

Meeting Report

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



Seoul, Republic of Korea
15–16 December 2015



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WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC

English only

MEETING REPORT

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

Convened by:

WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC

AND

MINISTRY OF FOOD AND DRUG SAFETY
REPUBLIC OF KOREA

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15–16 December 2015

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NOTE

The views expressed in this report are those of the participants of the Fourth 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 Fourth Workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region in Seoul, Republic of Korea from 15 to 16 December 2015.

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Keywords:

Health personnel – education / Vaccines – standards / Quality control / Equipment and Supplies - Standards

ABBREVIATIONS

AEFI	adverse events following immunization
APEC	Asia-Pacific Economic Cooperation
GCP	good clinical practice
GLO/VQ	Global Learning Opportunity for Vaccine Quality
GMP	good manufacturing practice
GRP	good regulatory practice
GVAP	Global Vaccine Action Plan
HIC	high-income countries
IDP	institutional development plan
IGAD	Intergovernmental Authority on Development
ISO	International Organization for Standardization
JICA	Japan International Cooperation Agency
LMIC	low- and middle-income countries
LR	lot release
MA	marketing authorization
MFDS	Ministry of Food and Drug Safety, the Republic of Korea
MIC	middle-income countries
NCD	noncommunicable diseases
NCL	National Control Laboratory
NIID	National Institute of Infectious Diseases, Japan
NRA	National Regulatory Authorities
PAHO	Pan American Health Organization
PSUR	periodic safety update reports
PV	pharmacovigilance
QMS	quality management system
RA	Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific
RASC	Regional Alliance Steering Committee
RAWG	Regional Alliance Working Group
RCM	Regional Committee Meeting
RSS	regulatory system strengthening
TGA	Therapeutic Goods Administration, Australia
WHO	World Health Organization
WPR	Western Pacific Region

SUMMARY

The Fourth Workshop for National Regulatory Authorities (NRAs) for Vaccines in the Western Pacific Region was held in Seoul, the Republic of Korea from 15 to 16 December 2015.

The Workshop objectives were:

- (1) to review and update the Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific's Workplan 2015–2016;
- (2) to discuss expanding the scope of the Alliance to include medicines and medical devices; and
- (3) to agree on ways of improving strategic planning, quality management system, risk communication and information exchange between NRAs.

The two-day Workshop was hosted by the Ministry of Food and Drug Safety, the Republic of Korea with secretarial support from WHO's Regional Office for the Western Pacific. It was attended by 55 participants, including 26 representing NRAs of 14 countries – Australia, Brunei Darussalam, Cambodia, China, Fiji, Japan, the Lao People's Democratic Republic, Malaysia, Mongolia, New Zealand, Papua New Guinea, the Philippines, the Republic of Korea and Viet Nam. Two partner agencies – Japan International Cooperation Agency (JICA) and the International Vaccine Institute (IVI) – plus WHO staff, also attended.

The participants were updated on global and regional regulatory system strengthening (RSS) achievements and future directions to be taken. Participants then had a chance to provide feedback on future directions. The Member States shared experiences and lessons learnt on recent RSS activities and identified capacity gaps and areas for improvement and potential solutions. Three countries (Cambodia, the Lao People's Democratic Republic and the Philippines) delivered updates on their respective NRA strengthening activities. Viet Nam gave a presentation on vaccine pharmacovigilance.

Part of the workshop involved introducing the 2015 International Organization for Standardization (ISO) standard for quality management systems (QMS). Group discussions were held to enable a better understanding of the principles and concepts. Participants were also updated on the latest theories of risk communication, and group work on the methodology of communication was enabled through group discussions.

Discussion on the scope and future direction of the Alliance (especially on its expansion) was brought to high level attention and immediate feedback. The Regional Alliance Steering Committee (RASC) expressed diverging opinions on expanding the scope of the Alliance from vaccine stream to other medical products (e.g. therapeutic medicines, diagnostic and medical devices). The current vaccine stream would remain as a working group and continue with the already agreed terms of reference, back to back with other product streams.

The participants also reviewed the Regional Alliance Secretariat Workplan 2016–2017 and shared information. The participants agreed, in principle, that NRAs should continue the effort of self-assessment to identify/refine capacity gaps and establish an updated institutional development plan with goal(s), key milestones and roadmap. They agreed to share these with the Regional Alliance in a timely manner. The NRAs were encouraged to keep the government's regulatory standards up to date and harmonized with international standards. The secretariat was charged to conduct a survey on broadening the scope of the current NRA Alliance.

1. INTRODUCTION

1.1 Background

The First Workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region was held in November 2011 in Seoul, the Republic of Korea. The First Taskforce Meeting 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 2013 RASC was organized as the governing body of the Alliance. The 2013 RASC refined the concept paper details, workplans and other governance details of the Alliance such as the establishment of technical working groups. The Third Workshop was held in Manila, Philippines in September 2014. Here the implementation of the RASC Workplan was reviewed, and a plan for the five working groups to support implementation of the institutional development plan (IDP) was proposed.

The Regional Framework for Implementation of the Global Vaccine Action Plan in the Western Pacific was endorsed by the Immunization Technical Advisory Group and Regional Committee Meeting in 2013–2014. As part of this framework, strengthening the vaccine regulatory capacity in the region and coordinating the collaborative platform were identified as critical strategic actions to ensure the use of vaccines of assured quality. In addition, World Health Assembly resolution WHA67.20 on regulatory system strengthening called on Member States to engage in global, regional and subregional networks of NRAs. This will enable the pooling of regulatory capacities to promote greater access to high-quality, safe, efficacious and affordable medical products. It will also promote international cooperation between national regulatory authorities. Based on recommendations from WHA67.20 (2014), WHO has developed a new strategy for regulatory system strengthening. This will ensure that WHO NRA policy, assessment processes and assessment tools used and capacity development efforts for strengthening NRAs are harmonized and integrated with convergence for all product categories. It will also ensure that NRA strengthening efforts better serve the needs of Member States.

The Fourth Workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region was held in Seoul, the Republic of Korea from 15 to 16 December 2015, together with the Third Regional Alliance Steering Committee (RASC) Meeting at the end of the workshop. This workshop aimed to update the Regional Alliance's Workplan for 2016–2017 according to the predefined general and specific objectives of the Alliance. It aimed to discuss WHO's draft new strategy on globally harmonized policy and tools for regulatory system assessment in the regional context and to identify possible regional and national approaches. It also aimed to consult with Member States to expand the scope of the Regional Alliance to include medicines and medical devices. Another aim was to develop a draft regional action plan to improve strategic planning, a quality management system and risk communications of NRAs for vaccines and medicines for low- and lower-middle-income countries whose current regulatory capacity is limited.

