Asia Pacific Regional Regulatory Partnership for Malaria Elimination

Inaugural planning meeting, Bangkok, 31 March – 1 April 2016

Meeting Report
Table of Contents

Acknowledgment .................................................................................................................. 3
List of abbreviations ............................................................................................................. 4
Summary and recommendations ............................................................................................. 5
Key messages from the presentations .................................................................................... 11
Small Group Discussion: Day 1 (March 31) Session 1 .......................................................... 15
Small Group Discussion: Day 2 (April 1) Morning Session .................................................. 17
Concluding Remarks and Next Steps ................................................................................. 20
Appendix 1 ............................................................................................................................. 21
Appendix 2 ............................................................................................................................. 26
Appendix 3 ............................................................................................................................. 37
Appendix 4 ............................................................................................................................. 42
Appendix 5 ............................................................................................................................. 45
Appendix 6 ............................................................................................................................. 46
Appendix: 7 .............................................................................................................................. 47
Appendix 8 ............................................................................................................................. 48
Acknowledgment

This meeting was co-hosted by Asia Pacific Leaders Malaria Alliance, Asian Development Bank (Centre of Regulatory Excellence, Singapore), Australian Department of Health - Therapeutic Goods Administration and WHO Prequalification Program. The organizers are also particularly grateful to the donors Gates Foundation, DFAT and World Bank and the product development partners Medicines for Malaria Venture (MMV) and PATH.
## List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ADB</td>
<td>Asian Development Bank</td>
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<tr>
<td>APLMA</td>
<td>Asia Pacific Leaders Malaria Alliance</td>
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<td>ASEAN</td>
<td>Association of Southeast Asian Nations</td>
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<td>CIRS</td>
<td>Centre for Innovation in Regulatory Science</td>
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<td>CoRE</td>
<td>Centre of Regional Excellence</td>
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<td>DFAT</td>
<td>Australian Department of Foreign Affairs and Trade</td>
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<td>FDA</td>
<td>Food and Drugs Administration</td>
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<td>G6PD</td>
<td>Glucose-6-phosphate dehydrogenase</td>
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<td>MMV</td>
<td>Medicines for Malaria Venture</td>
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<td>NMRA</td>
<td>National Medicine Regulatory Authority</td>
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<td>PPWG</td>
<td>Pharmaceutical Product Working Group</td>
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<td>RDT</td>
<td>Rapid Diagnostic Test</td>
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<td>RRPME</td>
<td>Regional Regulatory Partnership for Malaria Elimination</td>
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<tr>
<td>SEARO</td>
<td>Southeast Asian Regional Office</td>
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<td>TGA</td>
<td>Therapeutic Goods Administration</td>
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<td>WHO HQ</td>
<td>World Health Organization Head Quarters</td>
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<td>WPRO</td>
<td>Western Pacific Regional Office</td>
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At the 10th East Asia Summit in November 2015, Regional Leaders endorsed the APLMA Leaders Malaria Elimination Roadmap. Achieving rapid, universal access to new malaria medicines and diagnostic tests is critical to tackle the challenges and gaps for malaria elimination in the region. These challenges include addressing increase in resistance to artemisinin-based medicines and expediting the review and approval of new antimalarial drugs and diagnostic tools. Diagnostics such as simple point-of-care rapid diagnostic tests to determine the glucose-6-phosphate dehydrogenase (G6PD) status of individuals is needed in order to enable safe treatment of P. vivax malaria by established 8-aminoquinoline antimalarials, such as primaquine and tafenoquine (which is still under development).

It is recognised that access by communities to new antimalarial commodities requires more than regulatory approval alone. For wider use, the commodities may need to be included in a national essential medicine list, be integrated into a national malaria program, and be included on the procurement list. However, regulatory approval is a necessary and critical first step.

Delays in obtaining regulatory approval for critical medicines and diagnostic tests have been one of the biggest barriers to access. In order to be able to achieve the goal of malaria elimination in the region by 2030, in particular in the countries most affected by deaths and loss of workforce productivity through malaria infection, it will be critical to develop ways to permit faster review and approval of new antimalarial medicines and diagnostic tools, without compromising on legal requirements and appropriate scrutiny of the products.

**Regional Regulatory Partnership for Malaria Elimination:**

To address these regulatory barriers to access, Asia Pacific Leaders Malaria Alliance, Asian Development Bank, Australian Department of Health - Therapeutic Goods Administration and the WHO Prequalification Program, jointly co-hosted the inaugural planning meeting in Bangkok to explore the establishment of a Regional Regulatory Partnership for Malaria Elimination.

The meeting was co-chaired by Therapeutic Goods Administration (Australia), and the Food and Drug Administration (Thailand), with the objective to support rapid access to new antimalarial treatments and diagnostic tests by expediting the assessment of breakthrough products, with an initial focus on P. vivax malaria.

To achieve this objective, a range of priorities and actions were agreed at the Regional Regulatory Partnership for Malaria Elimination meeting. Implementation of these recommendations would have a broader impact in strengthening access to quality medicines in the Asia-Pacific.

The following recommendations have been developed based on extensive discussions carried on during the two days among various regulators and technical agencies from the Asia Pacific region.
<table>
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<tr>
<th>GOAL</th>
<th>Establish a Regional Regulatory Partnership for Malaria Elimination</th>
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<tr>
<td>STRATEGIES</td>
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<tr>
<td>2 Build on existing foundation</td>
<td>3 Explore various models</td>
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<tr>
<td>6 Focus Anti Malarial commodities</td>
<td>7 Prioritize key products</td>
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<tr>
<td>10 Establish Guidelines</td>
<td>11 Develop Work Plan</td>
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**Focus Areas**
**Overall Goal:**

1. Establish a regional regulatory partnership to improve the efficiency and quality of the regulatory review for new antimalarial treatments and diagnostic tests

The regional regulatory partnership is a collaboration between Asia Pacific Regulators, APLMA, the Asian Development Bank, WHO as well as the developers of new products such as MMV and PATH. The partnership will also include regional capacity building initiatives such as those supported by CORE and the Bill and Melinda Gates Foundation. This initiative is a voluntary partnership and the stakeholders may choose to “opt in”.

**Proposed strategies:**

2. Build on the ongoing and foundational work of country-specific regulatory processes, and bilateral and multilateral agreements between regulators:

   a) Explore joint assessments for fast-tracking registration processes, which already exist in some of the countries of the region for various malaria commodities
   b) Establish confidentiality agreements between regulators so as to enable sharing of assessment reports
   c) Ensure to carry out collaborative evaluation will encompass national differences such as organisational arrangements for regulation of medicines and diagnostic tests; requirements for risk management plans etc.

