Meeting Report

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

17–19 September 2014

Manila, Philippines

World Health Organization
Western Pacific Region

Participants of the Third Workshop for the National Regulatory Authorities for Vaccines in the Western Pacific Region, 17–19 September 2014, Manila, Philippines

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WORLD HEALTH ORGANIZATION

REGIONAL OFFICE FOR THE WESTERN PACIFIC

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MEETING REPORT

THIRD WORKSHOP FOR NATIONAL REGULATORY AUTHORITIES FOR VACCINES IN THE WESTERN PACIFIC REGION

Convened by:

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NOTE

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

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for Member States in the Region and for those who participated in the Third Workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region in Manila, Philippines from 17 to 19 September 2014.

CONTENTS

Keywords:

Vaccines – Standards/ Immunization programmes/ Health personnel – education

ABBREVIATIONS

AEFI	adverse events following immunization
the Alliance	Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific
APEC	Asia-Pacific Economic Cooperation
DTP	Diphtheria, Tetanus and Pertussis
ECBS	Expert Committee on Biological Standardization
EVM	Effective Vaccine Management
GLO/VQ	Global Learning Opportunity for Vaccine Quality
GMP	Good Manufacturing Practice
IDP	Institutional Development Plan
JICA	Japan International Cooperation Agency
MFDS	Ministry of Food and Drug Safety, the Republic of Korea
NCL	National Control Laboratory
NIFDC	National Institutes of Food and Drug Control, China
NIID	National Institute of Infectious Diseases, Japan
NRA	National Regulatory Authority
NRS	National Regulatory System
PV	pharmacovigilance
QMS	Quality Management System
QRM	Quality Risk Management
RASC	Regional Alliance Steering Committee
RAWG	Regional Alliance Working Group
TGA	Therapeutic Goods Administration, Australia
VSS	Vaccine Safety Surveillance
WHO	World Health Organization

SUMMARY

The Third Workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region was held in Manila, Philippines from 17 to 19 September 2014.

The workshop objectives were:

1) to review and implementation of the work plan of the Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific (the Alliance) and future directions to support vaccine regulatory capacity strengthening in the Western Pacific Region;
2) to discuss and agree on a proposed plan for five working groups recently formed by the Regional Alliance Steering Committee (RASC) to support implementation of the institutional development plan (IDP) in Western Pacific Member States; and
3) to strengthen and align the work of four WHO collaborating centres for standardization and evaluation of biologicals in the Region with the work of the Alliance.

The three-day workshop was organized by the WHO Regional Office for the Western Pacific. The workshop was attended by 30 participants representing national regulatory authorities (NRAs) of 11 countries – Australia, Cambodia, Fiji, Japan, the Lao People's Democratic Republic, Malaysia, Mongolia, Papua New Guinea, the Philippines, the Republic of Korea and Viet Nam – one partner agency, Japan International Cooperation Agency (JICA) and WHO staff.

The participants noted the update of a concept paper on the Alliance that describes the Alliance's governance and working groups. The participants welcomed the Regional Director's letter to all Member States of the Region reaffirming the official launch of the Alliance. The participants discussed regional priorities for working group activities in: regulatory system strengthening; marketing authorization and licensing activities; lot release and laboratory testing; vaccine safety surveillance; and international collaboration.

NRAs in Cambodia, Malaysia, the Philippines and Viet Nam went through validation of self-assessment in 2013–2014. Their representatives presented their progress in implementing their IDPs. Representatives from the NRAs of Fiji, the Lao People's Democratic Republic, Mongolia and Papua New Guinea reported their challenges in IDP implementation, including limited financial and human resources. The Alliance Secretariat agreed to provide information on global and regional training plans to assist Member States in implementing IDP in 2015.

Member States may support greater participation of NRA experts in the priority areas and actions of the Regional Alliance Working Groups (RAWGs) and finalize their institutional development plans (IDPs) and send them to the Secretariat by 25 October 2014.

As the Secretariat of the Alliance, WHO will further review Member State IDPs and update the Alliance work plan, develop terms of reference for the RAWGs, organize transition of RASC Chairperson, Vice-Chairperson and Rapporteur and explore possible funding sources for the Alliance. The Secretariat will also organize a teleconference with the RASC before the next NRA workshop and regular teleconferences with NRA colleagues.

WHO will also continue discussing with countries to build consensus on emerging global and regional regulatory issues to address public health threats.

1. INTRODUCTION

1.1 Meeting organization

Member States have been attending the workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region annually since 2011. The first workshop was held in November 2011 in Seoul, the Republic of Korea, and the first taskforce meeting was followed in May 2012 in Canberra, Australia. The second workshop and the second taskforce meeting were held together in March 2013 in Manila, Philippines, where the concept paper was endorsed and the Alliance was officially launched. This was followed by the first meeting of the Regional Alliance Steering Committee (RASC) in Seoul, the Republic of Korea in October 2013. The RASC was organized with the governing body of the Alliance. The RASC refined the concept paper details, work plans and other governance details of the alliance such as the establishment of technical working groups. The third workshop was held in Manila, Philippines from 17 to 19 September 2014.

1.2 Meeting objectives

The workshop objectives were:

1) to review the implementation of the work plan of the Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific (the Alliance) and future directions to support vaccine regulatory capacity strengthening in the Western Pacific Region;
2) to discuss and agree on a proposed plan for five working groups recently formed by the Regional Alliance Steering Committee (RASC) to support implementation of the institutional development plan (IDP) in Western Pacific Member States; and
3) to strengthen and align the work of four WHO collaborating centres for standardization and evaluation of biologicals in the Region with the work of the Alliance.