1.2 Meeting objectives

The workshop objectives were:

- (1) to review and update the Alliance's Workplan 2015–2016;

- (2) to discuss expanding the scope of the Alliance to include medicines and medical devices; and
- (3) to agree on ways to improve strategic planning, quality management system (QMS), risk communication and information exchange between NRAs.

2. PROCEEDINGS

2.1 Opening session

Dr Yeowon Sohn, Director-General of the National Institute of Food and Drug Safety Evaluation, Ministry of Food and Drug Safety delivered the opening remarks. She acknowledged the importance of the regulatory framework for vaccines and the need for ideas for future improvements. She concluded her remarks by hoping for a fruitful outcome of the Workshop. Dr Klara Tisocki, Coordinator of the Essential Medicines and Health Technologies Team in Division of Health Systems, 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. She stated that the World Health Assembly had adopted a resolution on regulatory system strengthening for medical products (WHA67.20). This resolution mandates WHO to continue establishing norms and standards for medicines regulation, to support regulatory capacity-building, to enhance collaboration among regulators and to strengthen safety monitoring programmes. Participants introduced themselves, and a chairman, vice-chairman and rapporteur were nominated. The chairman was Dr Chung Keel Lee, Special Adviser to the Minister of Food and Drug Safety, the Republic of Korea, the vice-chair was Mr Tan Ann Ling, Director, National Pharmaceutical Control Bureau, Ministry of Health, Malaysia. The rapporteur was Ms Melody Zamudio, Director, Center for Drug Regulation and Research, Food and Drug Administration of the Philippines.

2.2 Session 1: Update from WHO (Moderator: Malaysia, Mr Tan Ann Ling)

The objective of session 1 was to update Member States on global and regional RSS achievements and future directions from the perspective of the WHO Secretariat, and to obtain feedback from Member States on future directions. It was composed of updates on the global and regional levels.

2.2.1 Session 1.1: Global update

(a) Developing a more effective and sustainable approach to regulatory system strengthening

Mr Michael Ward, Coordinator, Regulatory System Strengthening Team, Department of Essential Medicines and Health Products, WHO shared the global update on regulatory system strengthening. He emphasized that:

- (1) NRAs were on a critical path to innovation and access to safe and effective medical products;
- (2) the degree to which NRAs fulfilled their mandates in an effective, efficient and transparent manner had a direct impact on innovation, access and public health;
- (3) there was a reason why so many efforts were being directed at building the capacity of regulators worldwide; and

- (4) competent NRAs were important to a well-functioning health system, as recognized in resolution WHA67.20 on regulatory systems strengthening.

WHO has been benchmarking regulatory systems for vaccines since 1997 using a standardized tool and process that have undergone many rounds of refinement. More recently, efforts have been exerted to develop an integrated tool for use with respect to vaccines, medicines, medical devices and blood products. To date, WHO has helped strengthen over 127 NRAs through this process, in addition to complementary activities in promoting regulatory convergence, harmonization and information/work-sharing. WHO is one of the largest providers of training to regulatory authorities.

WHO supports the strengthening of regulatory systems in accordance with numerous World Health Assembly resolutions and promotes access to essential medical products as one of the key enablers of health and equality. The challenge lies in strengthening the capacity of regulatory authorities to regulate in a manner that is consistent with timely access to priority medicines.

Important things to consider include the fact that weak regulatory systems do not serve the interests of consumers, patients, industry or the health care system. At the same time, as countries develop regulatory capacity, it is important that regulatory systems should be science-based and should respect international standards and best practices. They should also adopt an approach that focuses on what cannot be done by others while leveraging the work of other trusted NRAs and regulatory networks for the rest.

As regulators can no longer “do it alone” in an increasingly complex global regulatory environment, the same holds true for development and supporting agencies. There are some positive trends and models: for example, the African medicines regulatory harmonization initiative, discussions around RSS in South-East Asia and the Call for Action of the First Intergovernmental Authority on Development (IGAD) Regulatory Conference, which recommends that collaborating and development partners “adopt a coordinated approach to support according to a single, established development plan”.

In conclusion, all regulators have a duty to ensure the efficiency, effectiveness and transparency of operations. At the same time, not all regulators have the resources or capacity to perform all regulatory functions. Decisions have to be made nationally on which areas to focus on and build capacity, and on which areas rely on other regulators’ work. Good regulatory practices (GRP) and flexible regulatory frameworks are essential in meeting the challenges of an increasingly complex global regulatory environment. RSS supports these efforts through the use of a structured benchmarking tool, process and policy that promotes regulatory cooperation and a coordinated in-country approach to strengthening regulatory systems.

(b) WHO assessment policy using the Global Benchmarking Tool, Rev 2015

Mr Lahouari Belgharbi, Scientist, NRA Assessment Group Leader, Regulatory System Strengthening Team, Department of Essential Medicines and Health Products gave a presentation on WHO assessment policy using the Global Benchmarking Tool. The presentation started with a recap of the development of the Global Benchmarking Tool, 1997–2015 and WHO internal and global international consultations, 2013–2015. From 1997 up to the present, many consultations and meetings have been conducted to formulate the Global Benchmarking Tool. Finally, the Tool is ready for use, and 2016 will be a testing and transition period.

The Second International Consultation was held in 2015. Its aim was to seek advice to proceed with the testing of the WHO Phase 1 Global Benchmarking Tool and to conclude the integration of other tools and products. The objectives were to strengthen national regulatory systems for all health products and technologies and to advise WHO about the implementation of resolution WHA67.20. Other objectives were: to provide guidance on the development of a phase II benchmarking/assessment tool for advanced/stringent regulatory systems, and to discuss and agree on a way forward on the concept of centres of excellence to build upon the reference NRA concept using a similar approach to that of the Pan American Health Organization (PAHO).

It is recommended that work associated with the use of the tool should be completed to meet a level consistent with WHA67.20 across product lines. The maturity level continuum (implementing the tool) should be kept in mind, with prioritization and further discussion required, building on existing work. In a second phase, guidance and tools that allow for modular progression to advanced levels of maturity/performance should be further developed. Guidance should be formulated for promotion, along with a tool to measure reliability – according to a GRP framework. The importance of transparency was highlighted. This is needed to outline and implement a proposal on the publication and sharing of information on the outcomes of benchmarking/assessment, including a global electronic platform accessible to NRAs and others.

