Meeting Report

First Meeting of the Regional Alliance Steering Committee for National Regulatory Authorities for Vaccines in the Western Pacific

Seoul, Republic of Korea
29–30 October 2013
Participants of the First Meeting of the Regional Alliance Steering Committee for National Regulatory Authorities for Vaccines in the Western Pacific.
Seoul, Republic of Korea, 29–30 October 2013
REPORT

FIRST MEETING OF THE
REGIONAL ALLIANCE STEERING COMMITTEE FOR
NATIONAL REGULATORY AUTHORITIES FOR VACCINES
IN THE WESTERN PACIFIC

Convened by:

NATIONAL INSTITUTE OF FOOD AND DRUG SAFETY EVALUATION
MINISTRY OF FOOD AND DRUG SAFETY
REPUBLIC OF KOREA

In collaboration with the

WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC

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29–30 October 2013

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NOTE

The views expressed in this report are those of the participants in the First Meeting of the Regional Alliance Steering Committee for National Regulatory Authorities for Vaccines in the Western Pacific and do not necessarily reflect the policies of the World Health Organization.

This report has been prepared by the National Institute of Food and Drug Administration and Drug Safety Evaluation, Ministry of Food and Drug Safety, the Republic of Korea in collaboration with the World Health Organization Regional Office for the Western Pacific for the participants in the First Meeting of the Regional Alliance Steering Committee for National Regulatory Authorities for Vaccines in the Western Pacific, which was held in Seoul, the Republic of Korea, from 29 to 30 October 2013.
SUMMARY

The First Meeting of the Regional Alliance Steering Committee for National Regulatory Authorities for Vaccines in the Western Pacific was held from 29 to 30 October 2013 in Seoul, the Republic of Korea.

The objectives of the meeting were:

(1) to discuss the governance of the Regional Alliance Steering Committee (RASC) and update the Regional Alliance (RA) concept paper;

(2) to finalize the RA work plan;

(3) to discuss and finalize the Regional Alliance Working Groups (RAWGs) for the regulatory system, the six functions of a National Regulatory Authority (NRA) and information/communication;

(4) to discuss the promotion of international collaboration and coordination and the way forward for resource mobilization for the RA; and

(5) to share information and best practices among RASC member countries.

The meeting was organized into seven sessions. Presentations covered a progress report from the Secretariat; the updated work plans for RASC and the Secretariat; formulation and terms of reference for the RAWGs; sharing of information, best practices and experiences; and regulatory convergence.

The meeting was attended by regulatory experts from the NRAs of seven Member States: Australia, China, Japan, Malaysia, the Philippines, the Republic of Korea and Viet Nam; staff members from WHO Headquarters; and representatives from partner organizations, including the Japan International Cooperation Agency (JICA) and the International Vaccine Institute (IVI).

The proposed work plans were accepted by the meeting attendees and will be finalized for endorsement in the next NRA plenary workshop in 2014. The formation of five Regional Alliance Working Groups (RAWGs) was proposed, based on terms of reference, and endorsed. The individual working groups’ specific terms of reference and objectives will be further refined and shared electronically with RASC member countries for finalization. The governance and membership rules were also discussed. The WHO WPRO Secretariat, will expand the concept paper with the additional information from the meeting discussions regarding the governance of RASC and its operation, then share it with all Member States and publish it on the Sharepoint.
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1. INTRODUCTION

The First Meeting of the Regional Alliance Steering Committee for National Regulatory Authorities for Vaccines in Western Pacific was held from 29 to 30 October 2013 in Seoul, the Republic of Korea. The Meeting was attended by seven Member States.

1.1 Objectives

(1) to discuss the governance of the Regional Alliance Steering Committee (RASC) and update the Regional Alliance (RA) concept paper;

(2) to finalize the RA work plan;

(3) to discuss and finalize the Regional Alliance Working Groups (RAWGs) for the regulatory system, the six functions of a National Regulatory Authority (NRA) and information/communication;

(4) to discuss the promotion of international collaboration and coordination and the way forward for resource mobilization for the RA; and

(5) to share information and best practices among RASC member countries.