Expected outcomes of the workshop were that participants would update the Alliance's work plan for 2014–2015 covering Member States IDPs, and actions for the Steering Committee and Secretariat, including a documented scheme of operating regional alliance working groups (RAWGs) for 2014-2015. Member States were asked to identify training needs for WHO's Global Learning Opportunity for Vaccine Quality (GLO/VQ) 2015. Training and collaboration needs for WHO collaborating centres on biological standardization should be identified.

2. PROCEEDINGS

2.1 Opening session

Dr Mark Jacobs, Director, delivered the opening remarks on behalf of Dr Shin Young-soo, WHO Regional Director for the Western Pacific. He acknowledged the need for an independent and competent national regulatory system to ensure the supply of quality-assured vaccines to support the success of the immunization programme. WHO has set minimum requirements for the functionality of NRAs for quality assurance of vaccines, but many countries in the Region still lack fully functional regulatory systems. With this, the Alliance was established and governed by the Steering Committee, overseeing five working groups based on the Alliance’s priorities. The Alliance is an authoritative platform to help address NRA challenges across the Region. Through the Alliance, Member States can promote closer collaboration to harmonize and implement international regulatory standards. The Alliance will also enhance information sharing and foster collaborative exchange programmes to build capacity among NRAs.

2.2 Update from the Secretariat

2.2.1 Highlights from the 23rd Technical Advisory Group on Immunization and Vaccine-Preventable Diseases in the Western Pacific

Dr Sergey Diorditsa shared the draft Regional Framework for Implementation of Global Vaccine Action Plan in the Western Pacific Region. Immunization safety and regulation activities in the Region include:

1) strengthening national surveillance capacity for vaccine safety including adverse events following immunization (AEFI) surveillance through developing safety communication guidelines, responding to vaccine safety incidents and conducting training;

2) strengthening national regulatory capacity through validation of NRA self-assessment in vaccine-procuring countries (Cambodia, Mongolia, Malaysia and the Philippines in 2013–2014), contributing to the programme of the WHO headquarters to conduct NRA assessments for vaccine-producing countries (China and Viet Nam in 2014 and establishment of the Alliance as regulatory forum in 2013); and

3) strengthening national capacity for effective vaccine management (EVM) through conducting EVM assessment, developing plans and implementing activities in several countries.

With the support of the EPI Technical Advisory Group and the Regional Committee for the Western Pacific, significant progress has been made in the control of vaccine-preventable diseases. The Region has maintained polio-free status, progressed towards elimination of measles and maternal and neonatal tetanus, and accelerated control of rubella and hepatitis B. The introduction of new and underutilized vaccines, including Japanese encephalitis vaccine, has also helped decrease disease burden.

In October 2014, the draft regional framework, with existing and new regional goals, will be submitted to the Regional Committee for the Western Pacific for the Regional Committee's consideration and potential endorsement.

2.2.2 Ensuring the quality, safety and efficacy of vaccines in the Western Pacific

Dr Jinho Shin reviewed the recommendations of the TAG to the Regional Office for the Western Pacific, from the 2009 recommendation to formulate the Alliance onwards. The most recent TAG meeting in June 2014 recommended drafting the Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific 2013–2020.

WHO aims to ensure that 100% of vaccines used in national immunization programmes are of assured quality. A vaccine of assured quality is defined as a vaccine that is regulated by an independent and functional NRA as assessed by WHO and against the NRA-published set of indicators, and when there is no unresolved reported problem with regulated vaccines.

The key regulatory functions to ensure that vaccines are of assured quality are: (1) marketing authorization and licensing, (2) pharmacovigilance with focus on adverse events following immunization (AEFI), (3) lot release, (4) laboratory access, (5) regulatory inspections, and (6) regulatory oversight of clinical trials.

The criteria for assessing NRA functionality differ across countries based on the source of vaccines used in national immunization programmes. Vaccines are produced domestically, procured independently or procured through UN agencies. As of September 2014, four out of five vaccine-producing countries and three out of 13 self-procuring countries are functional while all 19 procuring countries in the Region are still becoming functional.

As part of the strengthening activities, priorities for 2014–2015 were given to the NRA self-assessment and re-assessment of China in April 2014, while NRA assessment of Viet Nam was planned in the second half of 2014 or later. For procuring countries, high demand for NRA strengthening from Malaysia, Mongolia and the Philippines was noted.

There are four WHO collaborating centres on standardization and evaluation of biological medicines in the Region: Therapeutic Goods Administration (TGA), Australia; National Institute of Infectious Diseases (NIID), Japan; Ministry of Food and Drug Safety (MFDS), Korea and the National Institutes of Food and Drug Control (NIFDC), China. Support on training and testing, together with trainers, testers and potential trainees, was presented. Upcoming activities were discussed with focus on the NRA assessment and follow-up visit.

The concept paper was reviewed. A second edition of the concept paper is available.

The issues and challenges that the Alliance is facing were presented. The Alliance was formed and officially launched in March 2013 with expectations of meeting demands of low- and middle-income countries in establishing and strengthening vaccine regulatory systems and functions. The Alliance is also expected to provide advice on developing and implementing regional strategies to assure the quality, safety and efficacy of vaccines.