Harmonization of tools with a single set of functions, indicators, sub-indicators and assessment guidance (including, for example, PAHO fact sheets or equivalent) is important. Developing strategy to ensure a smooth transition from the existing to a future global, unified NRA benchmarking/assessment tool is needed. A transition phase is required to address the PAHO reference model and the shift to the Global Assessment Tool. The reassessment model should be further developed, taking into consideration the need for organization reassessment using: (a) ongoing monitoring, (b) abbreviated or abridged assessment, and/or (c) full assessment. It is important to reduce the burden on the countries assessed: for example, by populating the reassessment database with existing information. We need to identify types of changes that are critical in triggering a reassessment.

2.2.2. Session 1.2: Regional update

(a) Global and regional developments in regulatory cooperation

Dr Klara Tisocki gave a presentation on global and regional developments in regulatory cooperation. The presentation was composed of WHO's mandate on regulatory system strengthening, the importance of regulatory systems for universal health coverage and the roles of NRAs in medical product regulations. It also covered the changing regulatory landscape in the Western Pacific Region (WPR), regulatory challenges, and the need for regional collaboration, regulatory convergence and harmonization.

The following questions on regulatory system strengthening for WPR countries were posed to the participants for feedback:

- What critical issues do low- and middle-income countries (LMIC), middle-income countries (MIC) and high-income countries (HIC) country regulatory authorities face and how are they prioritized?
- What issues do LMIC face in utilizing/implementing international norms and standards, including WHO's, in a sustainable way?

- What are the major gaps in legislative frameworks, regulatory systems, sustainable resource flow (national/donors' resources) institutional structures, workforce size, capacity and competencies?
- In what ways could those gaps be addressed?
- In what ways could MIC and HIC partner with LMIC in the region to help fill those gaps?
- What recommendations have already been put forward to strengthen regulatory systems?
- What obstacles exist to implementing those recommendations?
- What steps could be taken to remove those obstacles through expanding the scope and work of the Regional NRA Alliance?
- What incentives and controls would be needed to support efforts at national level?
- What type of coordination would be needed to support all external efforts by various stakeholders to build regulatory capacities fit for purpose in each country's own setting?

Dr Tisocki emphasized that promoting NRA partnerships and regulatory networks to develop joint programmes of work to move towards convergence of regulatory practices could be achievable in the short to medium term. The use of modern information technologies and technology platforms could also facilitate regulatory exchange in secure environments, between regulators on key issues, leading to convergence.

(b) Regional update on regulatory system strengthening for vaccines

Dr Jinho Shin started by presenting the regional mandate and NRA status for vaccines. Regional priority actions in achieving Global Vaccine Action Plan (GVAP) Strategic Objective 5.4 (2013–2020) include strengthening NRA systems and facilitating relevant technology transfer. This will contribute to securing the global supply of quality vaccines and strengthening the regulatory capacity under the Regional Alliance for NRAs for Vaccines.

One of the main activities for vaccine RSS is building secretariat capacity. In senior management support, NRA strengthening in the GVAP Regional Framework 2013–2020 was endorsed in the Regional Committee Meeting (RCM) resolution in October 2014. However, the operation of Regional Alliance Working Groups (RAWGs) is delayed, as specific terms of reference need to be developed for well-defined technical inputs, processes and outputs. A report on the 2014 NRA Workshop has been published. WHO Regional Office for the Western Pacific vaccine safety surveillance guidelines and vaccine communication guidelines are at the proofreading stage.

There has been technical assistance for the following countries:

- Malaysia: lot release in Ministry of Food and Drug Safety (MFDS) twice (2014–2015), National Institute of Infectious Diseases (NIID) once (November 2014)
- Philippines: follow-up (February, April 2015)
- Viet Nam: NRA assessment (April 2015)
- Cambodia and the Lao People's Democratic Republic: monthly virtual conference (April to September 2015)
- Cambodia and the Lao People's Democratic Republic: vaccine/medicine joint mission for self-assessment, institutional development plan (IDP) elaboration and producing roadmaps in March and June

- Cambodia and the Lao People’s Democratic Republic: quality management system (QMS) training courses in October and November (reported in Global Immunization Newsletter)
- Cambodia, the Lao People’s Democratic Republic and the Philippines: MFDS baseline survey to support five priority countries in August and September.

Global learning opportunities (GLO) and other learning opportunities:

- pharmacovigilance (February – India, September – Singapore)
- pharmaceutical cold chain (June – Turkey)
- good manufacturing practice (GMP) (June – Korea)
- good clinical practice (GCP) (July – South Africa)
- hands-on lot release (September and November – Republic of Korea)
- equipment use (September – Republic of Korea)
- WHO Implementation Workshop on Changes to Approved Vaccines, November 2015
- Global Vaccine Safety Initiative Annual Meeting, October 2015.

Dr Shin also updated Member States on the regional collaboration, biregional collaboration and regulation system strengthening country support workplan 2016–2017.

2.3 Session 2: Update from Member States (Moderator: Philippines, Ms Melody Zamudio)

The objective of session 2 was to share Member States' experiences and lessons learnt on recent RSS activities and to identify capacity gaps, areas of improvement and potential solutions. Three countries (Cambodia, the Lao People’s Democratic Republic, the Philippines) delivered updates on their respective NRA strengthening activities. Viet Nam gave a presentation on vaccine pharmacovigilance. The presenter from Cambodia was Mr Cheap Thonvuthy, Vice-Chief, Essential Drug Bureau, Department of Drugs and Food, Ministry of Health. The presenter from the Lao People’s Democratic Republic was Ms Soulyvanh Keokinnaly, Deputy Chief, Public Health Pharmacy Management Division, Food and Drug Department, Ministry of Health. The presenter from the Philippines was Ms Mallenrose Kristine Ofrecio, Food–Drug Regulation Officer III, Licensing and Registration Division, Center for Drug Regulation and Research, Food and Drug Administration. The presenter from Viet Nam was Mr Ha Hoang Phuong, Officer, Drug Quality Management Division, Drug Administration. Presenters shared NRA self- and validation assessments, issues in NRA strengthening, NRA strengthening activities and a long-term roadmap for RSS. They shared ideas on the quality management system, financial sustainability/ political support and challenges, NRAs’ strengths, areas for improvement in vaccine regulation and implementation of their IDPs. They also provided updates on actions taken.

