

# Regional Review Meeting on Immunization

*Bangkok, Thailand, 9–12 October 2012*



**World Health  
Organization**

Regional Office for South-East Asia



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## Abbreviations

AEFI	adverse event following immunization
AFP	acute flaccid paralysis
BHU	Basic Health Unit
bOPV	bivalent oral polio vaccine
CDC	United States Centers for Disease Control and Prevention
CHU	Community Health Unit
cMYP	comprehensive multi-year plan
CRS	congenital rubella syndrome
CSO	Civil Society Organizations
cVDPV	circulating vaccine-derived poliovirus
DHO	District Health Officers
DoV	Decade of Vaccine
EPI	Expanded Programme on Immunization
GAVI	GAVI Alliance for Vaccines and Immunization
Gol	Government of India
GVAP	global vaccine action plan
Hib	haemophilus influenzae type B
HLMM	high-level ministerial meeting
HR	human resources
HSS	health system strengthening
IBD	invasive bacterial disease
IMB	Independent Monitoring Board
INGO	International Non Governmental organizations
IPV	inactivated polio vaccine
IRI	intensification of routine immunization
IT	information technology
IVD	Immunization and Vaccine Development
JE	Japanese encephalitis
LQAS-CS	lot quality assurance sampling–cluster survey

MCH/EPI	Maternal and child Health /Expanded programme on Immunization
MCV1	measles containing vaccine (first dose)
MCV2	measles containing vaccine (second dose)
MNTE	maternal & neonatal tetanus elimination
MR	measles-rubella vaccine
NCIP	National Committee for Immunization Practices
NGO	Non Governmental Organization
NIP	national immunization programme
NRA	National Regulatory Authority
NUV	new and underutilized vaccines
NUVI	new and underutilized vaccine introduction
OPV	oral polio vaccine
PHO	Provincial Health Office
PoA	plan of action
QA	quality assurance
QC	quality control
R&D	research and development
RI	routine immunization
SAGE	Strategic Advisory Group of Experts
SEAR	South-East Asia Region
SIA	supplementary immunization activities
SOP	standard operating procedures
Td	tetanus diphtheria
tOPV	trivalent oral polio vaccine
TTSP	time and temperature sensitive pharmaceutical products
TT	tetanus toxoid
UNICEF	United Nations Children's Fund
VAP	vaccine action plan
VAPP	vaccine associated paralytic polio
WHO	World Health Organization

# 1. Introduction

The Regional Review Meeting on Immunization was held from 9 to 12 October 2012 in Bangkok, Thailand, to review regional progress, exchange best practices, address challenges, and discuss future activities. Dr Sangay Thinley, Director, Family, Health and Research, WHO South-East Asia Region, welcomed the participants and read the message from Dr Samlee Plianbangchang, Regional Director, WHO South-East Asia Region.<sup>1</sup>

Dr Arun Thapa, Coordinator Immunization & Vaccine Development, WHO South-East Asia Region, presented the following regional priorities for 2013-2014:

- Increasing and sustaining high routine immunization coverage.
- Polio eradication and certification.
- Measles mortality reduction targets 2015.
- New and underutilized vaccine introduction.
- Ensuring vaccine safety and NRA strengthening.

The meeting brought together immunization stakeholders that included representatives of the ministries of health, national immunization programme managers, members of technical advisory groups and representatives from immunization partners and donor organizations.<sup>2</sup> Dr Ajay Khera, Deputy Commissioner, Child Health and Immunization, Ministry of Health and Family Welfare, India was nominated as the chairperson, and Dr Tajul Islam Abdul Bari, Programme Manager, Ministry of Health and Family Welfare, Bangladesh as co-chairperson. Dr TSR Peiris, Epidemiologist, Ministry of Healthcare and Nutrition, Sri Lanka was nominated as the rapporteur.

The participants discussed the strategies for increasing and sustaining routine immunization coverage and related areas such as surveillance, polio

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<sup>1</sup> The message from Dr Samlee Plianbangchang is available in annex 1.

<sup>2</sup> The list of participants and agenda are available in annexes 2 and 3, respectively.

eradication, measles mortality reduction, new and underutilized vaccines and vaccine safety. The summary of specific topics and recommendations are included in this report.

## 2. Intensifying routine immunization (IRI)

All countries in the Region have been implementing IRI programmes since the “call for action” at the high level ministerial meeting (HLMM) in August 2011 and the subsequent endorsement of 2012 as the “Year of Intensification of Routine Immunization in SEAR” at the Sixty-fourth session of the Regional Committee in September 2011. Despite the varied timing of the official launching of the IRI programmes in the countries, IRI activities were implemented according to detailed national plans. A summary of activities carried out by all countries is provided in Table 1. India, Indonesia and Timor-Leste presented a detailed account of their country experiences in implementing IRI during the meeting.