2.2.3 NRA strengthening: global strategy and support to region and country

Dr Nora Dellepiane de Rey Tolve presented an update of NRA strengthening, particularly on global strategy and support to regions and countries. With the EMP restructuring process, the Quality, Safety and Standards team was transferred from the Immunization, Vaccines and Biologicals department to EMP in November 2012. This transfer aligned policies, objectives, strategies and procedures for strengthening regulatory capacity for all medical products and health technologies.

The organizational structure of the EMP (including the RSS position) were shared, along with the RSS' strategic objectives, information on the EMP training inventory and how RSS collects the training-related information from different teams in the department.

2.2.4 WHO NRA assessment policy to for strengthening NRAs in the area of Medicines, Vaccines, Medical Devices, Diagnostics, Blood and Traditional Medicines

Mr Lahouari Belgharbi explained the role and mandate of WHO in health products and health technologies regulation. WHO develops internationally-recognized norms, standards and guidelines and provides technical assistance and training. WHO reforms, alignment of the workplan to World Health Assembly resolutions, activities, achievements, new challenges, the assessment policy, process and tool for assessment and opportunities for Member States were also discussed.

In regulation of health products, NRAs are accountable to the Government and the public. Decision-making processes should be transparent. Monitoring and evaluation mechanisms should be built into regulatory systems to assess attainment of objectives and policy impacts. WHO’s five-step capacity-building process to become a functional NRA and the recommendations of WHO and Pan American Health Organization for harmonized regulatory functions for medicines, medical devices, diagnostics and vaccines were discussed. A new tool for assessing all product categories is in development and will be ready in early 2015.

Using the NRA assessment tool, 114 out of 194 countries have been assessed by WHO for progress and impact from 1997 to 2014. Capacity-building activities have also been conducted through institutional and in-country trainings.

2.2.5 Vaccine Standardization

Dr Dianliang Lei discussed the norms and standards set by WHO for biologicals in support to EPI and NRAs. The standards are a tool for global harmonization of specifications. The timeline for informal consultation, Expert Committee on Biological Standardization (ECBS) submissions and implementation workshops from 2013–2016 were presented, along with guidelines and recommendations on vaccine standardization that are in-development and revision.

Ongoing collaboration between Expert Committee on Specifications for Pharmaceutical Preparations /ECBS and APEC to develop a draft on Good Review Practices will be presented in the ECBS meeting in October 2014.

Selected topics for implementation workshops include: stability evaluation of vaccines; standardization of biotherapeutics; vaccine lot release; combined vaccines based on Diphtheria, Tetanus and Pertussis (DTP); regulatory risk assessment; post-approval changes; typhoid conjugate vaccine; and GMP for biologicals. Challenges in implementation include fitting new standards into regulatory frameworks as regulators need training on the new standard and industry may not be prepared to respond to it.

Seven WHO collaborating centres met in March 2014 to develop standards and their application into regulatory practice. The collaborating centres have continued to provide technical support to NRAs/NCLs and manufacturers.

2.3 Update from the Member States on NRA assessments and IDP implementation

Four countries (Cambodia, Malaysia, the Philippines and Viet Nam) delivered updates on their respective NRA assessment and IDP implementation status. Presenters introduced their institutions, provided contact details and showed their organogram. They shared their NRA's strengths and areas for improvement in vaccine regulation as well as the assessors' recommendations during the validation of NRA assessment. They also provided updates on actions taken.

Next steps included a common request for continued support from WHO especially on capacity building. Topics on implementing IDPs were discussed during breakout sessions.

2.4 Assessors' perspective on what to do and how to do for IDP implementation

2.4.1 Countries introducing/improving regulatory system

Mr Belgharbi shared his perspective on introducing and/or developing a national regulatory system (NRS). In developing laws and determining a responsible institution, key actions include strategic planning, quality assurance, monitoring system, gaining public confidence and trust, seeking resources and accessing scientific through networking and how these areas help improve the regulatory system.

When introducing and developing a regulatory system, countries may:

1) update laws, ordinances and regulations that to cover all products and health technologies;
2) update mandates according to the needs and changes in the Organization and provide an enforcement power;
3) have an institutional plan consistent with the Vision and Mission of the Organization;
4) have a recall management system;
5) seek support from internal and external experts; and
6) establish a Quality Management System (QMS).

Regulatory development includes six key elements and actions:

1) Legal framework: collaborate with other functional NRAs and WHO for technical support, establish a task force that involves legal experts, and clarify mandates and enforcement powers of institutions.
2) Strategic planning, IDP and business model: seek technical support from WHO or business management experts.
3) Experts: develop an inventory of internal and external expertise and delegate experts to relevant functions.
4) Transparency and accountability: address conflicts of interest and confidentiality, publish decisions, annual reports and performance indicators regularly, establish a hotline and consult with stakeholders for feedback.
5) Financial and human resources: identify resource needs, obtain a budget line that gradually increases support to NRA activities and establish a system for fees.
6) Recall system: establish standard operating procedure or guidelines for a recall system where lot management is traceable by a national network that involves industry and NRA focal points at the peripheral level.

Participants can refer to the NRA assessment tool and work on the indicators for more information.

2.4.2 Countries introducing/improving expedited review procedure

Dr Dellepiane de Rey Tolve discussed vaccine assessment in the prequalification team on behalf of Ms Carmen Rodriguez Hernandez. WHO uses the same scientific principles in prequalification of vaccines to assess product safety, quality and performance efficacy as those used by well-resourced national regulators.