Viet Nam gave a presentation on national vaccine pharmacovigilance. The presentation was on the country’s NRA structure, vaccine immunization network, pharmacovigilance legal provisions and the handling process for adverse events following immunization (AEFI). It also covered sharing AEFI information, along with further process in case of quality defects and national AEFI data.

2.4 Session 3: Quality management system (Moderator: Australia, Dr Elisabeth Kerr)

The objective of session 3 was to broaden knowledge on QMS and to gain a better understanding of principles and concepts through group discussion.

Mr Abdul Razak Abu Bakar, Principal Consultant, Quality, Environment, Safety and Health Section, SIRIM¹ Training Services was invited to give a presentation on the concept of the quality system. This comprises a set of interrelated processes that work together to meet an objective (assuring product quality, efficacy and safety). He shared a message from the United States Department of Health and Human Services Food and Drug Administration that quality should be built into the product, and testing alone could not be relied on to ensure product quality.

International Organization for Standardization (ISO) 9001 is a standard that is globally recognized for QMS. It applies to any organization (manufacturing or services). ISO 9001 stipulates what must be done (but not how) and focuses on meeting the requirements of customers.

QMS follows a PDCA cycle: that is, plan – do – check – act. The implementation cycle was explained in detail: (1) understanding the organization and its context; (2) demonstrating leadership and commitment; (3) establishing quality objectives and planning; (4) determining and providing the resources (support); (5) planning, implementing and controlling the processes (operation); (6) monitoring, measurement, analysis and evaluation; and (7) improvement.

Group work was done on a Strengths, Weaknesses, Opportunities and Threats (SWOT) analysis, setting strategic objectives and key performance indicators. The group was divided into four according to function, lot release and lab access, marketing authorization, pharmacovigilance and regulatory inspection. Below are the results of the group work.

Lot Release and Lab Access Working Group

<i>Strengths</i>	<i>Weaknesses</i>
<ul style="list-style-type: none"> • There are six high-income countries (four are OECD HICs) • There are five national control laboratories (NCLs) that are established and competent • There are four WHO collaborating centres for standardization and evaluation of biologicals • Hands-on training courses are available. 	<ul style="list-style-type: none"> • Regulatory system and implementation of lot release (LR) are not well established for all self-procuring countries • There is a limitation on lab testing in self-procuring countries (i.e. Malaysia and the Philippines) • There is no system for LR • LR is not well implemented • Mechanisms to access lab testing are lacking • Resources of secretariats are scarce • There is a lack of experts in vaccines • There are language barriers • Political approaches are different.

¹ SIRIM, formerly known as the Standards and Industrial Research Institute of Malaysia (SIRIM), is a corporate organization wholly owned by the Malaysian government.

<p><i>Opportunities</i></p> <ul style="list-style-type: none"> • Support from WHO: <ul style="list-style-type: none"> ➤ WHO has announced strengthening of the regulatory system ➤ Coordination is to be provided ➤ This is a global learning opportunity (GLO) • WHO guidelines on LR Financial support is available from international agencies for low-income countries. 	<p><i>Threats</i></p> <ul style="list-style-type: none"> ➤ Technology changes are too fast to catch up ➤ Development of novel vaccines is very rapid ➤ Development and application of new test methods are very prompt ➤ To apply the 3Rs principle (readiness, response and recovery) is time-consuming ➤ Emerging diseases (e.g. pandemic influenza) are estimated ➤ Numbers of counterfeit and substandard vaccines are rising ➤ There is a risk to all NRAs of losing public confidence.
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Strategic goal

- All Member States should have access to laboratory testing results when needed (sharing the confidential lot release information).
- All member countries should have a system of LR in place to verify traceability of vaccine lots used (sharing post-marketing lot information).

Key performance indicators (KPIs)

- Providing the procedure for Member States to obtain testing services from competent national control laboratories (NCLs).
- Providing training programmes and financial support on LR and lab testing for procuring countries and those supplied by the United Nations.

Marketing Authorization Working Group

<p><i>Strengths</i></p> <ul style="list-style-type: none"> • Member States have access to the same information for decision-making • Member States are made aware of information they can obtain. 	<p><i>Weaknesses</i></p> <ul style="list-style-type: none"> • Reliance: limited trust or confidence • Fear of legal constraints on reliance • No common understanding.
<p><i>Opportunities</i></p> <ul style="list-style-type: none"> • Community of Member States will leverage efforts and representation for negotiation • Participants or members of existing networks for harmonization and other aspects (ASEAN, PICs, etc.). 	<p><i>Threats</i></p> <ul style="list-style-type: none"> • Reliance not equal to data sharing • If regulatory processes are not similar, risk of deviation or contradiction • Member States may not share information easily (fear of losing trust, sovereignty, etc.).

Recommendations

- Develop best GRP and disseminate it to all Member States.
- Recommend that Member States should adopt it.
- Use a common platform to provide experiences of best practices and sharing of common issues to help decision-making or learning the benefits of using the information that can be made available.
- Build confidence and trust in a reliance system or mechanism among Member States.
- Document existing reliance mechanisms and develop a new one that Member States can use to help them in their decision-making or assessment for registration and marketing authorization (MA) and clinical trials.

Pharmacovigilance Working Group

<i>Strengths</i> <ul style="list-style-type: none">• Member States have access to the same information for decision-making• Member States are made aware of information they can obtain.	<i>Weaknesses</i> <ul style="list-style-type: none">• Reliance: limited trust or confidence• Fear of legal constraints on reliance• No common understanding.
<i>Opportunities</i> <ul style="list-style-type: none">• Community of Member States will leverage efforts and representation for negotiation• Member States participate or are members of existing networks for harmonization and other aspects (ASEAN, PICs, etc.).	<i>Threats</i> <ul style="list-style-type: none">• Reliance not equal to data sharing• If regulatory processes are not similar, risk of deviation or contradiction• Member States may not share information easily (fear of losing trust, sovereignty, etc.).

Prioritizing objective

- Strengthening pharmacovigilance system:
 - legislation
 - capability
 - capacity
 - reporting awareness and entry
 - causality assessment.

Example KPIs

- Reporting – 80% of provinces reporting to NRA by 2020:
 - raising awareness
 - education
 - barriers to reporting.

- Capability – resource and train staff:
 - all pharmacovigilance (PV) staff – WHO and internal – to be trained within 12 months of recruitment.
- Info from pharma – periodic safety update reports (PSURs):
 - requirement for PSURs to be submitted to the NRA according to the reporting cycle (and reviewed) by 2020.