**Table 1:** Summary of 2012 IRI activities in the South-East Asia Region

Country	Activities undertaken
<b>Bangladesh</b>	<ul style="list-style-type: none"><li>• District and upazila reviews and planning meetings</li><li>• Listing drop outs and left outs</li><li>• Training of mid-level managers and field workers and supervisors</li><li>• Providing additional vaccine transportation cost for hard to reach areas</li><li>• Support for volunteers for the vacant posts</li></ul>
<b>Bhutan</b>	<ul style="list-style-type: none"><li>• District wise mapping of hard to reach populations/areas which are under served by the Immunization program.</li><li>• Catch-up campaign for all floating population after assessment with district subset of population.</li><li>• Monthly facility-wise immunization activity review by unit heads (BHU &amp; CHU in hospital) for coverage, drop out and any existing discrepancy of data for the activity</li><li>• Quarterly review by DHO</li></ul>

Country	Activities undertaken
	<ul style="list-style-type: none"> <li>• Half-yearly review by National Immunization Programme and Health Information Management System (HIMS) and send feed back</li> <li>• Motivate general population especially women for immunization through behavior change interventions, studies.</li> <li>• Constant and consistent dialogue with the stakeholders keeping them informed particularly Local Government bodies through advocacies</li> <li>• Strategic involvement of CSO/NGO/INGOs for acceleration in campaigns and support</li> </ul>
<b>Democratic People's Republic of Korea</b>	<ul style="list-style-type: none"> <li>• A launching event highlighting the importance of RI during the introduction of pentavalent vaccine in July 2012. The High-Level advocacy meeting for IRI was addressed by the Minister of Health during the launching event</li> </ul>
<b>India</b>	<ul style="list-style-type: none"> <li>• 2012–13 declared as 'Year of Intensification of Routine Immunization in India'</li> <li>• 239 low performing districts identified for focused attention</li> <li>• An Immunization Technical Support Unit (ITSU) was established</li> <li>• Reach the unreached through immunization weeks</li> <li>• Modernizing alternative vaccine delivery (AVD) mechanism and enhancing human resources to improve access to immunization services</li> <li>• Branding and demand generation of routine immunization services and media sensitization</li> <li>• Regular programme reviews and monitoring</li> <li>• Web enabled mother and child tracking system</li> <li>• Strengthen AEFI &amp; VPD surveillance</li> <li>• Utilizing lessons learnt from polio eradication initiative for RI</li> </ul>

Country	Activities undertaken
Indonesia	<ul style="list-style-type: none"> <li>• <b>IRI action plan developed; identified 36 districts in 11 provinces</b></li> <li>• Strengthening local monitoring</li> <li>• Validation of target population</li> <li>• Assist in reviewing and revising immunization practice in low performing areas</li> <li>• Advocating community leaders in low performing area</li> <li>• Sweeping and re-visiting those children who missed and dropped out during routine services in low performing areas</li> <li>• Reaching hard to reach areas integrating immunization activities with activities of MCH, nutrition and malaria</li> <li>• Ensuring data accountability for reporting and recording</li> <li>• Mobilizing resources including from partnership with private sector</li> <li>• Media Workshop on IRI; launching of IRI by Minister of Health               <ul style="list-style-type: none"> <li>– Participated by Deputy Minister, Governors, Bapeda, Head of PHO including WHO, UNICEF and other partners.</li> </ul> </li> <li>• Signing agreements in support of immunization with Governors during launching</li> <li>• Advocating on strengthening of routine immunization during follow up measles campaign in 17 provinces up to the village level</li> <li>• Conducting a MLM training for EPI manager from 36 selected districts.</li> <li>• Cirebon identified as the study district to measure implementation and achievement.</li> <li>• Immunization Meeting in May 2012 – Advocating IRI and distribution IRI-IEC material               <ul style="list-style-type: none"> <li>– Assessment to identify challenges in routine immunization programme</li> </ul> </li> </ul>

Country	Activities undertaken
	<ul style="list-style-type: none"> <li>– IRI implementation monitoring</li> <li>– SEARO-GOI monitoring of the study district and review of the IRI implementation</li> <li>– Initiate the involvement of Lion’s Club on IRI</li> <li>– 12 districts in East Java to receive additional support for their routine immunization along with diphtheria campaign being conducted in that region</li> <li>• Workshop on immunization focusing on IRI by Indonesian Doctors Association (IDA)</li> <li>• IRI evaluation meeting in December 2012</li> </ul>
<b>Maldives</b>	<ul style="list-style-type: none"> <li>• In-country evaluation of EPI</li> <li>• Supervision trips conducted in five atolls (F, Dh, AA, GA, Gdh - along with Minister of Health)</li> <li>• At least one health care provider from 73 health facilities have been trained on EPI &amp; VPD including new vaccine</li> <li>• AEFI guidelines developed (draft)</li> <li>• National Immunization guidelines developed (draft)</li> <li>• Trainer’s Manual developed (draft), communication strategy and pentavalent vaccine guidelines for parents, media and health care providers developed</li> <li>• Immunization schedule revised, stickers printed</li> <li>• All EPI forms and reports have been revised ( to strengthen data collection, record keeping and maintenance and recording)</li> <li>• Participated in the Global Immunization Week</li> </ul>
<b>Myanmar</b>	<ul style="list-style-type: none"> <li>• Data/reason analysis by RHC for identifying missed children, mapping of missed children</li> <li>• Policy reviews, use of open vial policy, flexible immunization schedules</li> <li>• Revised micro plans to identify, missed children</li> <li>• Advocacy with State Social welfare Ministers chaired by the Health Minister; new EPI logo, IEC materials</li> </ul>