The prequalification process, evaluation principles, their importance to countries and NRAs and how they will influence the availability of assured quality vaccines were discussed. Specifically, prequalification provides an evaluation focused on programmatic needs. Prequalification also ensures follow up on complaints and reports of AEFIs, publishes the outcome of investigations, continually monitors the quality of prequalified vaccines through testing of samples reassessing products, targets audits and delists vaccines that do not maintain the established specifications and/or quality standards. Prequalification is also an opportunity for NRAs to save resources and focus on other priorities, since registration can be granted through a shorter procedure.

The differences in clinical data collected by NRAs and WHO were discussed (WHO will cover outside the country's territory). The procedures for accelerated national registration of WHO-prequalified pharmaceutical products the procedure for vaccines are being aligned for expedited review of prequalified products. The review of the procedures is online for comments and to be endorsed by relevant expert committees.

2.4.3 Reinforcing regulatory inspections in Western Pacific Region countries

Dr Alireza Khadem Broojerdi discussed the five-step capacity-building programme of WHO on inspection. Inspection performance can be improved through enhancing enforcement, competencies and skills. The process of strengthening the regulatory inspection starts from performing a gap analysis (assessment or observed audit) to addressing gaps by providing technical support, recommendations and training.

The Western Pacific Region has the highest number of trainings for regulatory inspection through in-country workshops among all regions. From 2009 to 2014, several activities including regulatory inspection workshops (Advanced-QRM) and observed and coached audits were conducted in China and Viet Nam. Major challenges encountered in improving regulatory inspection range from capacities of inspectors and the inspection process to enforcement and legal actions.

2.4.4 Countries introducing/improving lot release function

Dr Lei provided an overview of WHO's goal on vaccine quality assurance. Lot release of vaccines, one of the six regulatory functions of NRAs, is critical to ensure the quality of vaccines on the market.

WHO encourages networking among NRAs to address some practical issues. For instance, multiple testing can be costly and time-consuming due to the highly variable nature of many biological assays. Repetitive testing can also result in "false" classification out of specification results by chance, which then requires extensive investigation. In some cases, the same lot may be used to supply multiple countries.

Depending on the nature of the product, history of production and capacity of the National Control Laboratory (NCL), either further testing maybe required or recognition/acceptance of lot release certificates would suffice.

For vaccines produced and authorized domestically, initially, the NRA/NCL should test the vaccine in addition to critical review of the summary protocols. After confirmation of the consistency of the quality through testing, release of further lots should include full or selected testing or no testing depending on the nature of the product and established experience. If a vaccine is not authorized in the country of manufacture, the NRA who granted its authorization should take full responsibility of regulatory oversight.

For self-procured vaccines, the NRA/NCL of the procuring country must review the summary protocol as a minimum. Independent tests may be useful depending on the history of production, nature of the product and the capacity of the NCL. Recognition/acceptance of lot release certificates from the NRA/NCL of the manufacturing country or another competent NRA/NCL should also be considered as an alternative.

For vaccines supplied through United Nations agencies, WHO does not recommend further release by the NRA/NCL of receiving countries.

Quality management systems should be in place to support lot release activities. This includes trained and qualified personnel, record management and documentation, written procedures, internal and external audit systems, and oversight procedures. NRA responsibilities in lot release include:

1) to have sufficient capacity and expertise to effectively evaluate lot release protocols, and where required, be able to perform all relevant tests on samples;
2) to have the authority to demand appropriate samples;
3) to carry out activities independently of the quality-control activities performed by the manufacturer, including staff and facilities; and
4) to ensure that the mechanism for the independent lot release procedure is communicated clearly to the involved manufacturers.

2.4.5 Countries introducing/improving vaccine safety surveillance function

Dr Ananda Amarasinghe shared his perspective as an assessor of the IDP implementation in the context of vaccine safety surveillance. NRA assessment focuses on items, people and the system of vaccine safety surveillance (VSS) or pharmacogivilance. The IDP should be based on identified needs to improve VSS.

The indicators in the NRA assessment tool are related and complement one another. One contributor to a challenging VSS is poor sharing of data among NRA, NCL, national immunization programme, disease surveillance and pharmacovigilance (PV) staff. In introducing and implementing IDP activities in VSS: situation analysis is needed based on NRA assessment findings, to understand

the sources of gaps/weaknesses, identifying options to address gaps, the resources needed and the process to address them.

The use of priority- and feasibility-based approaches was discussed. The IDP should be discussed and reviewed by stakeholders to gather support and approval from higher authorities. Finally, it is important to monitor and evaluate achievements of set targets/timelines.

2.5 Member States' IDP implementation or improvement plan

This session was designed to assist Member States to develop/update/improve IDPs and to identify potential constraints faced by Member States in implementing IDPs. Participants were asked to identify the constraints they encounter in implementing their IDPs.