Regulatory Inspection Working Group

<p><i>Strengths</i></p> <ul style="list-style-type: none"> • Have existing regulation/law for inspection • Political support • Updating of policies to keep track of regulation changes. 	<p><i>Weaknesses</i></p> <ul style="list-style-type: none"> • Limitation on competent/trained inspectors in terms of number and training • Lack of robust IT system • Limited coordination with other units/offices • Insufficient sharing of information among different NRAs • Insufficient enforcement and follow-up actions • Inspection system not well established • Limited training on good distribution practice, good storage practice, GCP, good laboratory practice, good automatic manufacturing practice.
<p><i>Opportunities</i></p> <ul style="list-style-type: none"> • Financial and technical assistance from international/regional organizations: MFDS, WHO, JICA • Bilateral/multilateral collaboration/agreement (PIC(s), MFDS) • Existence of ASEAN harmonization and Regional Alliance • WHO Collaborating Centre for GMP Inspection Training • Media can be a tool for faster communication and information. 	<p><i>Threats</i></p> <ul style="list-style-type: none"> • Emerging new technologies without Member States regulations (e.g. new biotech product, stem cell, blood and blood products, biosimilars, monoclonal antibodies) • Limited political support • Political influence and intervention on technical matters • Limited funding and resources from government • If unattended, media can destroy the image of NRAs • Slow approval process for new laws.

Strategic objectives:

- to foster closer collaboration among NRAs
- to improve mutual recognition between NRAs
- to strengthen capacity-building activities for GMP inspectors.

2.5 Session 4: Risk communications in regulatory system (Moderator: New Zealand, Dr Chris James)

The objective of session 4 was to give an update on the latest theories of risk communication and to brainstorm on the methodology of communication through group discussions.

Mr Abdul Razak Abu Bakar continued the presentation on risk communication. Risk is a situation involving exposure to danger, and communication is any purposeful exchange of information about risks between interested parties. As an example of risk management and communication, the smallpox outbreak in Milwaukee, Wisconsin (1984) was introduced.

When planning a QMS, the risks and opportunities should be determined to ensure the intended outcome and to prevent/reduce undesired effects, and also to achieve continual improvement. The organization should plan actions to address these risks and opportunities and to integrate the actions into QMS and evaluate their effectiveness.

In preparing for crises, the person responsible should be identified and given phone/email and media training. An organization spokesperson should be identified and trained. Media tips, crisis management checklists, key audiences and media list, key messages, pre-approved statements, emergency personnel, equipment and drill sessions were introduced.

There was a presentation by Dr Syed Shah on perspectives on effective risk communication concerning vaccine safety. As an introduction, four types of information for actions were introduced: that is, correction, corrective actions, follow-up and strategic communication plans. As for corrective actions, training was emphasized to improve surveillance and patient care. The difference in risk perceptions among the public and experts was also mentioned.

There are five steps for strategic planning in communication: (1) identify the audience groups – primary, secondary and tertiary audience groups; (2) define SMART communication objectives (see below) in terms of key desired behaviour results and actions by each participant group; (3) prepare the strategic approach; (4) prepare for managing rumours, misconceptions and anti-vaccination arguments; and (5) develop monitoring and evaluation. For vaccine safety, there are many communication objectives, for example: unsafe injections, changing regulations, vaccine campaigns, inadequate monitoring and so on.

The communication impact should be evaluated to improve communication products, identify new target audiences and refine messaging over time. Polio immunization campaigns in China were mentioned during the presentation as an example of good communication. Dr Shah emphasized that specific, measurable, achievable, relevant and time-bound (SMART) communication objectives should be determined in terms of desired outcomes.

Group work was done on communication in so-called crisis management. The group was divided into two, and the following scenario was presented to each group:

Case: A country’s local media are reporting a serious increase in the number of measles cases in three main rural areas of a province/region/state. The main local newspaper is reporting “many children are dying and hospitals are near the breaking point” due to use of non-assured, non-WHO prequalified vaccines. Due to increased panic, the Minister of Health ordered an immediate situation update and appropriate communication response. You are to advise the Ministry of Health spokesperson on the best way to approach this issue from the standpoint of communication. Background information gathered:

- provincial MCV vaccine coverage: 80%
- type of vaccine used: MCV (single antigen), and product was prequalified by WHO
- lot release: released by national control lab, which found no problem.

The tasks and results of the group work are summarized in Table 1.

Table 1. Tasks and results of the group work

Group work tasks were given to both groups	Group 1	Group 2
TASK 1: Identify potential audiences: interested parties for your communication plan	Media, hospital, community leader, family of patients, general public, travellers	General public, media, politicians (local and central) health care professionals, schoolteachers, MA holder, WHO, Regional Alliance
TASK 2: Identify the best tools and medium to reach out to various interested parties (formulate a communication plan)	<ul style="list-style-type: none"> • Press conference: for general public • Media (radio, TV, social media): for general public • Meeting with interested parties (community leader, health care workers in hospitals) 	Newspapers, text message, interview (TV/radio), press release, social media
TASK 3: Develop three key messages for the target audience	<ul style="list-style-type: none"> • NRA is attentive to the issue and investigates the facts • NRA has the system in place to ensure the quality of vaccines: for example, vaccines in the EPI are qualified and quality 	<ul style="list-style-type: none"> • Vaccine used was of assured quality (prequalified, passed all lot release, distribution) • Children were not immunized; outbreak evaluation • Vaccination against measles should continue

	<p>assured by functional NRA</p> <ul style="list-style-type: none"> • NRA will issue public advisory once investigation is completed • Encouraged to report to NRA by phone and email 	
TASK 4: Do you recommend NRA action?	<ul style="list-style-type: none"> • Verify the fact by email, phone, fax, etc. • Verify vaccine registration and quality (GMP report, MA dossier, lot record) • Collect samples and test: check cold chain and label • Report to the public with statement • Product recall issue of confiscation • Adverse drug reaction (ADR) repeat to NRA. Share with WHO/Uppsala Monitoring Centre 	<ul style="list-style-type: none"> • Review of information (NRA, NRL, PV): <ul style="list-style-type: none"> - What kind of vaccine was used, which batches? - How was it used? - Look into PV and clinical data, if available - Contact MA holder and WHO/UNICEF - Vaccine distribution

Dr Shah summarized the group work as follows:

Risks with vaccines: Vaccines are designed to stimulate an immune response in the body against infectious diseases, and it is inevitable that this reaction carries a small risk to the health of a minority of vaccine recipients. This risk is outweighed by the significant benefits in terms of protection from vaccine-preventable diseases that vaccination provides.