Country	Activities undertaken
	<ul style="list-style-type: none"> <li>• MLM training</li> <li>• Provision of additional operation costs</li> </ul>
<b>Nepal</b>	<ul style="list-style-type: none"> <li>• Launching of IRI by minister of health, advocacy meeting with parliamentarians</li> <li>• Updating micro plans completed in 56 districts; building community ownership and utilization of local resources through appreciative inquiry approach started in two districts</li> <li>• Recruitment of vaccinators</li> <li>• Updating cold chain</li> </ul>
<b>Sri Lanka</b>	<ul style="list-style-type: none"> <li>• Development of National Immunization Policy</li> <li>• EPI coverage survey in Batticaloa (Eastern Province)</li> <li>• Review of EPI in districts in the northern province</li> <li>• In-service training of PHC workers in EPI on safe immunization procedures &amp; AEFI surveillance (North &amp; East)</li> <li>• Assessment of EVM (UNICEF)</li> <li>• Causality assessment workshop for AEFI</li> <li>• MLM training</li> </ul>
<b>Thailand</b>	<ul style="list-style-type: none"> <li>• Select districts in three Southern most provinces that have had diphtheria case reports in past four years</li> <li>• Assess the implementation of routine EPI immunization focusing on DPT vaccination</li> <li>• Organize a consultative meeting to review priorities</li> <li>• Develop training curriculum on data management and design communication materials</li> </ul>
<b>Timor-Leste</b>	<ul style="list-style-type: none"> <li>• Seeking active participation from District Management Team</li> <li>• Identify areas with low immunization coverage or inadequate services</li> <li>• Additional outreach activities with adequate funding and logistic support</li> <li>• Strengthen recording and reporting system</li> <li>• MLM training for 10 districts; all district managers will be trained on MLM by the end of 2012</li> </ul>

Country	Activities undertaken
	<ul style="list-style-type: none"> <li>• Identification of difficult to reach areas and additional outreach activities in two districts:               <ul style="list-style-type: none"> <li>– Aileu: 56 <i>aldeia</i> (hamlet)</li> <li>– Bobonaro: 72 <i>aldeia</i></li> </ul> </li> <li>• Supportive supervision</li> </ul>

In addition to reviewing of progress of IRI in the Region, several other related topics were discussed: aligning of comprehensive multi-year plans (cMYP) with national health plans, implementing the global vaccine action plans (GVAP) for achieving the decade of vaccines (DoV) goals, using opportunities provided by new and underutilized vaccine introduction (NUVI) for strengthening routine immunization, optimizing GAVI HSS funds for strengthening immunization delivery; and, responding to a diphtheria outbreak in Indonesia.

### **Recommendations**

- WHO-SEARO should work with Member States to develop and implement a tool (including use of IT) to closely monitor the implementation of IRI activities at all levels, of immunization services and strengthen surveillance systems to measure impact.
- Member States need to consider implementing the SAGE recommendation to phase the replacement of TT with Tetanus diphtheria (Td) at school entry/adolescents/adults (including pregnant women).
- WHO-SEARO should work with countries to develop and implement a user-friendly SOP to facilitate reaching un-reached children.
- Member States should consider using the regional VAP and national VAPs for decade of vaccines (DoV) as an opportunity to convert “2012 Year of Intensification of RI” to a multi-year intensification plan. GAVI HSS funds, where applicable, should be used to achieve the targeted immunization outcomes.

- Member States should quantify the political commitments, human resource, financial needs, communication, cold chain, and logistic requirements for strengthening routine immunization.
- Member States should align and integrate the strengthening of routine immunization with the eradication and elimination goals as well as with other communicable and noncommunicable disease programmes.

### **3. Polio eradication, certification, risk assessment and endgame strategy**

Significant progress has been made over the last 24 months toward polio eradication in the South-East Asia Region. The last case of wild poliovirus in the Region was reported from India on 13 January 2011; and, after more than a year without a wild poliovirus case India was removed from the list of endemic countries on 25 February 2012. Efforts for the next year and a half need to be focused on maintaining high population immunity and work towards polio-free certification and laboratory containment. There is an ambitious target for regional polio-free certification in February 2014. Sustaining the gains made towards polio eradication is only possible with a strong routine immunization programme that reaches all children. Countries need to achieve and maintain high population immunity in order to guarantee their polio-free status.

The Independent Monitoring Board (IMB) for Polio Eradication was established by the Director General, WHO in 2010 to monitor the progress of the global polio eradication efforts. They tasked the Centers for Disease Control and Prevention (CDC) in Atlanta, USA, to coordinate and work with the six WHO regional teams to standardize global risk assessment for the importation and circulation of wild poliovirus. Developing a risk mitigation plan is the programmatic product of the risk assessments and should help Member States allocate resources and coordinate activities that are evidence/data based.

The polio endgame strategy refers to the management of the post-eradication risks due to OPV. OPV can also cause in rare instances, paralytic polio and therefore, the continued use of OPV after the interruption of transmission of wild poliovirus is considered inconsistent

with eradication. Polio cases due to vaccine-associated paralytic poliomyelitis (VAPP) and outbreaks due to circulating vaccine-derived poliovirus (cVDPV) are the two main reasons for stopping the use of OPV for routine immunization in all countries. Previous endgame strategies have focused on sequential risk management: eradication, certification/containment, VDPV elimination and then post-OPV surveillance. Recent developments have allowed a major “rethinking”. The new diagnostics and global experience suggest that type 2 cVDPVs are currently the main “post-eradication” problem. Bivalent vaccine (bOPV) has proven to outperform trivalent (tOPV) for types 1 and 3 immunogenicity, which could be a viable option for replacing tOPV.