3. Explore a range of collaborating models for regulatory review to provide flexibility for all AP countries who are members of different international political alliances (e.g. ASEAN, South Asia, Pacific)

   a) The final regulatory framework finalized by each country will be treated as an independent (sovereign) decision which will be respected even in case it differs from an overall consensus
   b) The involvement in regulatory collaborations will be on a voluntary (“opt in”) basis

4. Encourage collaboration of national regulators with national malaria programs

   a) Inform the senior most officials from regulatory agencies and public health authorities/national malaria control programs on the work plan
   b) Establish key performance indicators for the partnership which will be linked with the work plan and the APLMA roadmap
5. Establish capacity building as a central theme of the partnership
   a) The primary approach for collaboration will be through “learning by doing” rather than merely attending training courses

Focus Areas:

6. Focus on malaria, but ensure wider impacts for other public health priorities as well
   1. Emphasise on streamlining and coordinating regulatory approval processes for medicines for other public health priorities as well such as tuberculosis

7. Conduct a portfolio analysis to identify initial product priorities for regulatory cooperation
   a) Potential priorities can include development of novel products targeting elimination of malaria such medicines under Phase III trial such as tafenoquine which are being developed as a single dose cure for *P. vivax* and rapid diagnostic tests which can manage risk of drug-induced haemolysis by screening individuals with severe G6P dehydrogenase deficiency

   b) Subsequently, the partnership can focus on new Artemisinin Combination Therapy fixed dose combinations (and new active ingredients) aiming to improve patient compliance and tackle resistance, expediting the market authorization of relevant WHO-prequalified essential medicines and diagnostics and rapid diagnostic tests for malaria diagnosis aiming at differentiation of the various Plasmodium species

8. Catalyse regulatory support to ensure evaluation of in-vitro RDTs’ are carried out seamlessly and assessed at internationally agreed standards for performance and stability
   a) Develop capacity building programs to establish local mechanisms for assessing diagnostics and their quality management by building on WHO prequalification of in vitro diagnostics

   b) Strengthen the involvement of IVD (medical device) regulators in subsequent meetings of the partnership, recognising that in some countries device and medicine regulation is carried out by different agencies of government

   c) Leverage developments of regional / international medical device regulatory initiatives such as IMDRF
9. Encourage regulators to collaborate on promoting product quality and not focus on regulatory reviews only

   a) Ensure the procurement of products of appropriate quality by development and implementing of high quality standards
   b) Foster closer working relationships among malaria commodity procurement programs and national regulators
   c) Develop mechanisms for collaboration between regulators experienced in GMP inspections of local manufacturers

Next Steps:

10. Jointly develop guiding principles for collaboration among Asia Pacific regulators, with the potential of a regional or sub regional regulatory review. Key elements of the collaboration would include:

   a) A complete and comprehensive review can be carried out by the NMRA’s
   b) Countries within the ASEAN PPWG framework can possibly undertake a joint review based on ASEAN polices and PPWG protocols
   c) An initial review can be carried out by a regional stringent regulator, such as the TGA with the support of external international experts such as regional Asian authorities and WHO
   d) Agree on a pilot project involving a small group of countries may be a preferable for an initial approach to prepare for the joint assessment
   e) Conduct a pre-review meeting of participating regulators can be arranged to build the framework of such reviews

11. Develop a detailed work plan jointly with members, supported by the APLMA Secretariat, after further consultation with ASEAN PPWG members and other Asia-Pacific regulators and public health departments

   a) Identify a focal point for coordination of activities related to registration at a regional level can be considered
   b) Establish mechanisms to involve regulators from malaria-affected countries in the Asia-Pacific region who were unable to attend the inaugural meeting
   c) Identify specific priorities for intervention, with new products to address \( P. vivax \) malaria proposed for first consideration
   d) Outline the initial commitments for joint regulatory assessment of new products and for regulatory strengthening
   e) Enumerate work plan in detail to integrate existing national and regional initiatives
f) Clarify the type of support required from regulators from individual countries involved in collaborations and how the external partners such as WHO, CORE or other technical organisations could support them

g) Explore requirements and potential sources of funding for implementation of these actions

12. Organize biannual meetings for the leaders of the partnership to foster bilateral and multilateral collaborations between Stringent Regulatory Authorities, National Regulatory Authorities and partners

a) These meetings would be used to provide the Regional Regulatory Partnership with appropriate planning, oversight and accountability
b) Stakeholders will use these meetings to:
   o Develop and implement models for regulatory collaboration
   o Review progress, discuss challenges, set priority actions and announce new commitments
   o Gather information and report back regularly on progress to Asia-Pacific leaders
Key messages from the presentations

1. Welcome Remarks:

Speaker: Ben Rolfe, Asia Pacific Leaders Malaria Alliance (APLMA)

Key Messages:

- Emphasized the objectives of APLMA along with the new roadmap
- Introduced the dashboard as a critical reporting tool

Speaker: Boonchai Somboonsook, Thai FDA

Key Messages:

- Declared the meeting open
- Emphasized on the importance of improving access, product and process innovation
- Highlighted the need to identify gaps to raise standards of capacity in the region in order to eliminate malaria by 2030

Speaker: John Skerritt, Therapeutic Goods of Australia

Key Messages:

- Focused on the development of a well-developed action plan in collaboration with all the regulatory and technical agencies

Speaker: Raj Long, Bill and Melinda Gates Foundation

Key Messages:

- Suggested that we apply principles which lead to improving access to quality medicines for malaria with a focus on vivax, to other disease profiles
- Focused on the need to develop a set of principles that will improve access without compromising sovereignty, safety and efficacy
- Requested to adapt from the principles and framework of malaria elimination to battle other diseases like dengue or other disease areas requiring different approaches
- Emphasized that this should not be treated as “business-as-usual” and create a clear action plan around it

Speaker: Douglas Ball, Asian Development Bank

Key Messages:

- Focused on ADB’s role in strengthening regulatory collaborations in the health sector
• Enumerated ADB’s focus on strengthening national health systems and fostering cross-border collaboration

2. Overview of RRP concept and meeting objectives:

Speaker: Prof. Paul Lalvani, Senior Technical Advisor, Access to Quality Medicines

Key Messages:

• Introduced the participants
• Outlined the objectives of the conference, the approach and suggested endpoints
• Illustrated the key components of partnership comprising of the Malaria Elimination Roadmap, anti-malarial commodities and regulatory strategies

3. Overview of malaria in Asia Pacific:

Speaker: Chansuda Wongsrichanalai, WHO Malaria Specialist

Key Messages:

• Showed the prevalence, mapping and trend of resurgence, standard treatment guidelines and development of artemisinin resistance of P. vivax
• Elaborated on the purpose and objectives of Emergency Response to Artemisinin Resistance in the GMS (ERAR)


Speaker: John Skerritt, Deputy Secretary, Department of Health, Australia

Objectives: Lay out the objectives of the APLMA Roadmap and the challenges that lay ahead.

Key Messages:

• Provided the background and findings of the Regulators’ Working Group on malaria report which was established in 2014 during the group meeting on May 14-15, 2014 in Bangkok
• Highlighted the key areas along with the recommendations and the action points of the report
• Informed that the APLMA malaria elimination roadmap was endorsed during the 10th East Asia Summit
• Laid out the priorities of the roadmap wherein the importance of inter sectoral integration was stressed upon

5. Overview of case studies and models on joint regulatory collaboration:

Speaker: Samvel Azatyan, Group Lead, Technical Assistance and Laboratory Services
Objective: Regulatory collaboration: regional efforts to improve access to medicines

Key Messages:

• Focused on WHO’s strategy to support the national regulatory authorities for medical products, their present status, and the challenges faced by them along with listing out the benefits of regulatory harmonization
• Recognized the major impediments to improving access to quality medicines such as the limited capacity of NMRAs’ thereby resulting into unacceptable delays. Laid out WHO’s holistic approach to assist NMRAs’ towards improving insufficient regulatory capacity and harmonizing technical requirements
• Presented a case study of regulatory harmonization of the REC based approach in Africa and its outcomes and share the findings of WHO’s support in implementation of ASEAN harmonized requirements for drug registration (SIAHR)
• Enumerated the success factors and lessons learnt during their journey and lay out the importance of goal setting, prioritization and strategy development supported by the pillars of good governance