Risks with communication: Communicating without appropriate training and/or without preparation and when you do not communicate meaning, you are agreeing to circulating information that may create confusion, errors and delays. This needs immediate control to reduce potential risks, damage to trust and misinformation to the community at large. The communicator provides the intended participants with information about the expected type (positive or negative, good or bad) and magnitude (low or high, weak or strong) of potential outcome from a behaviour or exposure. Risk in communication happens before and during a vaccination session/campaign as a preparation for any serious adverse events caused by vaccines, medicines or medical products, to encourage positive behaviours and lessen any negative impact. Risk in communication involves a two-way flow of communication between health care providers and health authorities, parents, guardians and vaccine recipients, and the public at large. To communicate risks effectively, health care providers, health workers, teachers and other influencers, programme managers and the NRA need to have adequate knowledge about vaccine risks and benefits. They need effective communication skills and the ability to use clear and simple language that the public understands. It is also important for them to be aware of the way the audience perceives risks from immunization, vaccines and medical products.

A crisis related to a vaccine: This is an unexpected series of events that may happen after a vaccine has been administered to a population group (during or at the end of a campaign). A crisis

may arise when something goes wrong: for example, as a result of genuine vaccine reactions or due to immunization-related errors that cause caregivers to refuse immunization of their children. A crisis may be caused by media publicity about an AEFI, even if it may have no basis or is triggered by unfounded rumours. A vaccine safety-related event such as AEFI could lead to a crisis for the Ministry of Health at the national level if it is not well managed and quickly acted upon. It is likely to become public through a combination of channels (e.g. mass media, the Internet, social media platforms, mobile phone and word of mouth). The crisis may be made worse by a cover-up that is subsequently discovered. This is why programme managers must act in a timely manner by mobilizing the communication task force, the technical group, spokespersons and media partners to dispel any misinformation quickly before it becomes a crisis. Crisis communication is a combined effort by health and immunization programme managers, the regulatory authority and local leaders to communicate with the public using all appropriate channels. Messages should assure the public that a vaccine safety issue is being investigated and will be resolved, and that the immunization programme will continue. Below is a list of attributes of good communications:

- clear (understandable and jargon-free)
- concise (summary of key ideas or messages)
- concrete (evidence-based)
- correct (accurate)
- complete (establishes most of the facts)
- courteous (taking values into account)
- consistent
- timely

2.6 Session 5: Future of Regional Alliance

The objective of session 5 was to discuss the scope and future direction of the Regional Alliance. Dr Shin provided an overview of the history, vision, strategic objectives and challenges of the Regional Alliance for NRAs for Vaccines in the Western Pacific. Mr Michael Ward and Dr Tisocki gave a presentation on considerations and questions on the Regional Alliance for NRAs.

The vision of the Regional Alliance is that WHO Member States in the Western Pacific Region will strive to promote and support strategies and programmes to develop and strengthen NRAs to ensure that all vaccines – especially those used in national immunization programmes – are of assured quality.

The general objectives of the Regional Alliance are:

- (1) to establish the Regional Alliance for NRAs in the Western Pacific Region;
- (2) to develop and strengthen a medicines regulatory system with a focus on vaccines;
- (3) to promote and advocate the concept of functional NRAs to obtain government commitment and external partners;
- (4) to improve sharing of information, best practices and communication among NRAs;
- (5) to contribute to increasing global/regional production of assured quality vaccines through assessed functional NRAs; and
- (6) to promote convergence of the regulatory framework to facilitate access to affordable and assured quality products.

Expanding the scope of the NRA Regional Alliance to cover other medical products was also discussed. The rationale for expansion includes:

- multiple regulatory responsibilities for most RA members (regulation of food, medicines, biologicals and other medical products, such as devices, medical products of human origin, etc.);
- the need for reliance on other NRAs and work-sharing – no NRA can do it alone;
- a critical need for regulatory system strengthening in multiple countries in the Western Pacific Region for regulation of vaccines, medicines and other medical products;
- leveraging and optimization for the highest impact with the limited resources available for NRAs, and from donors to support RSS;
- regional capacity to support RSS in well-developed NRAs in the Region;
- geographic coverage;
- the advantage that the RA has the broadest inclusive coverage of countries compared with other regulatory networks that only partially include countries (e.g. ASEAN, APEC);
- existing structures and processes being in place, having been endorsed by Western Pacific Member States;
- regular RASC and Regional Office for the Western Pacific Secretariat meetings, with communication channels already established; and
- existing investments now available to RA, and NRA able to provide broader benefits to member NRAs.

There was an in-depth discussion on the expansion. Mr Naoyuki Yasuda from Japan cautioned that it could interfere with the current Alliance's objectives if the scope of the Alliance were expanded beyond vaccines. The authorities needed to be cautious and consider the potential negative impact. Mr Ward responded that when NRA functions were examined, most of the scope of what they did went beyond the scope of vaccines. Part of the reason for expansion is to use the same tools for other processes. Professor Chung Keel Lee suggested thinking about this in two ways, considering: (a) in technical aspects, the majority of functions are quite similar for vaccines and drugs, and (b) in terms of support issues, there may be some difficulty.

Dr Atsushi Kato mentioned that our action was based on GVAP, which targets vaccines. Therefore the target is now the same. If we broaden it, it includes noncommunicable diseases (NCDs), but NCDs affect different countries and regions differently. If the goal of GVAP were expanded, then he would agree with it, but if not, expansion would be difficult.

Dr Tisocki mentioned that the focal person for NRA would be moving to the essential medicine team, but that would not affect any of the existing workplans. Looking at the regulators, these resources are affecting and benefiting other areas of the regulatory agency, not just vaccines. The difficulty is with low-income countries where there are very few staff. There, it can become such a burden to cope with various initiatives. An alliance can look at the needs of these countries and how to cope for the future. This will benefit countries where NRA strengthening is needed, and we can build robust regulatory systems.

Dr Elizabeth Kerr added that it had taken a great deal of effort to get this RA established. Part of it was obtaining political commitment, but the commitment was for vaccines. To expand further, we would have to gain commitment for other medicines. New regulatory strengthening tools prioritize medicines, but not medical devices. It is not certain that RA is the right forum for this. RA cannot set its own priorities because no single Member State has full knowledge about where the needs of each state lie. WHO has this knowledge, so we look to WHO for this.

Mr Belgharbi added that we might need more than one model to allow various NRAs to strengthen at their own speed. QMS is not a high priority at this stage. Expansion to medicines and medical devices needs more work from the Secretariat to guide the process.