The new polio endgame strategy focuses on parallel risk management with a phased removal of Sabin viruses, beginning with type 2; the elimination of VDPV type 2 in parallel with eradication of the last wild polioviruses by switching from tOPV to bOPV for routine EPI/campaigns; and, early introduction of inactivated polio vaccine (IPV) at least in high risk areas for VDPV to provide type 2 protection.

Consequently, the new polio endgame strategy could accelerate eradication and reduce long-term risks. Depending on IPV pricing, the new endgame could be cost-neutral through certification. A number of work streams need to address unresolved questions and risks (policy, R&D, vaccine supply, surveillance/validation, operations, financing). The switch of polio vaccines will need consensus and coordination at country, regional and global levels in terms of acceptability, cost, supply, and formulation. Any change in national immunization schedules will need adequate planning and careful timing.

### ***Recommendations***

Member States should support the national certification committees (NCC) towards completing the required documentation for regional polio-free certification by February 2014.

- Member States should work towards adapting the regional risk assessment tool and implementing polio risk assessment at the sub-national levels to develop and implement a risk mitigation plan that addresses immunity gaps.

- WHO-SEARO should, in consultation with Member States, develop an appropriate and realistic regional plan towards implementing the polio endgame strategy that addresses oral and injectable vaccine options and containment requirements.

#### **4. Maternal and neonatal tetanus elimination (MNTE)**

Neonatal tetanus is a major cause of neonatal death globally. Data on maternal tetanus can be difficult to obtain and estimates suggest that up to 30 000 cases occur annually. Neonatal tetanus alone was responsible for an estimated 787 000 deaths in 1987; 200 000 in 2000 and 59 000 in 2008. By 2012, the South-East Asia Region achieved MNT elimination in almost all Member States (except a few states of India and Indonesia) by decreasing the incidence of MNT to <1 case/1000 live birth per year. The last country in the Region to validate MNT elimination was Timor-Leste earlier this year. Since tetanus is caused by endospores found in the environment, countries need to sustain their elimination status by maintaining high population immunity with TT immunization among women of child-bearing age, safe delivery practices, and school immunization programmes where applicable.

India and Indonesia are the two countries in the Region that need to complete the validation exercises. Indonesia has one area of the country to complete (phase IV). It should focus on pre-validation in 2012 and validation in 2013.

India has validated 15 states and union territories: Andhra Pradesh in 2003; Haryana, Karnataka, Kerala, Maharashtra, Tamil Nadu and West Bengal in 2006; Chandigarh, Goa, Lakshadweep, Pondicherry, Punjab, and Sikkim in 2007; and, Himachal Pradesh and Gujarat in 2008. For the remaining 20 states and union territories, MNTE validation is proposed for Delhi, Mizoram, Orissa and Uttarakhand in 2012. A meeting was organized by the Ministry of Health and Family Welfare, India, on 9 August 2012 to develop a validation plan for the remaining states and union territories. The meeting was attended by central government and state officials from the Ministry of Health, UNICEF, WHO and other partners. MNTE data from Delhi, Mizoram, Orissa and Uttarakhand was reviewed and suitable

timelines were discussed for the validation exercises using LQAS-CS methodology.

UNICEF provided guidance on the postvalidation activities that should be part of a comprehensive country-level immunization and surveillance plan. A set of guidelines (August 2012-UNICEF) was developed by UNICEF and hard copies will be shared with all countries when available.

### **Recommendation**

- Member States that are partly validated should prepare to validate their remaining areas.
- Member States that have completed the MNTE validation exercise should develop a plan of action for maintaining and sustaining their validation status.

## **5. Measles and rubella**

The South-East Asia Region established measles mortality reduction targets that focus on achieving interim goals by 2015, as approved by the Sixty-third World Health Assembly and endorsed by the Regional Committee. The progress towards the current targets are: (i) achievement of national MCV1 coverage of greater than 90% in seven countries by 2011 (Bangladesh, Bhutan, Democratic People's Republic of Korea, Maldives, Myanmar, Sri Lanka and Thailand); the regional coverage increased from 61% in 2000 to 79% in 2011, but stagnated at 79% for the last three years; three countries, Democratic People's Republic of Korea, Maldives and Sri Lanka have reported MCV1 coverage greater than 80% in all districts; (ii) MCV2 has been provided by all countries in the Region through catch-up immunization campaigns in nine countries and through routine second dose in two countries; achieved 95% coverage with measles SIAs reaching over 290 million children against a target of 305 million children; (iii) achieving annualized measles incidence of less than 5 per million population in three countries (Democratic People's Republic of Korea, Maldives and Sri Lanka), the regional annualized measles incidence was 69.9% in 2000 and 36.01% in 2011 per million population. The Region had achieved a 78% reduction in measles mortality (44% if India is included) between 2000 to 2010.