Speaker: Milan Smid, Group Lead, Technical Assistance and Laboratory Services

Objective: Collaboration in registration supported by WHO PQ

Key Messages:

• Focused on the role of the Prequalification team in regulatory collaboration, its concept and principles
• Outlined the principles of WHO- PQT collaborative and enumerate the registration procedure
• Shared a few examples of WHO collaborations highlighting the scope and effectiveness of regulatory collaborations

6. Centre of Regulatory Excellence (CoRE) role in regional capacity development and collaborative partnerships:

Speaker: John Lim, Executive Director, CoRE Singapore

Objective: Enumerate the role of CoRE

Key Messages:

• Shared the mission of CoRE which seeks to provide a neutral platform to support networking and building regulatory leadership, both in industry and with national authorities
• Listed out the purpose and strategic goals of CoRE which centres around patient benefits through strengthening regulatory leadership, policy and systems innovation and networking
• Provided an overview of the education programmes with supporting examples and the ADB project in order to better understand the needs of the regulatory landscape prevailing in the region
• Shared that CoRE is developing a curriculum to build capacity, and doing research to support its assessment and development. It is also meeting with NMRAs and industry to develop the curriculum to meet their needs and desired competencies
• Informed about the landscape analysis of NMRA capacity in ASEAN countries undertaken by CoRE

7. Focus on vivax malaria:

Speaker: Chansuda Wongsrichanalai, WHO Malaria Specialist

Objective: Background and challenges and importance of adding \textit{P. vivax} as a priority

Key messages:

• Highlighted the background, overall prevalence, incidence, challenges faced, diagnosis and the radical cure for \textit{P. vivax}
• Enlisted the possible solutions and scaling up the access to this cure

Speaker: Stephan Duparc, Chief Medical Officer, MMV and Nick Luter, Head of Market Access, PATH

Objective: \textit{P. vivax} pipeline and status of development of
  o Medicines for \textit{P. vivax}
  o Diagnostics for \textit{P. vivax} related tests (G6PD)

Key messages:

• Focused on registration of the anti-malarial drugs for the \textit{P. vivax} radical cure.
• Enlisted various product development plans which are in the pipeline and their effect on affected populations
• Mapped out the G6PD landscape, its spread and WHO recommendations
Small Group Discussion: Day 1 (March 31) Session 1

Objective: Explore Asia-Pacific focused regulatory strategies to promote access to high priority *P. vivax* antimalarial medicines and diagnostics (“The What”)

Participants: The participants were divided into two groups headed by the following:

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<tr>
<th>Group 1</th>
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<tr>
<td>Chairs:</td>
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<tr>
<td>Dr Boonchai Somboonsook, Secretary General, Head of the Thailand FDA</td>
<td>Dato’ Eisah Binti A Rahman, Senior Director, Drugs Control Authority, Ministry of Health, Malaysia</td>
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<td>Dr Michael Wiseman, Australia TGA</td>
<td>Dr Milan Smid, WHO Pre-Qualification Programme</td>
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<td>Participants:</td>
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<tr>
<td>John Skerritt, Australia TGA</td>
<td>Harry Rothenfluh, Australia TGA</td>
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<td>Thol Sea, Cambodia</td>
<td>Sokhem Hiem, Cambodia</td>
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<td>Lamphone Syhakhang, Lao PDR</td>
<td>Phouthavanh Inlorkham, Lao PDR</td>
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<td>Tin Myo Khing, Myanmar</td>
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<td>Thazin Yi Hlaing, Myanmar</td>
<td>Tharnkamol Chanprapaph, Thailand</td>
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<td>Supat Phongsri, Thailand</td>
<td>Rungrawee Tipmontree, Thailand</td>
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<tr>
<td>Do Minh Hung, Viet Nam</td>
<td>Nguyen Thanh Huong, Viet Nam</td>
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Key points of discussion included:

1. What types of regulatory strategies could be deployed in accelerating market authorization at regional level?

   a) Greater information and data sharing, joint review of product dossiers, reliance on other agencies, mutual/reference recognition?
b) Greater and earlier engagement with product development organizations, while maintaining sufficient “distance”

c) What regulatory strategies can help to accelerate and possibly simultaneously synchronize national decisions that also address regional needs

d) What are countries already doing in order to accelerate access to needed health technologies

e) What types of challenges have the regulators experienced and how have these been addressed

2. Could some of these strategies be applied to specific product categories?

a) Could these strategies be applied for high priority public health products? Malaria products? Has this been tried previously? For which products and under what conditions?

b) Could these strategies be applied for medicines and diagnostics? Are there examples of accelerated review of diagnostics in Asia Pacific? Other parts of the world?

c) What would be the process for a ‘test-case’ or ‘pilot’ for conducting accelerated review of medicines and diagnostics? Could this be conducted together? How would it work?

3. What type of support would the countries need to pilot or scale some of these strategies?

a) WHO, academic organizations, technical organizations, policy and advocacy organizations can all provide support. What type of support would be needed?
Objective: Approaches to promote collaboration between Asia-Pacific regulators, with support from WHO, technical organizations, donors and other key stakeholders (“The How”)

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<td>Jeffery Smith, APLMA</td>
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Key points of discussion included:

1. **What should be the guiding principles for collaboration among Asia Pacific regulators for the potential of a regional or sub-regional regulatory review?**

   a) Are there any existing guiding principles for collaboration among Asia Pacific regulators? Is this regional? Sub-regional?

   b) Could national principles be applied regionally or sub-regionally? How can they be applied?

2. **What types of framework should be considered for promoting collaborations?**

   a) Are there economic/health/regulatory frameworks that can be leveraged?
b) What are the main components of the established regulatory framework in Asia Pacific?
c) Are there any innovative global frameworks which could be applied in the region?
d) Is it possible to leverage existing frameworks of Economic Communities (APEC, SAARC), as a platform to promote collaboration?

3. More specifically, what type of approach should be explored?

a) Could a smaller subgroup within the Asia Pacific region establish some type of collaboration?

b) Given the different levels of economic development of participating countries, could “twinning” be explored—stronger regulator with a developing regulator?

c) Should a pilot be tried? Between a smaller number of countries? Or specific antimalarial products?

4. What type of support would your country need to promote collaboration among other regulators?

An approach for Joint Assessments

Applicant submits dossier (Post WHO PQ or SRA review)

NMRA 1 → NMRA 2 → NMRA 3 → NMRA 4 → NMRA 5 → NMRA 6

Assessors gather and issue joint report

WHO

NMRA 1 → NMRA 2 → NMRA 3 → NMRA 4 → NMRA 5 → NMRA 6

DECISION

Day 0

Day 60

Day 65

Day 90

a) How can WHO or other technical organizations support national regulators in collaborative regional/sub-regional approach?

An approach was presented and discussed by both groups and subsequently in the primary session with all participants. The approach is similar to WHO’s collaborative review model, which is also being explored by PPWG for the ASEAN countries.