Dr Tisocki said she agreed that all those things had to happen. The first consideration is what RA is adding value to. The aim is not to settle the question today about whether or not to expand. The aim is just to start a discussion about whether expansion can be useful or whether there are other mechanisms to provide assistance. Five working groups already overlap with regulator functions for medicines. It is important to discuss the current situation before embarking on expansion.

Dr Shin suggested continuing this vaccine stream annual meeting. There is restructuring at WHO's Regional Office for the Western Pacific, and WHO has been criticized for not aligning the work of strengthening NRAs between product streams. WHO may be able to organize back-to-back meetings for both the vaccine stream and the medicine stream in 2016.

It was decided that the steering committee would take the next steps and prepare a questionnaire to give to the Member States. The expansion of the scope of Regional Alliance may also be considered at other meetings in addition to back-to-back meetings.

2.7 Session 6: RASC meeting

The objective of session 6 was to review the Regional Alliance Secretariat Workplan 2016–2017 and to share information with Member States.

Dr Shin went over the Workplan 2016–2017 with the participants and gained feedback on it. Following the review, Mr Michael Ward gave a presentation on WHO global learning opportunity (GLO) training and other learning opportunities and Dr Dianliang Lei gave a presentation on norms and standards meetings for 2016.

The workshop ended with closing remarks by Dr Sangja Ban from the host country. She emphasized that common visions and common issues were important. Collaboration in the NRA will contribute to enhancing its quality. It is also important to strengthen the NRA's partnership with governments. She thanked everyone for contributing their expertise.

Dr Tisocki also contributed to the closing remarks. Through updated global policy evolution in the global assessment tool, this common tool can be used in both the vaccines and medicines areas. The result of this assessment could bring about change. The new approaches will make the NRA stronger. Dr Tisocki thanked representatives for the updates on their countries. She called for more serious thought on closing the gaps. The participants had opportunities to learn about QMS and risk communications. The discussion on future directions for RA was very important. WHO's Regional Office for the Western Pacific will be seeking further ideas on using this model in a broader regulatory system strengthening. WHO's overall goal is to ensure quality and safety so that vaccines, medicines and other medical products contribute to regional and global public good.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusion

The RASC (observed by other NRA representatives) did not reach a consensus on expanding the scope of the Regional Alliance for NRA from vaccines alone to include all medical products (vaccines, medicines, diagnostic and medical devices). The participants charged the Secretariat to conduct a survey on the need to broaden the scope of the current NRA. The survey results will be discussed during the next Alliance meeting.

3.2 Recommendations

3.2.1 Recommendations to Member States

1. The NRA may wish to continue the effort of conducting self-assessment to identify capacity gaps and establish an updated institutional development plan with goal(s), key milestones and roadmap and share these with the Regional Alliance in a timely manner.
2. The NRA may wish to keep the government's regulatory standards up to date and harmonized with international standards.

3.2.2 Recommendations to WHO Secretariat

1. The Secretariat may wish to conduct a survey on the need to broaden the scope of the current NRA.
2. The Secretariat may wish to review the second edition of the concept paper and propose revising the draft according to the survey results. The updated concept paper will be presented and discussed during the next Regional Alliance Plenary Meeting.
3. The Secretariat may wish to update a dedicated secured SharePoint site to hold the central documents for the RASC (concept paper, workplan and governance rules, plus other information-sharing documentation).
4. TAG recommends that a decision on including a new target on further reducing mother-to-child transmission of hepatitis B in the *Regional Action Plan for Viral Hepatitis in the Western Pacific* be deferred until global guidance on the strategies and a means for measuring progress in reducing mother-to-child hepatitis B transmission, such as the addition of antivirals in late pregnancy, is provided.

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Annex 1. List of participants

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Annex 2. Timetable

Time	Tuesday, 15 December 2015	Time	Wednesday, 16 December 2015
0800-0900	Registration	0830-1000	Quality Management System Group presentation
0900-0925	Opening ceremony <ul style="list-style-type: none"> Opening speech Self-introduction 		
0925-0930	Group photo		
0930-1000	COFFEE BREAK	1000-1030	COFFEE BREAK
	SESSION 1. Update from WHO		SESSION 4. Risk Communications
1000-1030	1.1 Global update	1030-1100	4.1 Risk communication in regulatory system
1030-1100	1.1.a. Developments in regulatory system strengthening	1100-1130	4.2 Perspectives on effective risk communication
1100-1115	1.1.b. Assessment policy and tool		
	Discussion	1130-1230	Group discussion and presentation
1115-1145	1.2 Regional update		
1145-1215	1.2.a. Key events in medicines field in the region		
1215-1230	1.2.b. Key events in the vaccines field in the region		
	Discussion		
1230-1330	LUNCH BREAK	1230-1330	LUNCH BREAK
	SESSION 2. Update from Member States (20 minutes each)		SESSION 5. Future of Regional Alliance
1330-1350	2.1 NRA strengthening	1330-1340	5.1 History, vision, strategy and challenges
1350-1410	2.1.a. Cambodia	1340-1350	5.2 Considerations
1410-1430	2.1.b. Lao PDR	1350-1400	5.3 Questions
	2.1.c. Philippines		
1430-1450	2.2 Vaccine pharmacovigilance	1400-1500	Plenary discussion
1450-1530	2.2.a Viet Nam		
	Discussion		
1530-1600	COFFEE BREAK	1500-1530	COFFEE BREAK
	SESSION 3. Quality Management System		SESSION 6. RASC and NRA Representatives Meeting
1600-1630	3.1 Understanding ISO 9001:2015	1530-1615	6.1 Review of Secretariat Work Plan 2016-2017
1630-1800	Group discussion	1615-1630	6.2 Information sharing
		1630-1645	6.2.a. WHO Global Training and other learning opportunities
		1645-1650	6.2.b. Norms and standard meetings 2016
			6.2.c. Any other updates
		1650-1700	Closing of RASC and NRA meetings