Each country shared challenges in IDP implementation including:

1) Cambodia: there is limited financial and human resource to implement the IDP. Further development on marketing authorization and pharmacovigilance is needed. Capacity-building was requested.
2) Fiji: There is lack of technical expertise to support marketing authorization and pharmacovigilance and limited financial resources to implement the IDP. Capacity-building was also requested.
3) The Lao People's Democratic Republic: There is limited human and financial resources. Capacity-building for marketing authorization was requested especially on expedited review procedure. Other challenges included language barriers as all documents are in English and the cooperation between the NRA and PV. Ongoing reform of the regulatory system also contributes to the challenges.
4) Papua New Guinea: Major constraint is limited human resources.
5) Mongolia: There is a need for more financial support and the establishment of the institution's legal framework. Urgent technical assistance was requested for IDP implementation.
6) Malaysia: More training to implement lot release and lab access is needed.
7) The Philippines: Implementation of lot release. Financial resources are dependent on business plan approval. There are also limited human resources and the information technology (IT) system is not yet fully established, which makes the electronic conversion of dossiers a challenge.
8) Viet Nam: Trainings and workshops for marketing authorization and clinical trials were requested. For documentation, there is a challenge in the review of new standard operating procedures. Support is needed in GMP implementation and enforcement.

2.6 RAWGs priority topics

Dr Shin provided an overview of the RAWG priority topics, including review and update on the progress of formulating working groups. To obtain comments from the RASC on priorities and action plan participants were divided into five groups for discussion.

2.7 RAWGs discussion

On the second day of the workshop, the participants were divided into five groups according to RAWG functions:

- system;
- marketing authorization, licensing, oversight of clinical trials and regulatory inspection;
- lot release and laboratory access;
- pharmacovigilance, import, export and market surveillance; and
- international collaboration, harmonization and exchange of information.

The WHO Secretariat proposed regional priorities for each group to work on, and the participants modified the proposed priorities during the breakout session. Participants then presented their list of priority areas of work and developed an outline and the main points of the concept note.

The identified priority areas of work included Member State's NRA system strengthening and sustaining the activities of the Alliance. Participants also identified advocacy to gain support from donors and technical partners to contribute to NRAs and governance of the Alliance.

2.8 WHO technical assistance to countries in implementing IDP

2.8.1 WHO Strategy to strengthening regulatory capacity GLO/VQ training plans 2015

Dr Dellepiane de Rey Tolve shared the modalities that WHO follow in providing technical support to Member States. These include the Global Learning Opportunities for Vaccine Quality (GLO/VQ) a learning network that functions through WHO-accredited learning centres. The network targets NRA staff to build capacity to ensure vaccine quality, safety and efficacy. The network uses the competency-based and authentic models for learning. Other modalities include in-country training (based on identified gaps from the assessment and tailored to the needs of the country), placements, workshops, on-site consultancies, e-learning courses, joint review opportunities, mutual agreements between two NRAs on collaboration.

The selection of the appropriate interventions will be based on the IDP. Several GLO/VQ courses will be conducted in 2015 and others are in development. There are two new candidate training centres in the Region: the Ministry of Food and Drug Safety (MFDS), Republic of Korea for lot release hands-on training and the Japanese International Cooperation Agency (JICA), Japan.

2.8.2 WHO collaborating centres plan 2015

Representatives from WHO collaborating centres for standardization and evaluation of biological medicines shared their systems for supporting WHO. Three WHO collaborating centres – Therapeutic Drugs Administration (TGA), Australia; MFDS, the Republic of Korea and National Institute of Infectious Disease (NIID), Japan – presented their institutions, structural scheme, laboratory affiliations, departments responsible for quality assurance of vaccines and other biologicals, terms of reference and activities in collaboration with WHO.

The collaborating centres' primary terms of reference are: to support WHO in developing international written standards for regulatory evaluation of vaccines and other biological medicines and implementing these standards into practice; and to contribute to the development of international measurement standards and reference materials for vaccines and biological medicines.

Dr Elisabeth Kerr shared the TGA work plan for 2014–2018 and commitments. TGA's ongoing commitments include contribution to the Alliance and participation in international collaborative studies for influenza reagent potency calibrations.

Dr Atsushi Kato shared the vaccines approved and available in Japan and the number of lot release tests by NIID. International training programmes have been conducted by NIID and the Ministry of Heath, Labour and Welfare in collaboration with WHO. Malaysia has also requested assistance in setting up a national control laboratory.

Dr Sangjin Park presented the activities of the MFDS since designation as a WHO collaborating centre for biological standardization and evaluation in 2011 and as a WHO Global Training Center for GMP in 2007. Several hands-on training programmes for vaccine quality control for regulators have been conducted from 2012 to 2015. Capacity-building of NRAs for vaccines in the Region will be supported through training, technical advice and provision of equipment.

2.8.3 Discussion on WHO technical assistance to countries in implementing IDP

Participants were reminded that all trainings should be indicated in their IDPs to gain WHO support. The secretariat will identify courses to be included in GLO/VQ 2015 and will upload available resources to the WHO SharePoint (http://intranet2.wpro.who.int/sites/epi/nra_aefi). Countries should fill in the needed information and send it to the Secretariat.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

The RASC and other workshop participants acknowledged the update of the Regional Alliance's concept paper has been updated. They have also welcomed the Regional Director's letter to all Member States reconfirming the official launch of the Alliance.

The RASC has noted the implementation status of the RASC and Secretariat work plans 2014–2015 and accepted the updates in principle. Additional updates are expected after the Member States have consolidated the IDPs for further review and agreement. The RASC has also agreed to consolidate Member States' IDP to develop a regional work plan and identify support from the Alliance to implement IDPs (see Annex 1).