1.2 Opening remarks

Dr Sergey Diorditsa, Team Leader, Expanded Programme on Immunization, WHO Western Pacific Regional Office, delivered the opening remarks. He mentioned that, following the first workshop for NRAs for Vaccines in Seoul in 2011, where Member States had requested the WHO Western Pacific Regional Office to support and formulate a collaborative platform, and thanks to the tremendous support from task force countries and other countries in the Region, the Regional Alliance for NRAs for Vaccines in the Western Pacific had been launched in March 2013. He expressed great appreciation to the Ministry of Food and Drug Safety of the Republic of Korea for initiating and supporting the Regional Alliance, as well as the RASC Member States for their contributions.

He emphasized that there were a number of pending issues to discuss and decide, including strengthening RA governance, finalization of work plans, formation of the RA working groups and collaboration with other partners. He highlighted that the meeting would be an important milestone towards implementation of the RA work plan and the agenda had therefore been designed with more emphasis on discussion rather than just presentations. He also reminded participants that one of the objectives of RASC was to support countries in developing independent, competent and effective regulatory systems to oversee the supply of assured quality vaccines. He concluded by hoping for successful deliberations and once again expressed his sincere appreciation to the Ministry of Food and Drug Safety for organizing and supporting the meeting, as well as to all participants.

Dr Jin-ho Wang, Director General of the National Institute of Food and Drug Safety Evaluation (NIFDS), Ministry of Food and Drug Safety, Republic of Korea, extended a warm welcome and special thanks to all participants.
He stated that vaccination is one of the most effective primary interventions to prevent infectious diseases, and WHO has played a key role in expansion of the vaccine project to promote immunization and enhance public health. He expressed his deepest gratitude for the organization’s efforts and contributions. He also highlighted that the Republic of Korea has demonstrated significant progress in vaccine development and production and closely cooperates with WHO. The Korea Food and Drug Administration (KFDA), now the Ministry of Food and Drug Safety, signed a technical service agreement (TSA) with WHO in 2006, and was designated as a WHO Collaborating Centre in 2011. Since then, the Ministry has contributed to the establishment of international standards for biological, collaborative studies, as well as providing good manufacturing practice (GMP) training programmes. He emphasized that the most essential element of the vaccine project to prevent infectious diseases is the supply of vaccines of assured quality and, as responsibility for assuring the quality and safety of vaccines rests with NRAs, it is important to strengthen their regulatory functions. He expected the meeting to provide a good opportunity to increase NRA capacity across the Region.

1.3 Appointment of Chairperson, Vice-Chairperson and Rapporteur

It was proposed and agreed in the second NRA workshop in March 2013 that national regulatory authorities of seven Regional Alliance Member States should become members of the Regional Alliance Steering Committee, and also that each Member State, in alphabetical order, should serve as chairperson for one year to give an opportunity to every Member State. Thus, Dr Elizabeth Kerr, representative from the Therapeutic Goods Administration (TGA), Australia, was nominated as chairperson of RASC for the current year. Dr Kerr then proposed nominating the Vice-Chairperson and Rapporteur for RASC. Also going alphabetically, it was agreed by the Steering Committee that China would serve as Vice-Chairperson, and the Republic of Korea as Rapporteur.

2. PROCEEDINGS

2.1 Objectives and agenda

Dr Sergey Diorditsa, Team Leader, Expanded Programme on Immunization, WHO Western Pacific Regional Office, presented the objectives of the Regional Alliance Steering Committee.

He then highlighted the expected outcomes of the meeting as:

(1) clarification and endorsement of the governance of the RA and proposed eight RAWGs, in line with the work plan;

(2) endorsement of the RA work plan for 2014-2015;

(3) strengthening of existing collaboration and seeking of potential areas for international collaboration;

(4) coordination, in order to guide the RA work plan; and

(5) sharing of information and best practices.
2.2 Progress report from the Secretariat

In his presentation, Dr Md. Shafiquil Hossain, Technical Officer, Expanded Programme on Immunization, WHO Western Pacific Regional Office, gave a progress report on RA activities and programmes based on the general and specific objectives in the RASC concept paper.