Based on their measles burden and vaccination strategies, countries have implemented various aspects of measles surveillance: tracking and investigating suspected measles outbreaks, laboratory confirmation of outbreaks and case-based surveillance at health facilities. After completion of measles catch-up campaigns, case-based measles surveillance was initiated in Bangladesh, Bhutan, Democratic People's Republic of Korea, Indonesia, Maldives, Myanmar, Nepal and Sri Lanka. Thailand started case-based surveillance without conducting a catch-up campaign. India is conducting measles outbreak surveillance and aggregating data for national level reporting. The rate of laboratory testing for suspected cases has improved over the past few years from 16% in 2009 to 34% in 2011. Bhutan and Democratic People's Republic of Korea have tested 100% of suspected measles cases. Bangladesh and Myanmar have tested >90% of the suspected measles cases. Thailand and Indonesia have tested only a small fraction of suspected measles cases.

Of the six WHO regions, the Americas, Europe, Eastern Mediterranean, Western Pacific, and African Regions have established measles elimination goals. The Americas and Europe regions have also established rubella elimination goals. The South-East Asia Region has a measles mortality reduction goal by 2015 and remains as the only region to set a target year for measles elimination.

WHO-SEARO, in consultation with Member States and partners, is developing a new measles and rubella strategic plan for 2013–2020. It will focus on five key strategies:

- high population immunity through vaccination with two doses of measles and rubella containing vaccines;
- effective surveillance, monitoring and evaluation;
- outbreak preparedness and response & case management;
- communication to build public confidence and demand for immunization;
- research and development.

### **Recommendations**

- Member States should review their measles mortality reduction action plan and accelerate the implementation of strategies to achieve the regional 2015 interim targets.
- The action plans should include detailed budgets that address strategies and specific assistance needed for increasing routine coverage of MCV1 while introducing MCV2; and, implementing case-based measles surveillance that includes surveillance for rubella and CRS.
- Member States that have programmes already achieving measles elimination targets should prepare costed-measles elimination and rubella/CRS control plans with a target year. Member States planning MR/measles campaigns should consider integration with other immunization/non-immunization programmes (i.e., OPV, insecticide-treated bed nets, etc.)

## **6. New and underutilized vaccine introduction (NUVI)**

Since the August 2011 EPI managers' meeting, the Region has achieved significant progress towards introducing new and underutilized vaccines. For example, by the beginning of 2012, all countries in the Region completed the introduction of hepatitis B. In December 2011, India started the introduction of pentavalent vaccine in two southern states. A post-introduction evaluation was conducted in July 2012 and six more states will be introducing pentavalent vaccine towards the end of 2012.

The Government of Myanmar has worked to develop a plan to start co-financing immunizations with particular focus on the introduction of Hib containing pentavalent vaccine in November 2012. In addition to Myanmar, other countries in the Region have already introduced pentavalent, or are in the process of introducing pentavalent vaccine are: Democratic People's Republic of Korea in June 2012, Timor-Leste in November 2012 and Maldives in December 2012.

Sri Lanka introduced MMR vaccine for one-year old children and Japanese encephalitis (JE) (SA 14-14-2) vaccine at nine months of age. Bangladesh introduced MR vaccine for nine-months old children in July 2012; and Nepal introduced rubella vaccine through a series of supplementary activities in 2012.

WHO-SEARO continues to support sentinel surveillance for invasive bacterial disease (IBD) and rotavirus surveillance sites in selected countries in the Region: Bangladesh, India, Indonesia, Myanmar Nepal and Sri Lanka. The Government of India (GoI) has started IBD sentinel surveillance at 11 sites to provide data for the impact evaluation of Hib containing pentavalent vaccine introduction. GoI has also revived their rotavirus sentinel surveillance network last year.

There are nine functioning national committees for immunization practices (NCIP) in the Region. Two consultative workshops were conducted in Bhutan and Myanmar since August 2011. WHO-SEARO will continue to take steps to help strengthen the capacity of the NCIPs.

### ***Recommendations***

- WHO-SEARO should assist Member States in reviewing the set of criteria used for making the decision to introduced NUV into national EPI schedules with sustainability being the main consideration.
- WHO-SEARO and Member States should conduct sero-surveys, burden of disease studies, and social research to guide an evidence-based approach to NUVI with a strong communication strategy and adequate forecasting of human resources, cold chain, and funding requirements.
- WHO-SEARO and Member States should explore alternative financing mechanisms to fund NUVI and consider options like pooled vaccine procurement systems.

## **7. Vaccine safety and quality**

All countries in the Region have introduced at least one new vaccine. Several countries are planning to introduce two or three additional new vaccines by 2015. Although these new vaccines have many advantages such as a single injection to protect against multiple diseases, they are not without regulatory challenges.

These new vaccines that are accessible to low- and middle-income countries are more complex in their formulation and production, than the traditional vaccines. Consequently, national regulatory authorities (NRAs) have need to increase their expertise. India, Indonesia and Thailand that produce WHO pre-qualified vaccines have moved forward to upgrading their NRAs (re-assessments were conducted in Indonesia in June 2012, Thailand in July 2012 and scheduled for India in December 2012).

Since 2008, training workshops on AEFI investigation, monitoring and causality assessment have been used to increase the number of regional facilitators. The workshops have become regional and national forums for sharing experiences, identifying solutions and developing strategies. Vaccine post-marketing safety surveillance requires NIP to monitor AEFIs and NRAs to ensure that vaccines meet regulatory standards.