It was agreed that the next annual meeting will be on 15 September 2015, and the fourth workshop will be on 16–18 September 2015. The venue will be announced once decided.

RASC have noted the proposed plan on formulating RAWGs and their priority areas and agreed, in principle, on regional priorities for working group activities to better implement global/regional common standards and immunization policies at country level (see Annex 2).

3.2 Recommendations

Member States may:

1) support greater participation of NRA experts in the priority areas and actions of the RAWGs (refer to Table 1); and
2) finalize their IDPs in datasheet format defined in NRA self-assessment tool kit version 6.0 (or NRA IDP monitoring template) and send them to the Secretariat by 25 October 2014.

The WHO Regional Office for the Western Pacific, as the Secretariat, has committed to:

1) further review Member State IDPs and update the Alliance work plan accordingly;
2) organize a teleconference with the RASC before the next NRA workshop to discuss the programme agenda of the fourth Regional NRA workshop;
3) organize regular teleconferences with NRA colleagues to review and update the work plan and discuss other matters of collaborative work;
4) organize the transition of Chairperson, Vice-Chairperson and Rapporteur (China will be proposed to take the Chair's role at the RASC in 2015);
5) develop priority-based, task-oriented, time-limited terms of reference for RAWGs applying the specific, measureable, achievable, relevant and time-bound (SMART) approach;
6) continue discussing with countries to build consensus on emerging global and regional regulatory issues to address public health threats; and
7) explore, together with RASC, possible funding sources for the activities of the Alliance.

Annex 1. Report of the Regional Alliance Steering Committee meeting for national regulatory authorities for vaccines in the Western Pacific Region

16 September 2014
Manila, Philippines

The second meeting of the Regional Alliance Steering Committee for National Regulatory Authorities for Vaccines in Western Pacific was held on 16 September 2014 in Manila, Philippines and was attended by six Member States. The objective of the second meeting was to review and update the work plan of the Regional Alliance for National Regulatory Authorities for Vaccines (the Alliance).

1. Opening Remarks

Dr Sergey Diorditsa expressed his gratitude to the participants for attending the meeting and for their support to the Alliance. He presented the milestones of the Alliance Secretariat's work plan since the first meeting in Seoul, Republic of Korea in October 2013. The Alliance Secretariat has:

1) issued a letter from the Regional Director to health ministers of Member States to inform and raise awareness of the formulation of the Alliance;
2) finalized the second edition of the concept paper;
3) assisted NRAs of Malaysia, Mongolia and the Philippines to assess functionality gaps and develop institutional development plans (IDP) with the participation of regional experts;
4) provided assistance and participation in WHO NRA assessment in China; and
5) provided trainings on adverse events following immunization (AEFI), causality assessment and communication capacity-building for nine countries in the Region.

The EPI Technical Advisory Group, at its 23rd meeting in June 2014, extended its support to the Alliance for strengthening and exchange of information and collaboration in the Region. The Region has many challenges to face including limited financial and human resources in strengthening NRAs to oversee the quality of vaccines for use in both public and private sectors.

Priorities for working groups to consider include:

1) participation in the regional initiative on validating NRA assessment and implementing IPDs;
2) provision of trainings on laboratory testing for vaccine quality;
3) vaccine registration and expedited review in United Nations-procuring countries;
4) laboratory collaboration with South-East Asia and Western Pacific biregional National Control Laboratory Network; and
5) regulatory harmonization and convergence of legislation, regulations, processes and practices.

The Alliance was formed with high expectations to meet various demands from low- and middle-income countries in establishing and strengthening vaccine regulatory system and functions.

2. Selection of Chair, Vice Chair and Rapporteur

Dr Diorditsa explained that leadership of the Regional Alliance Steering Committee (RASC) meeting should be rotated yearly in alphabetical order of Member States. The first meeting was chaired by Australia, represented by Dr Elisabeth Kerr. This year, in the absence of China, Dr Atsushi Kato of Japan, was selected and agreed as Chair. Dr Sangja Ban was selected as Vice Chair, and Mr Ann Ling Tan as Rapporteur. It was agreed that China will take over the leadership next year.

3. Update from the RASC

Dr Kerr, chair of the previous meeting, presented a brief history of the Alliance, starting from April 2011 when the first WHO NRA Strategic Forum was held in Bangkok, Thailand. The concept paper was drafted in 2012 during the first Taskforce Meeting in Australia. The concept paper is the foundation for the Alliance, a second edition is currently available. Building the capacity of regional members is the RASC's primary objective and the wok plan should be related to the general and specific objectives of the concept paper. These objectives will be achieved through the working groups.

4. Update from RA Secretariat

Dr Jinho Shin laid down the strategic objectives to meet the six goals of the Regional Alliance. Comments from the participants were acknowledged and the work plan was revised accordingly as discussed in the following sections.

General Objective 1: Establish Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific Region

It was agreed that the next RASC meeting will be convened on the third week of September 2015. Mr Lahouari Belgharbi suggested using video or teleconferencing to improve participation of regulators from Member States and institutions if they are unable to attend in person. The participants agreed to have a teleconference in March 2015 to monitor progress.

The Alliance Secretariat acknowledged the support from Food and Drug Administration Philippines in providing a short-term consultant to ensure the Secretariat's effective functioning at the Regional Office for the Western Pacific, and looked forward to continued support for the Secretariat. It was agreed that for easy implementation, the concept paper should include details for biennium activities and that the monitoring and evaluation should be done every six months. The Member States confirmed that there are no regional activities published in the NRAs websites and/or partners' websites.