Annex 3. Table A3.1 Secretariat workplan for January 2016 to December 2017

General Objectives		Specific Objectives	Plan of action	Status	Remarks
1. Establish [and sustain] Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific Region.	1.1	Establish a periodic mechanism of consultation and decision-making among members to operate the NRA Regional Alliance (Governance).	Organize RASC videoconference/ teleconference in Q1–Q2 2016 & 2017.	Planning	
			Organize F2F RASC and NRA workshop Q3–Q4 2016 & 2017.	Planning	
	1.2	Determine the type of management support required to implement the NRA Regional Alliance's vision (Secretariat).	Develop a business case to present to Member States for seconded staff or rotational post or other means to support the Secretariat function by Fifth NRA Meeting.	Planning	
	1.3	Submit for endorsement the NRA Regional Alliance concept paper, including a workplan and roadmap for supporting partners, to Member States (Endorsement).	Revision?	Awaiting decision on revision of concept paper	
1.4	Publish the NRA Regional Alliance strategic workplan and disseminate it to all Member States as well as actual and potential supporting partners (Publication).	Pending concept paper revision	Awaiting decision on revision of concept paper		
		Publish on Regional Alliance website, country NRA website and partner's website.	Awaiting decision on revision of concept paper	Country and partner's website	
2. Develop and strengthen a medicines regulatory system with a focus on vaccines in the Western Pacific Region.	2.1	Promote and support the assessments of NRAs or reassessments of medicines regulatory authorities (NRA assessment).	Validation of NRA self-assessment in three Member States (Malaysia, Mongolia, Papua New Guinea) in 2016.	Planning	
			International assessment in three Member States (Viet Nam, Cambodia, Lao	Planning	

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		People's Democratic Republic) in 2017.		
	2. Support the development and routine monitoring of an NRA institutional development plan (IDP monitoring).	Follow-up visit to Cambodia, Lao People's Democratic Republic, Philippines, Viet Nam	Planning	
		Support in implementation of activities in IDPs in all 12 countries	Upon request	GLO/VQ training (many); MFDS hands-on training (HOT); JICA training on strengthening NRA for vaccine quality and safety
	2. Identify and coordinate regional needs for priority support (Technical and financial support).	Identify and coordinate regional needs for priority support (technical and financial support) at annual workshop 2016–2017.	To be planned	
3. Promote and advocate the concept of functional NRAs to obtain commitments from governments and external partners.	3.1 Obtain commitments from governments in the Region.	[New] Write letter to ministers of health in all 37 countries/areas to inform them of new direction of Regional Alliance, its governance and strengthening the regulatory capacity.	Pending	
	3.2 Obtain commitments from strategic partners in technical and financial areas.	Support RASC or RD to write a letter to all partners to inform Regional Alliance and appeal for support.	Pending (medicines/ medical devices?)	
		Invite partners to Regional Alliance meetings/other related meetings.	Ongoing	JICA, need to expand the list to be more inclusive.
4. Improve sharing of information, best practices and	4.1 Increase exchange of routine and critical regulatory information to support relevant and evidence-based decisions,	Support in updating the existing networking, affiliation information and	Ongoing	Identify contact person in each NRA/NCL. Share information via

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communication among NRAs.	as well as to ensure timely action in case of high health risk or threat.	exploring barriers to information exchange.		email and SharePoint. Quarterly as a minimum? <ul style="list-style-type: none"> • medicines • vaccines • medical devices
		Organize a session for communication capacity-building.	Ongoing	In collaboration with EURO?
		Develop concept note on timely regulatory action against health risk and threat (e.g. pandemic).	Ongoing	Mapping existing guidelines?
		Build communication capacity in crisis.	Ongoing	
4.2	Promote and develop collaborative exchange mechanisms to learn about best practices (Best practices).	Develop concept note including plan on collaborative exchange mechanism to learn the best practices.	Not initiated	
		Support in implementing the exchange programmes/visits.	As per request	National Pharmaceutical Control Bureau (NPCB)–MFDS (GMP training, Sep 14); NPCB–NIID (lot release training, Oct 14) NRA twinning: Food and Drug Administration of the Philippines (FDA PHL) – MFDS; Mongolia (MNG)? ToR exists; they can be expanded and published

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				on the website Model lab access memorandum of understanding (MoU) to be developed?
	4.3 Promote development of country policies consistent with WHO regional and international standards (Consistent policies).	Promote regulatory harmonization and convergence.	Ongoing	Covered by Regional Alliance meetings/ training programmes, implementation workshops on particular functions/topics.
5. Contribute to increasing global/regional production of vaccines of assured quality through assessed functional NRAs.	5.1 Assist vaccine-producing countries in developing a roadmap for WHO vaccine prequalification (PQ) (Prequalification).	Organize training workshop on PQ procedures.	Upon request	Need to develop detailed action plan
		Mapping of vaccine prequalification application by country.	Upon request	- China already on board - Viet Nam
		Help prepare the PSF for vaccine prequalification.	Upon request	
	5.2 Support NRAs to establish stringent oversight of domestic vaccine manufacturers and products released, and to detect critical deficiencies in good manufacturing practices (GMP) or defects in quality product manufacturing (GMP and supply chain oversight enforcement).	Organize and implement in-country training programmes.	Upon request	Need to develop detailed action plan with countries
6. Promote convergence of regulatory framework to	6.1 Establish a standing working group to organize and coordinate work.	Support in developing RAWG and coordinating activities.	Need support from NRAs	

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facilitate access to affordable vaccines of assured quality.		Support in promoting convergence within the Region.	Need support from NRAs	Implementation workshop; participation in global written measurement standards
		[RASC-2 New] Support the establishment of Sub-Regional Causality Assessment Committee (SRCAC) for AEFI for Pacific island countries: RD memo with concept note to PIC health ministers.	RD letter – declined; awaiting Pacific island countries immunization programme strengthening (PIPS) consultation.	Desk review only
		[RASC-2 New] Support polio endgame strategy: raise awareness of bOPV switch and facilitate NRA plan in producing countries (China, Viet Nam – develop monitoring & evaluation tool).	Ongoing	Followed up with China and Viet Nam regulators Jul–Sep 2015
		[RASC-2 New] Support polio endgame strategy: raise awareness of bOPV switch and facilitate national registration of bOPV and IPV – develop monitoring and evaluation tool.	Ongoing	Country mapping
		[RASC-2 New] Support/promote on-label use of vaccine in a controlled temperature chain: technical support on hepatitis B birth dose CTC on-label requirements.	Ongoing	Intern; presented at 2015 TAG

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		[RASC-2 New] Support/promote influenza maternal immunization – regulatory information on PMS data and review of prescribing information.	Ongoing	
		[RASC-2 New] Promote and participate in laboratory collaboration with SEAR NCL Network: related ongoing activity – SEAR/WPR biregional development of working reference standards for Japanese encephalitis, polio.	Ongoing	Briefing note reported to SEARO–WPRO RD meeting in Nov 2015 Planned for Aug–Sep 2016

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