORCE COMMITTEE

Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific

On 11 March 2013, the Regional Alliance Taskforce Committee meeting was held at the WHO Regional Office for the Western Pacific with the following objective:

- (1) to develop the Steering Committee and the Secretariat workplan for the Regional Alliance of NRAs for Vaccines in the Western Pacific.

The meeting was opened by welcome speeches from Dr Md. Shafiqul Hossain, EPI Technical Officer, WHO Western Pacific Regional Office; Dr Klara Tisocki, EMT Team Leader, WHO Western Pacific Regional Office; Mr Lahouari Belgharbi, EMP Scientist, WHO Headquarters; and Dr Ivana Knezevic, EMP Team Leader, WHO Headquarters. The day-long meeting was chaired by Dr Chung Keel Lee from the Korea Food and Drug Administration (KFDA).

1. Dr Hossain presented the objectives and agenda. He mentioned that the main objectives of the meeting were: to finalize the concept paper, roadmap and workplan for review by Member States in the plenary session; to finalize the formation of the Regional Alliance Steering Committee and Working Groups; to finalize the terms of reference; and to prepare for the Second Workshop for NRAs for Vaccines in the Western Pacific.
2. Dr Elisabeth Kerr from the Therapeutic Goods Administration, Australia, presented the latest draft concept paper and Dr Seog-Youn Kang from KFDA, the composition and terms of reference for the Regional Alliance Steering Committee, Working Groups and Secretariat, for finalization in plenary session on 12 March. Ms Bai He from the China State Food and Drug Administration presented the latest drafts of the Regional Alliance road map and workplan.

Participants from Taskforce countries discussed in detail the membership of the Regional Alliance Steering Committee (RASC). Below are questions raised in the discussion, with the corresponding replies:

- (1) The Regional Alliance Steering Committee is the main driver and will also convene the meeting once a year. Is this enough follow-up? In answer to this question, technical activities will be followed up by a working group and the Secretariat will definitely be part of that group and will inform the Steering Committee from time to time.

- (2) Who will take care of the workplan? Mr Belgharbi stated that countries will outline their strengths and weaknesses in their IDPs, which will be submitted to RASC and partners, who will then provide relevant support through the Regional Alliance.

Regarding the Regional Alliance workplan, it was discussed that the workplan will be finalized upon the development of IDPs by the 12 countries.

3. Four countries, Australia, China, Japan and the Republic of Korea, gave presentations on the possible support from their institutions to the Regional Alliance for NRAs for Vaccines

in the Western Pacific. These countries would also like to review country workplans/IDPs and then make commitments according to priority and availability of expertise.

Mr Belgharbi discussed the next steps for the Regional Alliance for NRAs for Vaccines in the Western Pacific. Dr Hossain then reviewed the agenda for the Second Workshop for NRAs for Vaccines and discussed individual responsibilities in the workshop.

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ANNEX 2

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**SECOND WORKSHOP FOR NATIONAL REGULATORY AUTHORITIES FOR VACCINES
IN THE WESTERN PACIFIC REGION
Manila, Philippines, 12-14 March 2013**

TENTATIVE TIMETABLE

Time	Tuesday, 12 March 2013	Time	Wednesday, 13 March 2013	Time	Thursday, 14 March 2013
08:00-08:30	Registration	08:30-08:45	Feedback from day 1	08:30-08:45	Feedback from day 2
08:30-08:45	Opening ceremony	08:45-10:00	Group session: NRA self-assessment - continuation	08:45-10:00	Plenary: Country presentation on NRA status and IDP Brunei, Cambodia, Lao, Mongolia Singapore, Fiji 10 minutes each per country
08:45-09:15	Self-introduction				
09:15-09:25	Objectives and agenda of workshop				
09:25-09:30	Administrative announcement				
09:30-09:45	Group photo				
09:45-10:15	COFFEE BREAK	10:00-10:30	COFFEE BREAK	10:00-10:30	COFFEE BREAK
10:15-10:30	1. Working session - Regional Alliance (RA) for National Regulatory Authorities (NRAs) for vaccines	10:30-12:00	Group session: NRA self-assessment- continuation	10:30-11:30	Country presentation on NRA status and IDP New Zealand, Malaysia, Philippines, Papua New Guinea, Viet Nam 10 minutes each country
10:30-10:45	Plenary: 1.1 WHO NRA strategic forum 1.2 Update on Regional Alliance for NRAs for vaccines in the Western Pacific Region 1.3 Update from Regional Alliance taskforce committee meetings 1.4 Concept paper for Regional Alliance for NRAs for vaccines 1.5 Formation and terms of reference of Regional Alliance for NRAs for vaccines in Western Pacific Region			11:30-11:45 11:45-12:15	3. Working session - capacity building Plenary: 3.1 Regulatory science 3.2 Good Regulatory Practices Resource
10:45-11:00					
11:00-11:45					
11:45-12:30					
12:30-13:30	LUNCH BREAK	12:00-13:00	LUNCH BREAK	12:15-13:15	LUNCH BREAK
13:30-14:00	2. Working sessions - NRA self-assessment	13:00-13:15	Plenary: 2.3 Introduction of developing IDP	13:15-14:45	3.3 WHO Collaborating Centre for Biologicals- Role of collaborating centres and technical assistance to countries of the Region. Presentation from WHO secretariat and four Collaborating Centers in Region 15 minutes each and 15 minutes discussion
14:00-15:00	Plenary: 2.1 Introduction of NRA assessment process 2.2 Demonstration of NRA assessment tool	13:15-15:00	Group session: Developing/updating Institutional Development Plan (Brunei, Cambodia, Lao People's Democratic Republic, Mongolia, Singapore, Fiji, New Zealand, Malaysia, Philippines, Papua New Guinea, Viet Nam)		
15:00-15:30	COFFEE BREAK	15:00-15:30	COFFEE BREAK	14:45-15:15	COFFEE BREAK
15:30-17:30	Group session: NRA self-assessment NRA self-assessment (Brunei, Cambodia, Lao, Mongolia, Singapore, Fiji, New Zealand, Malaysia, Philippines, Papua New Guinea, Viet Nam)	15:30-17:30	Group session: Developing/updating Institutional Development Plan (IDP)- continuation	15:15-16:00 16:00-16:15	4. Working session - Regional Alliance workplan Plenary: 4.1 Regional Alliance draft workplan 4.2 Donor proposal
17:30-17:50	Meeting of chairs and facilitators	17:30-17:050	Meeting of chairs and facilitators	16:15-16:30 16:30-17:00	Conclusions Closing remarks