General Objective 2: Develop and strengthen a medicines regulatory system with a focus on vaccines in the Western Pacific Region

The Secretariat shared its initiated support and assistance in NRA assessment:

1) NRA self-assessment validation in six countries (Brunei Darussalam, Fiji, the Lao People's Democratic Republic, Malaysia, Papua New Guinea and Singapore) which are in progress;
2) NRA assessment in three countries (China, the Philippines and Viet Nam: China's assessment has been validated while assessments in the Philippines and Viet Nam are planned for 2015);
3) Development and routine monitoring of NRA/IDPs through follow-up visits to countries, formation of working groups and coordination for implementation of activities.
4) The Secretariat will also plan to identify and coordinate Regional needs for priority support in the region for 2104-2015.

Member States participating in the RASC from 2013 to 2016 requested to be kept informed and updated by the Secretariat regarding RASC activities. Mr Tan requested WHO's support for training opportunities. Dr Nora Dellepiane de Rey Tolve informed the Member States of the training opportunities database established by WHO.

General Objective 3: Promote and advocate the concept of functional NRAs to obtain commitments from governments and external partners

The Regional Director's letter addressed to ministers of health to all 37 countries and areas in the Western Pacific was issued. The Secretariat is asked to focus on: (1) gaining political support and advocacy on strengthening the NRA in the country through gap analysis; and (2) gaining support from and advocacy with partners especially in technical and financial areas.

General Objective 4: Improve sharing of information, best practices and communication among NRAs

The Secretariat supports establishing and strengthening networks as well as exploring information barriers. The need to establish a database for RASC contact details of focal points from NRAs and NCLs and WHO was identified and developing and sharing a SharePoint site was proposed. Dr Dellepiane de Rey Tolve shared that WHO headquarters is updating the database of NRA contacts. It was suggested that database development should consider classifying information for sharing and for keeping confidential.

Part of the Secretariat's plan is to develop concept notes on information sharing on health risk and threat, including licensed vaccine product database, with the help of RAWGs. The Secretariat requested the RASC to share a contingency plan of risk management at regional level.

The Secretariat has also extended support to implement exchange programmes and visits on GMP, lot release training and NRA twinning for lab access function.

Several recommendations were made to the Alliance. In promoting policy development consistent with WHO standards, it is best for the Alliance to consider that several countries have policies, and that assistance in policy development should be prioritized over identifying stakeholders that influence policies. To address the lack of a strategic approach in policies, focus should be given to consistency with international standards that are based on up-to-date knowledge.

General Objective 5: Contribute to increasing global/regional production of vaccines of assured quality through assessed functional NRAs

Mr Lahouari discussed that in assisting vaccine-producing countries to develop a road map for WHO vaccine prequalification, two types of road map should be considered: (1) NRA's eligibility for prequalification application; and (2) expansion of product types to be prequalified for NRA's with a road map for eligibility. For instance, Viet Nam proposed to have separate road maps for both NRA and manufacturers on prequalification.

With support from Member States, developing detailed actions is needed to organize and implement in-country training programmes for enforcement of overseeing GMP and product distribution chain.

General Objective 6: Promote convergence of regulatory framework to facilitate access to affordable vaccines of assured quality

With the support from the Alliance's Member States, RAWGs should be established and performing to organize and coordinate specific tasks with the following priorities:

1) Support the establishment of Sub-Regional Causality Assessment Committee (SRCAC) for AEFI for the Pacific island countries and areas, (as indicated in a memo from the Regional Director with a concept note and letter to Pacific health ministers).
2) Support polio endgame strategy, with monitoring and evaluation tools – raise awareness of bivalent live attenuated oral polio vaccine (bOPV) switch from trivalent OPV, facilitate NRA plan in vaccine-producing countries (China and Viet Nam) and facilitate registration of bOPV and trivalent inactivated polio vaccine (IPV) in countries.
3) Support/promote on-label use of vaccine in a Controlled Temperature Chain (CTC) – technical support on hepatitis B birth dose CTC on-label requirements.

4) Support/promote influenza maternal immunization – regulatory information on post-marketing surveillance data and review of prescribing information.
5) Promote and participate in laboratory collaboration with SEAR NCL network: related ongoing activity – South-East Asia and Western Pacific biregional development of working reference standards for Japanese encephalitis, monovalent type 1 live attenuated oral polio vaccine.

Dr Diorditsa discussed CTC, how far CTC is involved with NRA and how it can affect AEFI. Practical issues on implementing off-label use of vaccines out of the recommended cold chain limits were also discussed and the need for NRA's attention on the practices of off-label use adopted by EPI was stressed. Guidance was requested regarding CTC so that NRAs will have a clear understanding be able to implement accordingly.

5. Update on Formulating Working Groups

Ms Cheryl Valerie Legaspi presented an overview of the terms of reference, membership, chair and the objectives of each working group. Experts were nominated from three countries – Japan, the Philippines and the Republic of Korea. They would confirm nominations from Australia for the working group once the Secretariat provides clear terms of reference. Malaysia will provide their nominations through e-mail.

The membership rules in the Alliance's concept paper will be followed. It was raised whether an RASC member can also become part of one of the RAWGs. Dr Kerr confirmed that an RASC member can join an RAWG as an individual expert. The RASC is made up of Member States, while RAWGs are composed of individual experts. It is important to understand the difference between the RASC and the RAWGs to avoid conflicts.