The chart illustrates the approach by showing various stakeholders to be engaged and the projected timeline. The approach leverages review by WHO with SRAs’ then brings together the NMRA’s for joint review after each country has conducted their own review. The
NMRAs’ then return to their respective offices to make an independent decision regarding the registration thus ensuring sovereignty in their final decision.
Concluding Remarks and Next Steps

1. Senior regulatory officials from EAS and Pacific countries have agreed to the establishment of an Asia Pacific regional regulatory partnership to develop ways to permit faster approval of new antimalarial medicines and diagnostic tools. The partnership is a critical step in implementing the APLMA Roadmap for Malaria Elimination in the Asia Pacific by 2030, as agreed to by EAS Leaders in 2015.

2. Delays in obtaining regulatory approval for critical medicines and diagnostic tests are some of the biggest barriers to achieving regional malaria elimination by 2030. Without regulatory coordination and rapid access to new technologies, drug-resistant malaria could spread beyond the Asia Pacific and result in globally untreatable malaria.

3. For the partnership to succeed, regulators of the region with support from WHO need to help navigate the complexity of regulatory models and existing partnerships in the region, and respect the sovereign rights of countries to make the final decision on which medicines and diagnostics should be approved. It will be critical for the partnership to work within existing domestic and regional regulatory and legislative frameworks to ensure country buy-in.

4. As presented earlier in the report, the delegates agreed to 12 priorities and actions, including meeting every six months to foster bilateral and multilateral collaborations. APLMA to help achieve the overall goal of malaria elimination.

5. During this meeting several regulators have already indicated their interest in collaborating with others for conducting joint reviews and building their capacities in regulatory sciences. For example, Lao-Thailand, Myanmar-Malaysia, Cambodia-Australia, Cambodia-Indonesia, all indicated their interests in working together.

6. Prior to the next meeting, a detailed and costed action plan needs to be developed and shared with the stakeholders. The action plan will include short-term and longer-term outputs (6 months-3 years).

The next meeting is planned for the fourth quarter of 2016.
Appendix 1

Participant List:

**Australia**

Dr John Skerritt  
Deputy Secretary, Department of Health  
National Manager  
Therapeutic Goods Administration (TGA)

Mr Michael Wiseman  
Director, Transparency and Advisory Management Section  
Prescription Medicines Authorisation Branch  
Therapeutic Goods Administration (TGA), Department of Health

Mr Harald “Harry” Rothenfluh  
Assistant Secretary, Manufacturing Quality Branch  
Therapeutic Goods Administration, Department of Health

Ms Bronwyn Duce  
Senior Health Policy Analyst – Malaria  
Health and Environmental Safeguards Branch  
Assistant Director, Development Policy Division  
Department of Foreign Affairs and Trade

**Cambodia**

Dr Thol Sea  
Chief, Essential Drug Bureau  
Department of Drugs and Food  
Ministry of Health

Mr Sokhem Hiem  
Chief, Drug Registration Bureau  
Department of Drugs and Food  
Ministry of Health

**Lao PDR**

Dr Lamphone Syhakhang  
Deputy Director General  
Food and Drug Department  
Ministry of Health
Ms Phouthavanh Inlorkham  
Deputy Chief  
Food and Drug Department  
Ministry of Health  

Malaysia  
Dato’ Eisah Binti A. Rahman  
Senior Director  
Pharmaceutical Services Division, Ministry of Health  

Ms Azura Abdullah  
Senior Principal Assistant Director  
Centre for Product Registration  
National Pharmaceutical Control Bureau, Ministry of Health  

Myanmar  
Dr Thazin Yi Hlaing  
Deputy Director General  
Myanmar Food and Drug Administration (FDA)  

Ms Tin Myo Khine  
Assistant Director General  
Myanmar Food and Drug Administration (FDA)  

Singapore  
Dr John Lim  
Executive Director  
Duke-NUS Centre of Regulatory Excellence  

Dr Silke Vogel  
Deputy Director  
Duke-NUS Centre of Regulatory Excellence  

Dr Mandy Ow Yen Ling  
Professor  
Duke-NUS Centre of Regulatory Excellence
**Thailand**

Dr Boonchai Somboonsook
Secretary General
Food and Drug Administration, Ministry of Health

Dr Tharnkamol Chanprapaph
Pharmacist, Senior Professional Level
Chief of Pre-Marketing Control Division
Food and Drug Administration, Ministry of Health

Ms Supatra Phongsri
Pharmacist, Professional Level
Food and Drug Administration, Ministry of Health

Dr Rungrawee Tipmontree
Senior Public Health Technical Officer
Malaria Elimination Coordination Section
Bureau of Vector Borne Diseases
Department of Disease Control
Ministry of Public Health

**Viet Nam**

Ms Nguyen Thanh Huong
Official, Drug Information and Advertising Management Division
Drug Administration of Viet Nam

**Asia Pacific Leaders Malaria Alliance (APLMA)**

Dr Benjamin Rolfe
Executive Secretary

Dr Paul Lalvani
Senior Advisor, Access to Quality Medicines

Dr Mary Moran
Senior Advisor, Innovation and Technology

Mr Jeffery Smith
Team Leader, Advocacy and Partnerships
Asian Development Bank (ADB)

Dr Douglas Ball
Regulatory Consultant

Bill and Melinda Gates Foundation (BMGF)

Dr Raj Long
Senior Regulatory Officer

Medicines for Malaria Venture (MMV)

Dr Stephan Duparc
Chief Medical Officer

Ms Penny Grewal Daumerie
Director, Access and Delivery Asia and Latin America

Dr Valerio Reggi
Consultant

PATH

Mr Nicholas Luter
Market Dynamics Specialist

WHO

Dr Milan Smid
Group Lead
Technical Assistance and Laboratory Services
WHO Prequalification Team – Medicines

Dr Samvel Azatyan
Group Lead
Capacity Building & Harmonization Support/RSS/RHT/EMP

Dr Chansuda Wongsrichanalai
Consultant, Western Pacific Regional Office
Appendix 2

Profiles of the organizations:

1. **Asian Development Bank (ADB):** The Asian Development Bank (ADB) is a multilateral development finance institution with 67 member nations, 48 of which are from Asia and the Pacific. ADB provides loans, technical assistance and grants to clients which are member governments, therefore who are also its shareholders. In addition, ADB provides direct assistance to private enterprises of developing member countries through equity investments and loans.

**ADB and Health:** The Operational Plan for Health, 2015–2020 was the result of a review of operations that concluded that the ADB needed to invest more in health. This plan provides a focused approach for addressing the health needs of ADB developing member countries by leveraging loans and grants to achieve Universal Health Coverage through strategic investments in health infrastructure, health sector governance, and health financing. The Operational Plan for Health 2015–2020 provides a wide range of integrated strategies and solutions to assist ADB developing member countries in meeting the United Nations post-2015 goal of expanding public and private health services. It includes provisions for increasing ADB health sector investments in the Asia and Pacific region from 1% to 2% (2014) of the total portfolio to 3% to 5% by 2020 ($700 million – $1 billion by 2020).

**ADB and Malaria:** The Regional Malaria and Other Communicable Disease Threats Trust Fund (RMTF) was set up in December 2013 with the specific remit to support developing member countries to develop multi-country, cross-border, and multisector responses to address malaria and other communicable disease issues. Malaria is a heavy burden for many countries in Asia and the Pacific with an estimated 2.2 billion people at risk region-wide. For the ADB, malaria elimination is an obvious public health best-buy that will reduce human suffering and foster economic gains through increased worker productivity, improved educational outcomes, and a more vibrant tourism sector. Through the RMTF, ADB is acting as both a catalyst and financing body for innovation, bringing together centers of excellence such as Harvard School of Public Health, Oxford University, Mahidol Oxford Tropical Medicine Research Unit, Duke-NUS Graduate Medical School Singapore, and the University of Tokyo to operationalize research on communicable disease surveillance and regulatory practices. The Trust Fund works on the premise that the “business-as-usual” response to malaria and other communicable disease threats is bound to fail, and progress demands innovative approaches. It also takes malaria elimination as an entry point to health systems strengthening and regional health security.