In addition to sharing of expertise and information between countries, all countries must have a functioning NRA to regulate safety, quality and efficacy of vaccines. The number of regulatory functions necessary is determined by the national procurement policy for vaccines (imported through UNICEF, directly procured through national procurement mechanisms and/or locally production). Post-marketing vaccine safety surveillance and licensing are required NRA functions for all countries.

The national immunization programmes in most countries in the Region do not have replacement plans of aging cold chain equipment, to meet new vaccine packaging requirements. They are relying on donors to support buying new equipment and often do not take into consideration the vaccine and biological specifications for the distribution and storage of new vaccines. There is no incentive for industry to develop products that meet the requirement for storage of time- and temperature-sensitive pharmaceutical products (TTSP) and distribution in developing-country settings.

NRAs are responsible for safety, quality and efficacy oversight in all countries, which involves mandatory oversight of vaccine production that includes compliance with quality assurance and quality control (QA\QC) procedures before a vaccine is licensed. NRAs are also required to ensure that there is adequate infrastructure to store and distribute TTSP. Ultimately, this oversight role is enforced with private and public sector TTSP distributors.

NRAs play a key role in enforcing good distribution and storage practices for TTSP. Governments, EPI managers, donors and vaccine safety/quality/ efficacy stakeholders should ensure that NRAs are included in training workshops on vaccine management and cold chain logistics. Increased cooperation between NRA and the EPI programme for AEFIs, should be extended to vaccine and cold chain equipment procurement.

### ***Recommendation***

- Member States should ensure that they have functioning national AEFI committees, and should provide causality assessment training to the members of the committee as well as public and private sector immunization experts to strengthen vaccine safety surveillance.
- Member States, donors and vaccine safety stakeholders should provide financial support to their national regulatory authority to build their capacity to regulate safety, quality and efficacy of newly introduced vaccines that includes an adequate risk communication strategy.

## **8. Summary of group discussions**

The participants were divided into four groups and four specific topics identified for the group discussions.

Group I discussed the topic “intensification of routine immunization services in urban areas”. The implementation of intensifying routine immunization (IRI) in 2012 has helped countries in the SEA Region to improve immunization service delivery mechanisms in their national immunization programmes at different hierarchical levels. However, the coverage is predominantly low in urban cities including slum areas. The

populations live in slums, urban, peri-urban or high risk areas in these cities. There are still many gaps in urban immunization activities regarding targeting and listing of mobile and migrant children. There are many issues in the service provision by public, private sectors or NGOs related to infrastructure, human resources, and timing of immunization sessions for working mothers and the cost and affordability of services.

The participants in Group I were requested to identify current gaps in urban immunization activities and make recommendation for the national, sub-national and municipality city corporation/urban council levels to intensify urban immunization activities.

<b>Group I: Intensification of RI in urban settings</b>	
<b>Current gaps</b>	<b>Proposed solutions</b>
Inadequate coordination with local authorities; inadequate monitoring of immunization services	A joint coordination committee headed by urban authorities; Coordination and synergizing activities: reviews and joint planning meetings to be conducted in priority low performing municipalities. A mechanism to share good practices; models of well performing municipalities to be used. Establishing a mechanism to monitor immunization in urban areas
Health care areas not clearly demarcated; certain areas without health care workers	Developing adequate infrastructure and clearly demarcating the health areas in the urban settings/joint planning by national programme and municipalities/urban councils to fill the gaps with the support of development partners and providing adequate human resources; Mapping the available human resources for immunization and mobilization from local governments and NGOs; when there is lack of human resources, the department of health to take action for filling vacancies. Arranging regular training performance reviews for immunization staff;

<b>Group I: Intensification of RI in urban settings</b>	
<b>Current gaps</b>	<b>Proposed solutions</b>
Allocation of funds not adequate in certain situations and not optimally utilized in others	Allocating sufficient funds and developing a mechanism to monitor funds utilization
Difficulties in getting the correct denominator population and the target population for immunization	Estimating the denominator and target population for immunization using the best possible methods with the available information
No birth registration system in some countries and incomplete information on private sector immunization.	Planning a birth registration system and strategies to monitor private sector immunization services

Group II discussed the topic “increasing routine immunization (RI) coverage in hard – to – reach areas”. In all countries in the Region, there are hard to reach areas for achieving high immunization coverage. It could be due to difficult geographical terrains, the distance to immunization sessions, sociocultural barriers or other barriers. These could be overcome with proper planning and implementation of activities to improve access and close monitoring of the progress. Often, the low immunization coverage has been reported repeatedly in the same administrative areas. This is true not only for immunizations, but also for other components of primary health care services. Yet, we have not been able to correct it. Hence, it is important to share experiences among different country participants to learn from each other how different countries have been increasing and sustaining immunization coverage in these hard to reach areas.

The participants in Group II discussed the nature/type of hard-to-reach areas and identified priority issues related to increasing immunization coverage. They shared experiences to identify the best practices and recommend action points applicable for the local, sub national and national levels for planning/implementation.