The six main objectives of the concept paper are:

(1) to establish a Regional Alliance for NRAs in the Western Pacific Region;

(2) to develop and strengthen the medicine regulatory system, with a focus on vaccines, in the Western Pacific Region;

(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 increased global/regional production of assured quality vaccines through assessed functional NRAs; and

(6) to promote the convergence of regulatory frameworks to facilitate access to affordable products of assured quality.

He highlighted the fact that most of the activities were already going on through collaborative efforts, but there were still some areas requiring more work. For example, as regards information-sharing between NRAs, due to reasons of confidentiality it is not always easy to establish a mechanism for the exchange of the routine and critical regulatory information essential to take timely action in an emergency. He stressed the need for more discussion and cooperation to come up with ways to address this issue.

He also reported progress on RA activities during the period from October 2012 to October 2013. The Alliance held a series of regional workshops on regulatory issues for vaccines, including the second workshop for NRAs for Vaccines in Manila, Philippines, and several meetings to establish the Regional Alliance for NRAs for Vaccines in the Western Pacific. The RA promoted and supported NRA self-assessment, including in nine new countries, as well as conducting re-assessment, validation of self-assessment and follow-up visits for four countries. The RA also provided training programmes on vaccine lot release and GMP inspections for several countries, such as China and the Philippines, and coordinated the attendance of NRA staff from countries to the Global Learning Opportunity (GLO) programme to improve regulatory capacity. Training courses on adverse event following immunization (AEFI) surveillance were also offered in several countries by the RA to strengthen AEFI monitoring and causality assessment.

He also stated that there were number of vaccine safety issues posing threats to the entire immunization programme in seven countries and there was a need for vigilance in the face of such issues. He requested support from experts from RA in this safety issue when it occurs.
He concluded by introducing the section of the WHO Western Pacific Regional Office website dedicated to vaccine regulation (http://www.wpro.who.int/topics/vaccine_regulation/en) and the RA website (http://www.wpro.who.int/immunization/documents/regional_nra_alliance_wpr/en/index.html), which facilitate sharing of information by NRAs. He requested advice and comments on how to manage and use the website.

2.3 Development and strengthening of the medicines regulatory system with a focus on vaccines in the Western Pacific Region: Member States’ institutional development plans

At the beginning of his presentation, Dr Hossain briefly introduced the history and background of the RA for the benefit of new attendees. The Alliance was initiated to provide a forum for countries with effective and competent NRAs as well as those with no or still embryonic regulatory systems to share regulatory information. After a long process of discussion and consultation, the RA was finally launched in 2013.

He summarized the current status of NRA assessment and institutional development plans (IDPs) of 10 countries, including validation in Viet Nam, Cambodia and China, as of October 2013. Countries have high expectations of getting support from the RA as a regional platform.

He stated that, as 45%-70% of proposed activities are focused on several functions (regulatory system, marketing authorization and pharmacovigilance), areas of weakness need to be addressed. More than 50% of activities should be delivered through training programmes, and technical support is needed in terms of quality management systems and development of regulations.

He explained the current status of activities based on six functions: (1) marketing authorization and licensing; (2) pharmacovigilance, including AEFI; (3) national lot release; (4) laboratory access; (5) inspections; and (6) oversight of clinical trials in countries with IDPs. There are demands for training programmes to strengthen regulatory capacities in the 10 countries.

Areas of focus for investment include:

(1) endorsing IDPs to get political commitment;

(2) ensuring political commitment and government support;

(3) legislation and regulations that are coherent and consistent;

(4) good regulatory practices to build capacity;

(5) good review practices for marketing authorization and clinical trials to focus on critical issues;

(6) quality management systems to ensure traceability;

(7) lot release and expedited review procedures for United Nations prequalification of vaccines;

(8) laboratory enhancement for already established national control laboratories;

(9) GMP training and regulatory inspections of distribution channels;
(10) oversight of clinical trials and ethical oversight; and

(11) pharmacovigilance, market surveillance and AEFI surveillance.

The IDP is just a step in the process of determining what needs to be done and, as agreed in the previous meeting, a comprehensive and coordinated plan needs to be set up to prioritize areas to work on first.