2. **Asia Pacific Leaders for Malaria Alliance (APLMA):** The Asia Pacific Leaders Malaria Alliance is an affiliation of Asian and Pacific Heads of Government formed to accelerate progress against malaria and to eliminate it in the region by 2030. The Prime Ministers of Australia and Viet Nam serve as the Co-chairs. It is not an organization, a program or a funding body. It does not involve formal country or organizational membership, nor specified contributions or other obligations. APLMA was formed by the 2013 East Asia Summit (EAS) in Brunei due to concerns amongst leaders about the rising risks of malaria...
resurgence, in particular due to increasing drug resistant malaria in the Greater Mekong Sub-region. By virtue of its Heads of Government status, APLMA has a policy-making capacity and can establish priorities for action, but it is not an implementation body. It works with and through national and international authorities. Firstly, to ensure Leaders are informed of the latest scientific evidence, and secondly to assist in translating the collective will of the region’s Leaders into coordinated action by relevant authorities. APLMA is served by a small Secretariat, currently based at the Asian Development Bank. It works closely with the Asia Pacific Malaria Elimination Network and both WHO Regional Offices. The Secretariat add value by taking the elimination agenda beyond Ministries of Health, to Heads of Government and through to Leaders, and central agencies of finance and foreign affairs.

3. Department of Drugs and Food, Ministry of Health of The Kingdom of Cambodia: It is the regulatory authority under the Directorate General for Health. It is authorized to ensure the safety, efficacy and quality of drugs, medical devices, general medical items, cosmetics and food. The goal of the DDF is a strengthened pharmaceutical sector that will become an integral part of health sector development. Part of this goal will be improved health of Cambodian people by alleviating poverty and developing the socio-economic climate. The DDF is also responsible for educating the pharmaceutical industry on how to improve their quality assurance obligations during drug manufacturing among other responsibilities listed below. Each Provincial Health Department has a Bureau of Drugs and Food. Operational Districts, Referral Hospitals, and Health Centers have pharmacists or staff responsible for the distribution, storage, dispensing and quality of drugs.

4. The Centre of Regulatory Excellence (CoRE): The Centre of Regulatory Excellence (CoRE) at the Duke-NUS Medical School in Singapore provides an neutral academic platform to foster regional regulatory capacity development and innovation in the Asia-Pacific, with a special focus on South-East Asia. The Centre promotes regulatory convergence, collaboration and policy innovation through education, research and thought leadership, with the aim of ensuring that patients in Asia have timely access to safe, effective and high quality therapeutic product through excellent regulation. CoRE was launched in November 2014. It is the first dedicated Centre in the Asia-Pacific supporting development of regulatory affairs professional leaders in national health regulatory agencies, pharmaceutical and medical device companies, and the wider biomedical industry. The Centre successfully draws upon a wide network of respected international and regional regulatory opinion leaders from national authorities, industry and academia to deliver programmes of applied relevance for senior regulatory staff and executives.

5. Food and Drug Department of Lao PDR (Lao FDD): The Food and Drug Department of Lao PDR (LaoFDD) is a governmental department under the Ministry of Health. Its vision is to ensure good quality, safety and efficacy of drugs and health products as well as their rational use for Lao people’s health protection. Its main roles are to develop and implement strategy, policy, law and regulation, enhance the enforcement of law and regulation governing drug and health products. Pre-marketing and Post marketing surveillances of drugs, quality assurance system including quality control and promoting rational use of
drugs are also important roles. Lao FDD activities related to malaria are through the Drug Control Division, the Hospital Pharmacy Management Division and the Narcotic psychotropic and Hazardous Substance Division. Anti-malarial drug registration and approval are under the Drug Control Division. Import control of antimalarials are under Hospital Pharmacy Management Division. Quality, safety and efficacy of anti-malarial drugs marketed in Lao PDR can be assured through premarketing and postmarketing control activities, regular sampling of the products for laboratory testing is also performed. A fast track or priority review channel for life-threatening medicines and medicines in urgent need for public health problems including HIV/AIDS drugs, anti-cancer, anti-TB, anti-malarial drugs were established.

6. Department of Food and Drug Administration, Ministry of Health, The Government of the Republic of the Union of Myanmar: The Food and Drug Administration (FDA) was established in 1995 as one of the divisions under the Department of Health. The FDA division was upgraded to a separate department in April, 2013. The aim of the department is to ensure the safety and quality of Food, Drugs, Medical Devices and Cosmetics in the country. FDA Headquarter is located in Nay Pyi Taw, the capital city of Myanmar, with five major divisions: Administrative division, Drug Control division, Food Control division, Cosmetic and Medical Device Control division and Laboratory division while preexisting Yangon and Mandalay branches acting are still as major branches, control activities have greatly expanded with the establishment of new FDA branches in other Regions and State. In addition, FDA has also established branches in important border trade zones such as Muse, Kawthaung, Myawaddy and Tamu. FDA is responsible for issuing GMP certificate for local food manufacturing businesses, import and export recommendation, import and export health certification. Drug control activities include marketing authorization and registration for new product, variation of existing authorization, quality control laboratory testing, adverse drug reaction monitoring, Good Manufacturing Practice inspection and licensing of manufacturer, wholesalers, enforcement activities, drug promotion and advertisements. FDA issues notification and import recommendation of medical devices. Regulation of cosmetics is with ASEAN Cosmetic Derivative and already implemented the cosmetic notification system.

7. Therapeutic Goods Australia, Department of Health, Australian Government (TGA): The Therapeutic Goods Administration is part of the Australian Government Department of Health with responsibility for administering a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods used in, or exported from, Australia. GA’s mission is to safeguard and enhance the health of the Australian community through the effective and timely regulation of therapeutic goods. The Australian community expects therapeutic goods in the marketplace to be safe, of quality and of a standard at least equal to that of comparable countries. During 2014 and early 2015 TGA officers participated in meetings and activities directly related to the work of the APLMA, including leading work on ways to improve access to quality medicines under APLMA. As part of this, the TGA organised and co-chaired a meeting of regional regulators, the WHO and others to develop a range of options for improving the availability of, and access to,
quality medicines and diagnostics (including newer and more effective treatments and tests). The meeting made 12 recommendations across four key areas, which were subsequently endorsed by a plenary meeting of APLMA and included in the advice to the East Asia Summit. The report contributed to the 2015 APLMA Leaders Malaria Elimination Roadmap.

8. **Thai Food and Drug Administration (ThaiFDA):** Thai Food and Drug Administration (ThaiFDA) is a governmental department under the Ministry of Public Health. Its main roles are to protect the people’s health in the consumption of health products and to promote the standards in health product safety, efficacy and quality. These roles are achieved by ensuring efficacy, quality and safety of health products and promoting consumer behavior. The health products include foods, drugs, psychotropic substances, narcotics, medical devices, volatile substances, cosmetics and hazardous substances that are available in the markets across the country. The FDA implements technical principles as guidelines for decision making with a focus on risks and benefits of health product consumption. In other words, consumers should gain the greatest benefits and be exposed to the lowest possible risks. The FDA’s operational measures include: pre-marketing control, post-marketing control, surveillance, consumer education, and international cooperation. ThaiFDA acts as the representative or co-representative of the nation in international meetings or negotiations to determine measures, standards or regulations in the control and supervision of health products and chemicals, as well as providing technical support to other regional or international agencies.