<b>Group II: Increasing routine immunization in hard to reach areas</b>	
<b>Current gaps</b>	<b>Proposed solutions</b>
Lack of well-defined strategies to reach different hard to reach populations: geographic (difficult terrain, remote islands, mountain areas, isolated remote villages); disaster-prone areas; border populations, migrant populations, urban slums, construction sites, conflict areas	<p>Mapping of hard-to-reach populations using GPS; social studies to understand better approaches to overcome cultural barriers for immunization</p> <p>Detailed micro-plans to cover all communities; using lessons learnt from polio and measles SIAs;</p> <p>Encouraging and facilitating home visits by health and social workers; Integration with other health services; joint approaches to reach the target populations; Identifying all stakeholders; collaboration with local NGOs, community level groups;</p> <p>Better monitoring of surveillance data and mechanisms for early detection of outbreaks; Re-designing advocacy and communication Strategies;</p> <p>Linking with other ministries- education; defence; transport, cultural affairs;</p>
Inadequate resources including trained human resources, transport and other logistics; difficulties in maintaining supplies including vaccines and cold chain facilities	Developing adequate infrastructure; Joint planning by national programme and Local authorities to fill the gaps with the support of development partners and mapping the available human resources for immunization and mobilization from local authorities and NGOs; arranging regular training and performance reviews for immunization staff
Difficulties in getting the correct denominator population and the target population for immunization	Plan for tracking births with maternal and child health services

Group III discussed the topic “identifying gaps in monitoring and evaluation (M&E) of RI and mobilizing national resources for further improving M&E component”. The implementation of intensifying routine immunization in 2012 has helped countries in the SEA Region to improve monitoring and evaluation mechanisms of their national immunization programmes at different levels. However, there are still many gaps related to monitoring and evaluation that exist in varying degrees at different levels.

The participants of Group III discussed and identified the current gaps in monitoring and evaluation (M&E) in terms of monitoring coverage of RI in the SEA Region and made recommendations to improve monitoring of coverage of RI at national, sub-national and health unit/block/PHC/municipality levels.

<b>Group III: Monitoring &amp; evaluation of IRI</b>	
<b>Current gaps</b>	<b>Proposed solutions</b>
Difficulties in getting the correct denominator population and the target population for immunization	Partnering with other ministries/agencies for developing M&E tools; Establishing stronger birth registration systems including relevant legislation;
Registration, record-keeping and reporting is weak at immunization session level	Use of IT based reporting systems; Regular sub-national data quality audits; Regular refresher training for data management; Regular local area monitoring and coverage evaluations in selected areas.

Group IV discussed the topic “gaps in relation to advocacy and communication for intensification of routine immunization”.

<b>Group IV: Advocacy and communication</b>	
<b>Current gaps</b>	<b>Proposed solutions</b>
Most countries have not conducted social studies targeting hard to reach populations and urban slums.	Establishing clear processes and timeline to develop advocacy and communication strategies including steps for research, designing, implementation, monitoring and evaluation;
Even available evidence is not used for getting attention of decision-makers.	Collating, reviewing and utilizing available evidence for advocacy and social mobilization;
Local health staff have not been trained to expand the local level activities to schools, NGOs, community leaders, parents; awareness and information gaps and lack of skills exists; risk communication skills are lacking.	Including social mobilization and communication in curricula of training for health workers including sessions for skills development;
Certain groups of working parents(manual labourers) are unable to bring children for immunization, as the timing is inconvenient.	Discussions at local levels for facilitating working parents to attend immunization sessions;

## 9. Partners' meeting

A partners' session was organized at the end of the regional review meeting. The session's objective was to provide a forum where technical agencies and development partners could discuss their roles to support countries to implement recommendations of the SEAR EPI managers' meeting and overcome challenges highlighted during the same. The session provided opportunities for all partners to openly and informally discuss issues affecting progress while clearly identifying respective roles and comparative advantages in supporting countries to overcome challenges – financial, technical or a lack of capacity.

The Immunization and Vaccines Development (IVD), WHO-SEARO team, WHO-SEARO, presented the funding situation related to regional priorities, funding gaps and human resource requirements and shortfalls. The surveillance network was also presented as a major priority and a cause for concern. Funding for polio eradication activities on which the network is highly dependant, is forecast to diminish sharply in the coming years as the Region approaches regional polio certification. Experiences in WHO's Western Pacific Region (WPR) were highlighted to show the decline in funding following their regional certification.

Open discussion with contributions from all partners followed the presentations which are highlighted below:

- The need to better forecast funding requirements for short- to medium-term linking to priorities was suggested for approaching donors and development partners to consider funding the programme.
  - Both UNICEF and WHO should consolidate their projections and needs for this exercise.
  - A more detailed analysis should be carried out on how WPR was affected and how they are managing with the decreased funding.
- While it was noted that donors have significantly increased their funding to support specific interventions and initiatives, it was advised that there is still a strong need to show integration or linkages to other health-related issues when approaching donors and framing activities for funding.
- On the subject of routine immunization (RI), partners agreed that there is a need for a global push to give RI greater visibility and higher priority on their agendas. Various partners also commended the South-East Asia Region's initiative to declare 2012 as the Year of Intensification for RI in the Region.
- In their presentations, countries showed highlighted progress on implementation of intensification activities demonstrating the level of commitment from governments in the Region.
- By organizing a ministerial meeting in August 2011 and passing a Regional Committee resolution, WHO was able to garner

political support for intensification of routine immunization (IRI) in the Region. Still, a clear lack of development partner investment called for greater consensus through a consultative process involving all stakeholders from the beginning of the planning stages.