2.4 Establishment of the Regional Alliance for NRAs for Vaccines in Western Pacific: Concept paper and governance update

In her presentation, Dr Kerr briefly went over relevant issues in the concept paper. The specific objectives of the Regional Alliance are to establish a periodic mechanism for consultation and decision-making among members, to operate the NRA Regional Alliance, and to determine the type of management support required to implement the RA’s vision. The recommended RA governance system should ensure the smooth operation of the Alliance as well as good planning and monitoring of its activities.

The activities of RASC:

(1) Regional Alliance taskforce to develop a concept paper and work plan to be presented to Member States for consideration and endorsement in 2013.

(2) The Regional Alliance Steering Committee (RASC) to be established by Member States to oversee the RA work plan at the 2013 meeting.

(3) Regional Alliance Working Groups (RAWGs) to be established by RASC as per the RASC work plan.

(4) The WHO Regional Office for the Western Pacific to appoint a staff member to serve as the focal point and a Secretariat to assist RASC and RAWGs.

The first and second activities have been already implemented, and activity 3 and 4 were up for discussion in the meeting.

2.4.1 Governance of the Regional Alliance Steering Committee

The purpose of RASC is to oversee the development and ongoing maintenance of the Regional Alliance programme.

Its roles and functions are:

(1) to oversee strategic direction;

(2) to review the process for future development;

(3) to oversee the work plan;

(4) to ensure that the programme is consistent with regional priorities;

(5) to monitor the effectiveness of the overall work plan.
2.4.2 Governance of the Regional Alliance Working Groups

The RAWGs are designed to plan, conduct and report about scientific and technical consultations of experts in defined areas, as recommended by RASC.

The roles and functions of the RAWGs are:

(1) to establish and update the roster of experts required for a defined area; moving to Secretariat role and function;

(2) to develop programme objectives/expected outcomes for experts’ meetings;

(3) to organize and conduct the meetings of scientific/technical experts;

(4) to report the outcomes of scientific and technical experts’ consultations; and

(5) to coordinate the above steps with RASC and the Secretariat.

2.4.3 Governance of the Secretariat

The WHO Regional Office for the Western Pacific, based in Manila, Philippines, will provide secretarial support to RASC and the RAWGs.

Its role and function are:

(1) to plan, organize and act as the secretariat for RASC and RAWG meetings;

(2) to provide support to RASC and the RAWGs outside their regular meetings;

(3) to maintain institutional memory of RA activities through archiving and maintaining a database of relevant information;

(4) to develop, manage and update the RA advocacy and information material;

(5) to coordinate with Member States regarding the RA work plan; and

(6) to report on progress to RASC.

Proposals about the governance rules for RASC and the RAWGs were discussed in details, including the rules regarding chairmanship and membership, etc. Secretariat was requested to update the concept paper on this basis agreement on governance rules for RASC and RAWGs.

It was emphasized that the Secretariat is the linchpin of RASC’s work and proposed that the Secretariat should invite expressions of interest from Member States for secondment of their staff to the WHO Regional Office for the Western Pacific to assist the work of the Regional Alliance.

2.5 Establishment of the Regional Alliance for NRAs for Vaccines in the Western Pacific: Updated work plan (2014-2015)

The updated work plans (2014-2015) for RASC and the Secretariat were presented for discussion and group endorsement. The objective of the work plans is to strengthen the regulatory system in an efficient and coordinated manner.
The next process is to submit the work plans to Member States for further consideration and comment before the next NRA workshop. The concept paper, including the work plans, will also be revised and submitted to the next RA meeting in July 2014 for finalization. The revised concept paper will be published on the RA website and the WHO Sharepoint. Member States with NRAs will be requested to upload the concept paper and related documents or the link to them on their websites.

The work plan for the RAWGs will be updated after the formulation of the working groups.

2.6 JICA’s cooperation for vaccine safety and quality

Dr Saeda Makimoto, Director, Health Division 3, Human Development Department, Japan International Cooperation Agency (JICA), explained JICA’s international training programme.