Thai FDA has participated in essential medicines and health products program of World Health Organization (WHO). As for regional collaboration, Thailand has participated in ASEAN Working group on Pharmaceutical Development for more than 30 years. This working group aims to improve skill and knowledge of Drug Regulatory Authority to assure that drugs are of good quality, safe and effective. Harmonization has been playing an important role in the regulatory aspects in recent years. ASEAN has harmonized many technical requirements in order to reduce and eliminate technical barriers to trade in many regulated products including pharmaceutical products. Pharmaceuticals Product Working Group (PPWG) is a working group established since 1999 and for harmonization on technical aspects of pharmaceutical registration. Thai FDA has actively participated in PPWG. As a member of APEC, Thai FDA has participated in Regulatory Harmonization Steering Committee (RHSC) of APEC Life Science Innovation. Thai FDA is a co-product champion of MRCT-GCP roadmap with PMDA of Japan. Thai FDA has experience on the joint-review of vaccine dossier for product registration with TGA - Australia organized with the support of WHO.

9. **World Bank Group:** The Health, Nutrition, and Population Global Practice of the World Bank Group provides financing, analysis, policy advice, and implementation support to help countries expand access to good quality, affordable health care. Improving access to medicines is an integral part of this objective.
Global Medicines Regulatory Harmonization (GMRH): The initiative was established in 2011 at the World Bank. This was set up as a Multi-Donor Trust Fund, with an initial contribution of US$12.5 million from the Bill & Melinda Gates Foundation. In 2014, the Governments of United Kingdom and the United States joined the trust fund as donors with commitments of GBP 3 million (approximately US$ 4.8 million) and US$ 1.5 million respectively. The initiative is managed by a small team in the World Bank’s Health, Nutrition and Population Global Practice that focuses on pharmaceutical governance and regulation. GMRH programs can be integrated into a single, overarching objective: to promote the harmonization of medicines regulation as a means to improve access to essential and quality medicines, by strengthening governance and regulatory systems of the pharmaceutical sector. This would include improving access to medicines for the three major infectious diseases that have received substantial attention in the last two decades: AIDS, TB, and malaria.

Profiles of the participants:

1. Douglas Ball, Asian Development Bank: He is an experienced public health pharmacist working as a regulatory consultant with the Asian Development Bank. He has a background in academia during which he collaborated with essential medicines programmes and with national regulatory authorities on pharmacovigilance and other issues. He has published widely in biomedical journals on pharmaceutical policy, access to essential medicines, the rational use of medicines and pharmacy practice research. He has wide international development consulting experience from Africa, the Middle East and Asia. He has worked with Health Action International (HAI) and the World Health Organization (WHO) on international medicine prices and availability, contributed to pharmaceutical systems assessments in countries receiving grants from the Global Fund to fight AIDS, TB and Malaria, performed clinical evaluations for the WHO vaccine prequalification programme and worked as scientific advisor to the GIZ-funded Fit For School school-based public health project in the Philippines, Cambodia, Laos and Indonesia.

2. Mary Moran, Asia Pacific Leaders for Malaria Alliance: She has over 25 years health experience, including 15 years specialising in innovation for neglected and tropical diseases, in particular research and development (R&D) funding, incentives, pipelines and access to medicines policy. Mary holds a number of expert advisory roles including as a member of the WHO Expert Working Group on R&D Innovation and Financing (2012-12), the UK Prime Minister’s Review of Antimicrobial Resistance, and as an innovation adviser to the European Commission, OECD, International AIDS Vaccine Initiative, Wellcome Trust and the Australian Government. She is an Honorary Senior Lecturer at the London School of Hygiene and Tropical Medicine.

3. Paul Lalvani, Asia Pacific Leaders for Malaria Alliance: Professor Paul Lalvani is the Senior Advisor, Access to Quality Medicines, Dean and Director of Empower School of Health and former head of Global Fund’s Procurement and Supply Chain Management. He has advised Roll Back Malaria, WHO Global Malaria Program and malaria programs of various Ministries of Health. He has 25 years of experience in procurement and supply,
which includes work in public and private sector, and in developed and developing countries. Prof. Lalvani has advised more than 30 countries in procurement and supply management, assessment of procurement systems to identify the gaps and make recommendations for improvement as well as various Ministries of Health, The Bill and Melinda Gates Foundation, George Soros’ Open Society Institute, World Health Organization, and Roll Back Partnership (where he is co-chair of the PSM working group).

4. Ben Rolfe, Asia Pacific Leaders for Malaria Alliance: Dr. Ben Rolfe is Executive Secretary of the Asia Pacific Leaders Malaria Alliance, the secretariat of which is hosted by Asia Development Bank. Formerly Pacific Lead Health Advisor at the Australian Department of Foreign Affairs and Trade, Ben has more than twenty years of experience in supporting health initiatives across 30 countries. His expertise focuses on health policy, systems strengthening and financing. Ben is currently based in Manila, having previously lived and worked for long periods in Cambodia, Nepal, India, Tanzania, Australia, Nigeria and Eritrea. Dr. Rolfe holds a PhD from the University of Wales and is a Fellow of the UK Faculty of Public Health.

5. Jeff Smith, Asia Pacific Leaders for Malaria Alliance: Jeffery Smith is Team Leader for Advocacy and Partnerships at the Asia Pacific Leaders Malaria Alliance (APLMA) Secretariat. A chemist by training, Jeff has 25 years’ experience leading clinical research, education and advocacy programs in malaria and HIV. The focus of Jeff’s work in the past decade has been building capacity and advocating for sustainable malaria and HIV drug resistance management and surveillance systems in the Asia Pacific region. Prior to joining APLMA in April 2015, Jeff led efforts in Asia for a global collaboration working to preserve the efficacy of current antimalarial drugs by tracking the emergence and spread of drug resistance for the Worldwide Antimalarial Resistance Network (WWARN). Simultaneously, Jeff coordinated the Mekong Molecular Surveillance Network for the University of Maryland Center for Vaccine Development. Before beginning to focus on antimalarial drug resistance in 2010, Jeff led research, education, and advocacy efforts for The Foundation for AIDS Research’s (amfAR) TREAT Asia program.

6. Raj Long, Bill and Melinda Gates Foundation: Raj Long Senior Advisor, Integrated Development–Bill & Melinda Gates Foundation, London, UK. Raj is a senior executive with over 20 years of experience in the pharmaceutical industry. Raj brings a wide range of expertise in regulatory strategy and management having worked with the EMA, US FDA, CFDA and other BRIC regulatory authorities. She is currently a Senior Advisor at the Bill & Melinda Gates Foundation (BMGF) responsible for Malaria and Neglected Diseases medicines portfolio and Foundation lead for Pharmacovigilance initiative in LMIC. Previously, she was the Global Head of Regulatory GEHC-MDX in the UK responsible for the regulatory organization and regulatory access globally in Americas, EMEA and Asia. Prior to joining GEHC, she was Vice-President of Regulatory International AGL in Novartis, Switzerland and also at Bristol-Myers Squibb, Princeton, USA. She was responsible for setting up strategic organizations in Asia, Latin America, Middle East and Africa with a focus on shaping drug development strategy. Raj has an outstanding track record in shaping
successful regulatory strategy in drug development that enables catalytic accelerated market access globally.

