Strengthening regulatory capacity with the Regional Alliance for NRAs for vaccine in Western Pacific.

Developing Countries Vaccine Manufacturers Network (DCVMN)

Dr Toda Kohei

7-9 October 2013
Hanoi, Viet Nam
Outline of presentation

- Background of formulating Regional Alliance for NRAs for Vaccines in Western Pacific
- Objectives of formulating the Regional Alliance
- Activities conducted to develop the concept paper, workplan, road map
- Governance of Regional Alliance
- Work plan of Regional Alliance
Regional Alliance for NRAs for Vaccines in Western Pacific is a regional collaborative platform to build the regulatory capacity.
Background-formulating Regional Alliance for NRAs for vaccines

- Situation analysis at Regional office/ NRA assessment
- Member State’s request to formulate Regional Alliance for NRAs for Vaccines in the first workshop for NRAs for vaccines in Seoul, November 2011
- Established taskforce committee-comprised of NRA Australia, China, Japan and Korea
- Requested to develop concept paper and workplan
The TAG supports the proposal for formulating a Regional Alliance for NRAs in the Western Pacific Region as a platform to strengthen NRA systems and functions (including NCL functions) in countries that lack functioning NRAs. The TAG asks the secretariat to support and conduct necessary activities to implement this Alliance in coordination with countries and other partners. The secretariat should consider this proposal as an agenda item in the 2013 Regional Committee Meeting (RCM).
Objective - Regional Alliance for NRAs for vaccines in Western Pacific

The objective is to support to establish and/or strengthen regulatory systems and required functions through effective and efficient co-ordinated mechanism.
Developing Regional Alliance concept paper, road map and workplan

WPRO developed zero draft concept paper.

Reviewed by taskforce committee and developed first draft concept paper. Also developed road map, workplan.

Shared with Member States for review and comments.

Shared 2\textsuperscript{nd} draft with Member States for review and comments.

Final draft for review and endorsement.
Regional Alliance taskforce committee meeting
Canberra, 31 May-1 June 2012

Drafted Regional Alliance concept paper, workplan and road map

Developing Countries Vaccine Manufacturers Network (DCVMN) meeting
7-9 October 2013, Hanoi
Outcomes

Concept Paper
For presentation to, and endorsement by, Member States.

Road map
Discussion of short and long term.

Workplan
Agreement on structure and composition (RA actions from Canberra meeting, IDP outcomes, etc).

RASC and RAWGs
ToRs, composition.

Support for Regional Alliance Technical, financial (obstacles and opportunities).
Second workshop for NRAs for vaccines in Western Pacific

Concept Paper endorsed by Member States and Regional Alliance for NRAs for Vaccines in Western Pacific officially launched on 14 March 2013
Regional Alliance- Governance

<table>
<thead>
<tr>
<th>Location</th>
<th>Name or title of the structure</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotation</td>
<td>Regional Alliance Steering Committee (RASC)</td>
<td>Permanent</td>
</tr>
<tr>
<td>Virtual meeting</td>
<td>Regional Alliance Working Groups (RAWGs)</td>
<td>According to theme of discussions</td>
</tr>
<tr>
<td>Western Pacific</td>
<td>Secretariat services to RASC and RAWG</td>
<td>Permanent</td>
</tr>
</tbody>
</table>
Regional Alliance- Governance

Regional Alliance Steering Committee (RASC)
- Oversee the Regional Alliance for NRAs for vaccines in Western Pacific
- Seven members (Australia, China, Japan, Korea, Malaysia, Philippines and Viet Nam)

Regional Alliance Working Groups (RAWGs)
- Technical areas

Regional Alliance Secretariat
- WPRO
Regional Alliance Working Groups (RAWGs)

- Proposed to establish 8 working groups
  - Regulatory system
  - 6 functions
  - Communication

- Provide technical support to countries to build the capacity as per workplan
Self-assessment and IDP from eleven countries in the Region

- Eleven countries conducted self-assessment and developed IDP.
- Regional Alliance activities already started in countries.
- Regional Alliance Steering Committee meeting will be held from 29-30 October in Seoul, Korea to review the detailed workplan.
- Regional Alliance Working Groups (RAWGs) will be developed in same meeting in eight areas.
- Co-ordinated support from functional NRAs countries (vaccine producing) will be developed in same meeting.
Countries with functional NRA will provide support to other countries.
Developing Countries Vaccine Manufacturers Network (DCVMN) meeting
7-9 October 2013, Hanoi

WPRO vaccine regulation webpage: http://www.wpro.who.int/topics/vaccine_regulation/en/
WPRO sharepoint: http://intranet.wpro.who.int/sites/epi/nra_aefi/default.aspx
THANK YOU