The objective of JICA’s international training initiative, entitled ‘Strengthening the administrative function for vaccine quality and safety security’, is to help regulators to acquire the knowledge needed to enhance regulatory capacities, particularly in the fields of lot release and laboratory access, and to identify challenges in their own countries. The training period is planned from 2013 to 2015 (three years) and a National Institute of Infectious Diseases (NIID) International Symposium on Safety, Efficacy of Vaccine and National Lot Release will be held on 23 January 2014. Target countries for the first year include Bangladesh, India, Indonesia, Mongolia and Viet Nam. Participants will be NRAs and/or National Control Laboratory (NCL) staff who are in managerial positions and engaged in lot release and/or laboratory access. Partners (implementing agencies) include NIID, in charge of lot release and laboratory access; the Ministries of Health, Labour and Welfare, in charge of other NRA functions; and also WHO Headquarters/Regional Office for the Western Pacific.

Other related collaborative activities are:

(1) an MR vaccine production in Viet Nam (2013-2017); and

(2) a drug and food safety project in Indonesia (planned for 2014-2019).

Counterpart: National Agency for Drug and Food Control

Planned activities include:

(1) strengthening NRA functions and systems in pharmacovigilance and post-market food safety;

(2) training for NRA staff and pharmaceutical companies etc.; and

(3) strengthening the capacity of NRA laboratories as regards technical and management aspects, including lot release of IPV, improvement of quality management, etc.

2.7 Promotion of convergence of regulatory frameworks to facilitate access to affordable products of assured quality

Mr Lahouari Belgharbi, Group Lead, NRA strengthening, WHO Headquarters, stated that, as public health policies aim to ensure all medicinal products are accessible, affordable and of assured quality, NRAs need to strengthen and update their scientific knowledge through
international collaboration and information sharing. In this respect, national regulatory capacities can benefit from regulatory convergence. He led two 15-minute workshops to exchange opinions on regulatory harmonization. Everyone was requested to fill out the forms provided on what they would like and expect in the future in terms of synergies, international collaboration, information sharing, regulatory convergence and mutual recognition by working together or individually.

2.8 Promotion and advocacy of the concept of functional NRAs to obtain government commitment and external partners

In this session, Mr Belgharbi led another two short workshops to share opinions on various ways to promote the NRA concept and to mobilize resources. For workshop 1, everyone was requested to fill out the forms on the elements to promote the NRA concept and obtain government commitment, the progress of activities and whether they are critical. For workshop 2, requested information concerned priorities to support, traditional partners for NRA activities, potential sources of support, the progress of activities and whether they are critical.

2.9 Formation of the Regional Alliance Working Groups

It was agreed that five working groups should be formed based on the following categorizations and their terms of references.

<table>
<thead>
<tr>
<th>Regional Alliance Working Groups (RAWGs)</th>
<th>Generic terms of reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. System</td>
<td>Legislation and regulations</td>
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<tr>
<td></td>
<td>Quality Management system</td>
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<tr>
<td></td>
<td>Strategic planning</td>
</tr>
<tr>
<td></td>
<td>Capacity-building, learning and training</td>
</tr>
<tr>
<td></td>
<td>Advisory experts’ committees</td>
</tr>
<tr>
<td>2. Marketing authorization, licensing, oversight of clinical trials, regulatory inspections</td>
<td>Clinical review, clinical safety, quality, efficacy, GMP inspection etc.</td>
</tr>
<tr>
<td>3. Lot release and laboratory access</td>
<td>Testing, validation, animal husbandry, biosafety, trend analysis</td>
</tr>
<tr>
<td>4. Pharmacovigilance, import, export, market surveillance</td>
<td>Causality, signal detection and reporting, data management</td>
</tr>
<tr>
<td>5. International collaboration, harmonization and exchange of information</td>
<td>Transparency, communication, exchange platform</td>
</tr>
</tbody>
</table>

It was endorsed that the Secretariat will start working immediately on establishing all five groups, develop specific terms of references and receive comments from Member States electronically.