- The limited number of partners participating in this session was noted with concern, despite the fact that all were invited.
- Feedback and continual information sharing with stakeholders was highlighted as an important way of keeping them engaged.

### ***Recommendations***

- As part of improving coordination and information sharing it was agreed that a partners' session should be organized at the next EPI managers meeting as well as for every meeting in the future.
- UNICEF should present their funding situation and priorities as done by WHO at the next partners' session in 2013. It was noted that both organizations should coordinate the session jointly in order to provide a complete picture to all partners.
- Depending on priorities and progress on intensification of immunization in the Region, countries should be encouraged to present their perspective during the partners' session as an example and reflection of impact in the countries.

## **Annex 1**

### **Message from Dr Samlee Plianbangchang, Regional Director, WHO South-East Asia Region**

In 2011 when we first declared 2012 as the year of intensification, estimated coverage of routine immunization in our Region was 73%, relatively low compared with other WHO Regions. We noted wide disparities between countries as well as within countries themselves, with varying rates among states, provinces and districts. The challenge we agreed last year was to strive to achieve a more uniform coverage of routine immunization for children in the Region and within countries. In order to accelerate and achieve targets set for elimination and eradication of vaccine-preventable diseases such as polio and measles, we will need to increase and sustain coverage of routine immunization in areas of low coverage.

As we started 2012, evidence in progress allowed us to cautiously celebrate a milestone as we saw India taken off the polio endemic list of countries – placing the Region on track to be certified polio-free by early 2014. Estimated coverage of routine immunization in the South-East Asia Region also increased to 77%. In 2011, 40.7 million children in India and 11.5 million children in Indonesia were immunized against measles through phased campaigns. With India targeting over 40 million children in the last 12 months, and over 76 million in the next 12, the Region is moving towards setting a measles elimination goal soon. These efforts have contributed significantly to achieving a 74% reduction in global measles-related deaths between 2000 and 2010 and will help reach the Millennium Development Goal 4 target of reducing child deaths by 2015.

During the earlier part of this year, Member States finalized and started to implement activities of their plans of action (PoA) for intensifying routine immunization based on risk assessments and mapping low performing, high-risk areas of priority.

Following the endorsement of the World Health Assembly, WHO was mandated to lead the efforts to coordinate partners and support Regions and countries to adapt the Global Vaccine Action Plan (GVAP) into national action plans as the roadmap to prevent millions of deaths through more equitable access to vaccines for people in all communities across the world.

In September, Member States reported to the Regional Committee on how they are progressing in implementing their plans of action and what some of their challenges have been to implement the same.

Reviewing the agenda and programme for the next few days, I hope the meetings and discussions will bear fruit and find solutions to some of the problems which have continued to hinder our progress. Only with collective efforts and partnering, will we be able to overcome the remaining barriers to increase immunization coverage in the Region.

I would like to highlight some of the subjects which the Regional Director hoped would be discussed in depth and for which actions will be taken to move these forward in the coming months and years.

- **Polio Eradication and Regional Certification process** – Sustaining sensitive and well performing surveillance systems will be the test for our region and we must step up to the challenge if we will succeed. Continued work on documentations and validation of surveillance systems, laboratory networks, data and all requirements to submit in time for regional certification commission by early 2014.
- **2012 Intensification of Routine Immunization** – implementation and progress on Plans of Action need to be analyzed. Lessons learned from first year of implementation should guide in developing corrective action to adjust plans and activities for next year when we will look more into coverage data change in targeted districts of each country plan.
- **Measles Elimination consultation process** – Feasibility studies and strategies for ensuring we can establish a regional measles elimination goal by 2013 needs to be thoroughly discussed and a clear timeline and action plan endorsed by all countries.

In the spirit of partnership, I wish you great success and reaffirm WHO's commitment and resources to ensure we continue progress in what is consider as one of the highest priorities in our region.

Once again, on behalf of the Regional Director, I thank you for your attention and continued commitment."

## Annex 2

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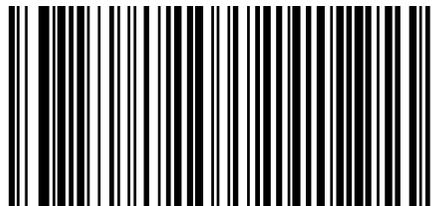
The Regional Review Meeting on Immunization is an important forum to share experiences, agree on common policies and discuss strategies to improve immunization services in the 11 Member States of the WHO South-East Asia Region. It also provides an opportunity for programme managers to interact and discuss common issues with donors and other immunization partners. This brief report provides highlights, conclusions and recommendations from the regional review meeting on immunization that was held in Bangkok, Thailand, from 9 to 12 October 2012.



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## **Annex 3**

# **Agenda**

Registration

Opening session

Technical Discussions:

- Strengthening Routine Immunization
- Polio eradication
- Measles mortality reduction and rubella control
- New and underutilized vaccine introduction (NUVI)
- Monitoring EPI
- Vaccine safety and quality
- Summary of Group Discussion
- Partners session

Closing session