7. **Hiem Sokhen, Cambodia:** He is a pharmacist who is currently serving as the Deputy Chief of Drug Registration bureau of Department of Drugs and Food, Ministry of Health of Cambodia.

8. **Sea Thol, Cambodia:** He is currently the Chief of Essential Drug Bureau of the Department of Drugs and Food, Ministry of Health of Cambodia. He worked as chief of pharmacy at the Pailin Referral Hospital of the municipal health department. He also worked as an analyst at the national health product quality control centre.

9. **John Lim, CoRE:** Dr John Lim is a medical graduate of the National University of Singapore (NUS), and holds Masters degrees in Health from NUS and in Health Policy and Management from Harvard University. He is a Specialist in Public Health Medicine, a Fellow of the Singapore Academy of Medicine, and Adjunct Associate Professor at the Duke-NUS Medical School and NUS Saw Swee Hock School of Public Health. He has held senior positions in Singapore’s Ministry of Health (MOH) and Ministry of Education. Following the establishment of the Health Sciences Authority (HSA), Dr Lim became Director of its Centre for Drug Administration in 2001. He was appointed HSA’s Chief Executive Officer in 2006 and led the organisation for eight years during a period of major development and growth.

10. **Mandy Ow, CoRE:** Dr. Ow joined the Centre of Regulatory Excellence (CoRE) at Duke-NUS Medical School in December 2015 to lead the development of a profiling system for the capacity needs assessment of regulatory systems in five countries of the Greater Mekong Subregion (GMS). This work is done as part of a CoRE-Asian Development Bank (ADB) collaborative project, “Results for Malaria Elimination and Communicable Diseases Control in Asia and the Pacific to strengthen the capability of NMRAs in the GMS”. Prior to joining CoRE, Dr. Ow was from the Office of Clinical Sciences and Academic Medicine Research Institute at Duke-NUS Medical School. As a mixed methods outcomes researcher, she designed and conducted several health outcomes and health services research studies collaboratively with principal investigators using focus group, interview and survey methods. She was also Research Scientist at the Singapore General Hospital, leading a project to develop a comprehensive, culturally sensitive conceptual framework of health domains.

11. **Silke Vogel, CoRE:** In 20 12, Dr. Vogel joined Duke-NUS Medical School as Associate Professor to lead the Voice Annotated Presentation Project and to facilitate clinical research projects. Later that year, she took on the role as Assistant Dean and subsequently Associate Dean of the Office of Graduate Studies. In her capacity she manages the administrative, academic and educational affairs of the PhD program, and develops new programmes and initiatives. In 2014, with the creation of the Centre of Regulatory Excellence (CoRE), she became the Deputy Director for the Centre. Her role is to implement education and research initiatives and oversee the strategic management of CoRE.
12. Lamphone Syhakhang, Lao PDR: Lamphone Syhakhang has been working for the Food and Drug Department, Ministry of Health for about 30 years. She has involved in many areas of work, especially in the development of the National Medicine Policy (NMP) since the beginning 1992 and the implementation of policy to put the theory into practice. This includes the development of law and regulations, Quality Control and Quality Assurance, Medicine Selection and Medicine Registration. She also has experiences in the areas of Rational Use of Medicines, Traditional Medicines, Drug Supply Management and Health Systems Research. She has been the Head of Delegations attending several ASEAN Working Group Meetings under the ASEAN Consultative Committee for Standards and Quality (ACCSQ) and Senior Officer Meeting on Health Development (SOMHD) e.g., PPWG, MDPWG, ACC and AWGPD meetings. She has recently been nominated as a focal point for the harmonization in pharmaceutical sector in Lao PDR, to take more responsibility in the implementation and cooperation of the harmonized standards, registration evaluation and Mutual Recognition Arrangement to move towards AEC and Beyond.

13. Penny Grewal, MMV: Penny Grewal Daumerieis Senior Advisor, Access and Product Management, Medicines for Malaria Venture (MMV), Geneva, Switzerland. She was the former Director Global Access at MMV and the former Head, Sector Health for the Novartis Foundation for Sustainable Development, Switzerland. Penny has 30 years of experience in improving patients’ access to treatment for malaria, leprosy, TB epilepsy. Her current work focuses on facilitating access to new effective antimalarials to ensure maximum patient impact after launch and inclusion in the WHO Malaria Treatment Guidelines. She works closely with National Malaria Control Programmes, WHO, the Global Fund, pharma partners and country stakeholders to ensure the acceptability, affordability and availability of new medicines. At the Novartis Foundation, Penny spearheaded the global drug donation programme of Multiple Drug Therapy for leprosy in collaboration with the WHO and of TB drugs to the Global TB Drug Facility. She has a Master’s of Business Administration (MBA) from INSEAD, Fontainebleau, France and B.A. Hons (Economics), Bombay University, India.

14. Thazin Hlaing, Myanmar: Dr. Thazin YiHlaing is the Deputy Director General of the Department of Food and Drug Administration of the Ministry of Health. She has a Master’s of Medical Science (Biochemistry) from the Institute of Medicine, Yangon. She also has a Bachelor’s of Medicine; Bachelors’ of Surgery from the Institute of Medicine, Yangon. She has 15 years of experience in management of drug laboratory as Assistant Director. Then she takes the responsibility for regulation of medical device & cosmetics in Myanmar up to now. She also undertakes to ensure public health and safety of food, drug, medical device and cosmetics as she was promoted to Deputy Director General in December 2015. She is interested in consumer’s health knowledge and she wants to raise public health education.

15. Tin Khine, Myanmar: Ms Tin Myo Khine is Assistant Director/ Quality Assurance Manager of Pharmaceutical Chemistry Laboratory, Department of Food and Drug Administration, Ministry of Health. She has participated in Regional Artemisinin Initiative Program (RAI) under National Malarial Control Program (NMCP) since 2014. She also has collaborated and cooperated with USP (PQM), Myanmar in the research program regarding
the quality of antimalarials and NOMCoL (Networking Official Medicines Control Laboratories) (Asia Pacific) program as head of pharmaceutical chemistry laboratory. She has a Master Degree of Pharmacy from the University of Pharmacy (Yangon). She has 5 years of experience as deputy drug controller in drug control division and 10 years’ experience in testing and management activities in drug quality control laboratory section of Department of Food and Drug Administration.

16. Michael Wiseman, Therapeutic Goods Administration: Mr. Michael Wiseman is currently the Acting Assistant Secretary of the Therapeutic Goods Administration’s Laboratories Branch. He has over 18 years’ regulatory experience working within regulatory organisations both in Australia and Canada. During this time Michael has worked in a range of different corporate and regulatory areas, including the Prescription Medicines Authorisation Branch that provides market authorisations to the highest risk medicines and the Complementary and Over the Counter Medicines branch’s that regulates lower risk medicines. Between August 2010 and December 2012 Michael undertook a secondment to Health Canada, Ottawa. During this time, Michael developed a new licensing model for manufacturers of natural health products and established formal work-sharing arrangements between Health Canada and TGA. This work-sharing arrangement resulted in the development of two joint Over the Counter medicines monographs, implementation of processes to identify and exchange generic medicine applications in common, and processes to identify and exchange from Desk Top Audits of foreign medicine manufacturing facilities. The work-sharing project demonstrated that genuine work-sharing between TGA and Health Canada is possible, feasible and achievable. The benefits to the prescription medicines program in particular are significant, though incorporating changes to entrenched work practices and views from reviewers within both agencies has been the biggest challenge to overcome.