As for leadership, the chairperson of each working group will be appointed by RASC, as presented by Dr Kerr in session three. The Secretariat will work on the proposal that a co-chairperson would contribute to progressing the work of working groups. There are further details that need to be worked out and this should be done electronically, perhaps via the Sharepoint.
2.10 Improvement of sharing of information and best practices, and communication between NRAs

2.10.1 Republic of Korea vaccine review and evaluation system

Dr Kwang-soo Ahn, Deputy Director, Biologics Division, Ministry of Food and Drug Safety, briefly introduced the vaccine market status in the Republic of Korea. The worth of the country’s vaccine market reached US$650 million in 2011 (2% of the global market) and the average annual growth over the six years from 2006 to 2011 was around 11%. A total of 201 products had been approved as of June 2013, 133 of them being manufactured domestically. He also presented the structure and organization of Ministry of Food and Drug Safety, specifically that section responsible for biological regulation, the Biopharmaceuticals and Herbal Medicines Bureau (BHMB) and its divisions. He shared information on the Republic of Korea’s vaccine regulatory framework from vaccine development through the market authorization process to evaluation of safety and efficacy. The Republic of Korea has demonstrated significant advancement in vaccine development over the years. The Government plans to support the advancement of domestic vaccines to the international market by strengthening cooperation with other countries, including sharing of information and signing of memoranda of understanding, as well as to help domestic vaccine manufacturers acquire pre-qualification from WHO.

2.10.2 Post-marketing control of vaccines in the Republic of Korea

Dr Eunju Kim, Deputy Director, Biopharmaceutical Quality Management Division, Ministry of Food and Drug Safety, gave an overview of the Republic of Korea’s regulatory system for vaccines, focusing especially on post-marketing controls in terms of: (1) manufacturing facility inspection; (2) pharmacovigilance; (3) national lot release; (4) product testing and review; and (5) advertisement control. Advertising of prescription drugs, including biological products, is prohibited in the country, except for vaccines used to prevent infectious diseases. The Republic of Korea is implementing strict laws on the advertising of drugs; for example, product information, such as on efficacy, may not be advertised in a false or exaggerated manner, and the content to be promoted is prescribed according to the related Act. Many participants showed a keen interest in the country’s advanced post-marketing surveillance system.

2.10.3 National lot release of biological products in the Republic of Korea

Dr Dokeun Kim, Senior Scientist, National Centre for Lot Release (NCLR), Ministry of Food and Drug Safety, shared the Ministry’s experiences in national lot release of biological products. NCLR, under the National Institute of Food and Drug Safety Evaluation (NIFDS) of the Ministry, is responsible for operating the national lot release system including testing, quality control and release of biological products. NCLR consists of three teams — Blood Product Team, Bacterial Vaccine TF Team and Viral Vaccine TF Team — as well as operating 24 laboratories for cell culture, sterilization and storage. In 2012, there were 2 049 lots of biological products lot-released (299 lots of bacterial vaccines, 600 lots of viral vaccines, 989 lots of blood products and 161 lots of botulinum toxins). The Centre has also published annual reports since 2009. Dr Kim explained the quality assurance system for lot release, which includes development of standard operating procedures for testing, validation of equipment and facility, maintenance of ISO 17025, and management of national biological reference materials. NCLR has also participated in international collaborative studies to establish international biological standards and has signed a Technical Service Agreement for Vaccine with WHO to strengthen laboratory capacities. In 2012, NCLR provided vaccine hands-on training programmes for experts of national clinical laboratories from five countries.
2.10.4 The history of progress of the Ministry of Food and Drug Safety, Republic of Korea

Dr Chung Keel Lee, Special Advisor to the Minister for Food and Drug Safety, presented his activities as a special advisor in line with the history of the Ministry’s progress. His duties include assessment of the current situation and establishment and execution of technical assistance and training programmes, as well as evaluation of follow-up measures for further improvement, etc. He has trained experts and regulators in the fields of GMP, good licensing practice, quality control and quality assurance for over 30 countries and has carried out inspections in over 30 countries, especially in the area of vaccines. Target trainees are regulators such as reviewers, inspectors, laboratory personnel and administrators at all levels, as well as drug/biologicals manufacturers, research and development institutes and universities. These training efforts also have contributed to the improvement of communication between the industry and regulators. The outstanding outcomes of the training activities include improved regulations, communication and collaboration with WHO and other regulatory counterparts, signing of a technical service agreement (TSA) with WHO, designation as a WHO global learning opportunity (GLO) training centre for GMP inspections and laboratory collaboration, as well as the upgrading of the Korea Food and Drug Administration to ministry level.