It was proposed that the chairs for each working group be nominated at this meeting as this opportunity comes only once a year. Dr Diorditsa proposed that the Secretariat will help nominate chairs of each working group and will keep the RASC informed with transparency. All agreed that the working group members and chairs should be accomplished within a month of the meeting.

Dr Shin presented the proposed regional priorities for each working group. Mr Belgharbi suggested certain strategic approaches in organizing the work plan of the working groups.

Dr Kerr emphasized the importance of reflecting and aligning important activities of the Secretariat work plan with working groups' activities. Mr Belgharbi proposed that working groups can focus on two to three directions: (1) support country activities for regulatory systems strengthening; (2) support Secretariat to strengthen at regional level governance functions; and (3) align working group activities with other initiatives/partners (donors, technical partners and professional organizations). Mr Belgharbi then presented the regrouped priority activities to the committee.

6. Update on Third Workshop

Dr Shin briefly presented the objectives, expected outcomes, programme agenda and proposed priority topics for breakout groups of the third workshop to be held on 17–19 September 2014.

Members were interested to know how the workshop participants will be grouped during the breakout sessions. Mr Belgharbi proposed to have a clear plan for each group with objectives, expected deliverables and outcomes. He offered to revise the proposed action plan of the five WGs.

Dr Shin reminded everyone to access the WHO Regional Office NRA/AEFI SharePoint site (http://intranet2.wpro.who.int/sites/epi/nra_aefi/default.aspx) since all relevant documents will be uploaded from time to time.

Annex 2. List of participants

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Annex 3. Meeting timetable

THIRD WORKSHOP FOR NATIONAL REGULATORY AUTHORITIES FOR VACCINES IN THE WESTERN PACIFIC REGION

Manila, Philippines, 17-19 September 2014

Time	DAY-1
0800-0830	Registration
0830-0945	Opening ceremony • Opening speech • Self-introduction • Election of officers: Chairperson, Vice-Chairperson and Rapporteur • Administrative announcements
0945-1015	*GROUP PHOTO AND COFFEE BREAK*
1015-1200	SESSION 1. Update from the Secretariat 1.1 Regional update (15-20 minutes each) • 23rd Meeting of the Technical Advisory Group on Immunization and Vaccine-Preventable Diseases highlight • National Regulatory Authority (NRA) strengthening in the Western Pacific 1.2 Global update • NRA strengthening: global strategy and support to region and country • NRA assessment • Vaccine standardization: support to Expanded Programme on Immunization and country NRA
1200-1300	*LUNCH BREAK*
1300-1500	SESSION 2. Update from the Member States on NRA assessments & Institutional Development Plan (IDP) implementation (10 minutes each) 2.1 Cambodia, since Jun 2013 2.2 Viet Nam, since Jul 2013 2.3 Mongolia, since Nov 2013 2.4 Malaysia, since Feb 2014 2.5 China, since April 2014 2.6 Philippines, since May 2014 SESSION 3. Assessors' perspective on what to do and how to do for IDP implementation 3.1 Countries introducing/improving regulatory system 3.2 Countries introducing/improving expedited review procedure 3.3 Reinforcing regulatory inspections in the Western Pacific Region countries 3.4 Countries introducing/improving lot release 3.5 Countries introducing/improving vaccine safety surveillance function
1500-1530	*COFFEE BREAK*
1530-1730	SESSION 4. Member States' IDP implementation or improvement plan (BREAKOUT) Update of IDP implementation or improvement plan
1730-1800	Meeting of chairs and facilitators
1800-1930	Reception

Time	DAY-2
0830-0845 0845-1000	Review of conclusions of Day-1 discussion SESSION 5. Regional Alliance Working Group (RAWG) priority topics • Secretariat overview
1000-1030	*COFFEE BREAK*
1030-1200	SESSION 6. RAWG Discussion (BREAKOUT) RAWGs (SYS, MA, LR, VS) to discuss • Review of terms of reference • Review of membership • Priority areas of collaborative work • Working Group action plan
1200-1300	*LUNCH BREAK*
1300-1500	SESSION 7. Group presentation
1500-1530	*COFFEE BREAK*
1530-1730	SESSION 8. WHO technical assistance to countries in implementing IDP 8.1 Global Learning Opportunity/Vaccine Quality (GLO/VQ) training plan 2014-2015 8.2 WHO Collaborating Centres (CC) plan training plan 2015 • Australia: Therapeutic Goods Administration (TGA) • China: National Institutes for Food and Drug Control (NIFDC) • Japan: National Institute of Infectious Diseases (NIID) • Republic of Korea: Ministry of Food and Drug Safety (MFDS) 8.3 Interagency collaboration and support (Japan International Cooperation Agency)
Time	DAY-3
0830-0845 0845-1000	Review of conclusions of Day-2 discussion SESSION 9. Discussion on WHO technical assistance to countries in implementing IDP • Country roll call - GLO training needs 2015 • Country roll call - WHO CC training/assistance needs 2015
1000-1030	*COFFEE BREAK*
1030-1200	(BREAKOUT) • Preparation of conclusions (moderator, rapporteur, facilitator, secretariat); • Preparation of IDP implementation roadmap (all country representatives)
1200-1300	*LUNCH BREAK*
1300-1430	Review of conclusions and next steps Closing

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