3. CONCLUSIONS

The meeting reached the following conclusions:

3.1 Governance

The Secretariat will update the concept paper on the governance of RASC, the RAWGs and the Secretariat, as discussed. The updated concept paper will be endorsed during the next Regional Alliance plenary meeting in July 2014.

(1) The work plan presented at the meeting was accepted. The Secretariat will send the updated RASC work plan to Member States for review and finalization well before the Regional Alliance plenary meeting.

(2) RASC will develop key performance indicators for each of the strategic general objectives and this will be presented as a scorecard.

(3) RASC will meet twice per year: (1) just prior to the annual NRA workshop; and (2) by teleconference in between annual meetings. RASC will retain the flexibility to hold additional face-to-face meetings if required.

(4) The responsibility for maintaining a roster of experts for the RAWGs will be transferred from the RAWGs to the Secretariat.

(5) The chairpersons of the RAWGs will be appointed by RASC.

(6) The other members will be appointed by the Chairpersons of the RAWGs and then endorsed by RASC. The Secretariat will continue to work on the proposal for vice-chairpersons (rather than co-chairpersons, as previously suggested) of working groups.

(7) Additional membership rules may be proposed by the Secretariat later for RASC consideration to ensure diversity and access to appropriate expertise.
3.2 Membership

(1) The concept paper will be updated to clarify the terms of reference and membership rules, including the agreed term and method of appointment of the Chairperson and Vice-Chairperson (appointment from annual meeting to annual meeting, in alphabetical order).

(2) If there is any change in nominations for RASC or RA meetings, the Secretariat should be informed and participants who attended the previous meeting should hand over related documents to the new nominee.

(3) New members will be provided with relevant documents and briefed before their first meeting. RASC members should always be updated on the rules, processes and work plan, etc. of RASC.

(4) RASC members will be required to complete a conflict-of-interest declaration.

3.3 Transparency/Relationships

(1) The WHO Regional Director for the Western Pacific will inform all Member States of the establishment of the Regional Alliance for NRAs for Vaccines in the Western Pacific and its governance, and request NRAs to strengthen their regulatory capabilities by utilizing the resources of the Regional Alliance.

(2) Member States can refer requests from other Member States for training/assistance in vaccine regulation to the Secretariat for coordination.

(3) The Secretariat is responsible for reporting the progress of the work of the Regional Alliance to Member States at the annual NRA workshop.

(4) RASC members who are also members of the Association of Southeast Asian Nations (ASEAN) will facilitate exchange of information between the two groups.

3.4 Support

(1) The WHO Regional Director for the Western Pacific will request key partners to support and further collaborate with the Regional Alliance.

3.5 Regional Alliance Working Groups (RAWGs)

(1) The RAWGs were proposed and endorsed in the meeting, and the terms of reference and objectives for the individual working groups will be further refined and shared electronically with RASC members for finalization.

(2) The terms of references of the RAWGs will define procedures for collaboration.

3.6 Next steps

The next steps to be taken are as follows:

(1) Expand the concept paper with the additional information discussed at the meeting regarding the governance of RASC and its operation: the WHO Secretariat then will share it with all Member States and publish it.
(2) Write a notice in the Weekly Epidemiological Bulletin to announce the outcome of the RASC meeting and the progress achieved so far by the WHO Secretariat.

(3) Prepare a roster of experts to organize the five RAWGs.

(4) Develop two standard operating procedures for running RASC and the RAWGs, and get them endorsed by RASC.

(5) Finalize the terms of reference of the RAWGs and get them endorsed by RASC.

(6) Officially announce to all Member States and WHO Headquarters the launch of the Regional Alliance for NRAs for Vaccines in the Western Pacific and its mandate by the Regional Director.

(7) Second NRA personnel to the WHO Western Pacific Secretariat to assist in implementation of the above activities and assist RASC and the RAWGs to implement their work plans.

(8) Utilize the centralized and dedicated Sharepoint, where all information will be available, including the updated concept paper.
LIST OF PARTICIPANTS, TEMPORARY ADVISERS, OBSERVERS/REPRESENTATIVES AND SECRETARIAT

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## ANNEX 2

### REGIONAL ALLIANCE FOR NATIONAL REGULATORY AUTHORITIES (NRAs) FOR VACCINES IN THE WESTERN PACIFIC

Seoul, Republic of Korea, 29-30 October 2013

### TIMETABLE

**Day 1, 29 October 2013**

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<thead>
<tr>
<th>Time</th>
<th>Topics</th>
<th>Reference to the RA concept paper</th>
<th>Responsibilities</th>
<th>Objective</th>
<th>Expected outcome</th>
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<tr>
<td>0830-0900</td>
<td>Registration</td>
<td>MFDS</td>
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<td>Welcome address</td>
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<td>Dr Sergey Diorditsa, Team Leader-EPI/WPRO</td>
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<td>Dr. Jin-ho Wang, Director General, National Institute of Food and Drug Safety</td>
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<td>Evaluation (NIFDS), MFDS</td>
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<td>0920-0935</td>
<td>Group photo</td>
<td>All</td>
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<td>0935-0950</td>
<td>Self-introduction</td>
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<td>0950-1000</td>
<td>Objectives and agenda</td>
<td></td>
<td>Dr Sergey Diorditsa, Team Leader-EPI/WPRO</td>
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<td>1000-1030</td>
<td>Coffee break</td>
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<td>1030-1115</td>
<td>Session 1: Progress report from the Secretariat</td>
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<td>a. Regional Alliance</td>
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<td>b. To update RA activities</td>
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<td>1115-1230</td>
<td>Session 2: Develop and strengthen medicines</td>
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<td>a. Regional Alliance</td>
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<td>b. Member states IDP</td>
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<td>c. Discuss and agree on priority activities</td>
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<td>d. Endorsed Regional Alliance work plan for</td>
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<td>2014-2016</td>
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<td>1230-1400</td>
<td>Lunch break</td>
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<td>1400-1530</td>
<td>Session 3: Establish Regional Alliance for NRAs</td>
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<td>a. Update on governance</td>
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<td>b. Regional Alliance Steering Committee</td>
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<td>c. Formation of 8 Regional Alliance Working</td>
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<td>Groups (RAWGs)</td>
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<td>d. Amend and adapt the current governance</td>
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<td>e. To discuss and agree on the 8 RAWGs</td>
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<td>1600-1730</td>
<td>Session 4: Establish Regional Alliance for NRAs</td>
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<td>b. Regional Alliance Steering Committee</td>
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<td>c. Regional Alliance Working Groups (RAWGs)</td>
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<td>d. Secretariat (WHO)</td>
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<td>e. Endorsed Regional Alliance work plan for</td>
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<td>0900-1000</td>
<td>Session 5: Promote convergence of regulatory framework to facilitate</td>
<td>Mr. Lahouari Belgharbi</td>
<td>To review existing and potential collaboration and coordination within and outside the Region</td>
<td>Strengthening existing and seeking potential areas of international collaboration and coordination in order to guide the RA work plan</td>
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<td>access to affordable and assured quality products</td>
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<td>Session 6: Promote and advocate the concept of functional NRAs to</td>
<td>Mr. Lahouari Belgharbi/ Dr. Sergey</td>
<td>To review resource gaps in order to meet RA objectives</td>
<td>Identify funding gaps and resources available to implement RA work plan</td>
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<td>obtain government commitment and external partners</td>
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<td>a. Resource mobilization</td>
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<td>1100-1200</td>
<td>Session 7: Improve sharing information, best practices, and communication among NRAs</td>
<td>Dr Kwang-Soo Ahn, MFDS</td>
<td>To share information and best practices among RASC member countries</td>
<td>Information and best practices shared.</td>
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<td>• Korea Vaccine Review/Evaluation System</td>
<td>Ms. Eun Ju Kim, MFDS</td>
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<td>• Post marketing control on Vaccines in Korea</td>
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<td>Continuation of session 7:</td>
<td>Dr Do Keun Kim, MFDS</td>
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<td>• National Lot Release of Biologics in Korea</td>
<td>Professor Chung Keel Lee, MFDS</td>
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<td>• GMP training programme</td>
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<td>Next steps</td>
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<td>1530-1700</td>
<td>Side meeting with selected countries (upon arrangement)</td>
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