17. Harald (Harry) Sebastian Rothenfluh, Therapeutic Goods Administration: He is currently Assistant Secretary, Manufacturing Quality Branch, Therapeutic Goods Administration, Department of Health, Commonwealth of Australia. A productive 9 years in biomedical research, which resulted in the publication of a chapter in a medical text book and 15 papers in peer reviewed journals such as Proceedings of the National Academies of Science, Journal of Virology and Journal of Human Reproduction. The research he conducted contributed to the body of knowledge about the mechanisms that diversify the antibody response to an infectious agent and generate memory to allow a speedier immune response to subsequent exposures. He has applied his technical, regulatory and management skills on the international stage during the time as Programme Manager of the WHO’s Medicines Prequalification Programme (PQP). During this time he gained knowledge and experience in the medicine regulatory challenges in Africa and China, for example by providing advice on national regulatory development plans under the UN Commission on Life Saving Commodities. Since returning to TGA he has expanded his understanding of global medicine regulatory challenges into the Mekong region as TGA lead of a Department of Foreign Affairs/TGA regulatory capacity building project design mission in the Mekong region.
18. John Skerritt, Therapeutic Goods Administration: Dr John Skerritt joined the Australian Department of Health in May 2012 and is currently the Deputy Secretary Regulatory Services Group. He was formerly the National Manager of the Therapeutic Goods Administration, until that position was absorbed into his current and expanded role. The Group comprises the Health Department’s regulators, including the TGA, the Office of the Gene Technology Regulator (OGTR), the Office of Chemical Safety and the Office of Drug Control. Dr Skerritt is a former Deputy Secretary in the Victorian Government and has extensive experience in medical, agricultural and environmental policy, as well as regulation, research management, technology application and commercialisation. He also has over 20 years’ experience at senior levels in international development as the former Deputy CEO of ACIAR (one of the Australian Government’s two development assistance agencies) and as former Chair of the Board of the International Water Management Institute. In 2012 he was the world-wide winner of the Rotary International “Global Alumni Service to Humanity Award”.

19. Boonchai Somboonsook, Thailand: Dr. Boonchai Somboonsook is Secretary-General of the Food and Drug Administration of Thailand (ThaiFDA). He received his Medical Doctor degree from Chiang Mai University, Thailand in 1981. After graduation, he worked in primary care hospitals in the northern area of Thailand, where he served as the Director of hospitals. In 1990, he received a Master’s Degree in Tropical Health (M.T.H.) from University of Queensland, Brisbane, Australia. In addition, he holds several advanced training certificates in the areas of Human Resource Management, Development Administration, Public Law, Service, Clinical Practice Community, and Preventive Medicine. He has served as Department Head Division Director in areas throughout his career. For example, he was the Director of the Bureau of Environmental Health, Department of Health, Ministry of Health in 1997. From 1999 to 2002, he served as a Deputy Secretary-General of the Thai FDA. Between 2002 and 2009, he served Director-General of the Department of Medical Sciences, and of the Department of Health Service Support, Ministry of Public Health. In 2011, he became the Director-General of the Department of Medical Sciences. He currently serves as the Secretary-General of the Thai FDA since 2012.

20. Tharnkamol Chanprapaph, Thailand: Tharnkamol Chanprapaph, Ph.D.Bureau of Drug Control, Thai Food and Drug Administration Dr. Tharnkamol Chanprapaph has been working in Thai Food and Drug Administration (Thai FDA) for more than 20 years. Dr. Chanprapaph has long experience in pre-evaluation of pharmaceutical products. Currently, she is a Chief of Pre-Marketing Control Division, Bureau of Drug Control. She has participated in many international and activities. She has participated in the ASEAN Consultative Committee for Standards and Quality Pharmaceutical Product Working Group (ACCSQ PPWG) Meeting since 1999. She attended many drug regulatory meetings and trainings such as ICDRA (International Conference of Drug Regulatory Authorities), CDER Forum for International Drug Regulatory Authorities, organized by Food and Drug Administration as well as WHO Prequalification Quality Assessment Training. Dr. Chanprapaph studied at Faculty of Pharmacy, Chiangmai University, Thailand and got
Bachelor of Pharmaceutical Sciences (Hon.) as her first degree. She holds M.Phil and Ph.D. in Pharmacology from University of Cambridge, United Kingdom.

21. Rungrawee Tipmontree, Thailand: Dr. Rungrawee Tipmontree is the Senior Public Health Technical Officer, working at Malaria Elimination Coordination section, Bureau of Vector Borne Diseases, Ministry of Public Health, Thailand. She has 20 years of experience in malaria program with various expertise including program evaluation, epidemiology, health facility survey, capacity building, international training, and IEC/BCC schemes.

22. Hui Sin Teo, World Bank Group: Hui Sin Teo is a Health Specialist in the Health, Nutrition, and Population Global Practice of the World Bank Group. Her areas of expertise include health financing, health service delivery planning, and pharmaceutical policy. Hui Sin has led and contributed to analytical work on fiscal space for health and public expenditure reviews, and conducted assessments on service delivery effectiveness and access to medicines. She has worked in a wide range of countries in the East Asia region, as well as in Eastern Europe. Within the area of pharmaceutical policy, Hui Sin is currently leading a study on medicines regulatory capacity and regulatory harmonization efforts in Southeast Asia. Prior to joining the World Bank Group, Hui Sin was an Assistant Director at the Ministry of Health, Singapore, overseeing health service regulation and quality of care in the long term care sector. She also managed the health sector budget and oversaw health financing strategy and policy in her role at the Ministry of Finance, Singapore. Hui Sin holds a Master in Public Policy degree from the John F. Kennedy School of Government.
Appendix 3

Concept Note

Background

In November 2014, at the 9th East Asia Summit (EAS), Heads of Government from the EAS and malaria-endemic Pacific countries agreed to the vision of *Asia Pacific free of malaria by 2030*. They requested the Asia Pacific Leaders Malaria Alliance (APLMA) Co-Chairs, the Prime Ministers of Australia and Viet Nam, to deliver a plan for attaining this goal. At the 10th EAS in November 2015, the Leaders endorsed the *APLMA Leaders Malaria Elimination Roadmap*.

The Roadmap lays out six priority actions that Leaders will need to implement in order to attain malaria elimination. The Roadmap calls for strong leadership to implement and maintain accountability for six priority actions that include:

1. Unite national efforts and regional actions
2. Map, prevent, test and treat the diseases, everywhere
3. Ensure high quality malaria services, tests, medicines, nets and insecticides
4. Improve targeting and efficiency to maximize impact
5. Mobilize domestic financing and leverage external support; and
6. Innovate for elimination.

The Roadmap indicates that Governments and all partners need to work collaboratively and cohesively in new and unprecedented ways; between countries, across agencies and sectors. Malaria elimination must intersect health, finance, environmental change, movement of people and goods, and delivery of new drugs and diagnostics.

The Challenge: Access to optimal malaria technologies

Achieving rapid, universal access to optimal malaria technologies is critical for tackling the challenges and gaps in the region. These challenges include addressing the increasing resistance to artemisinin-based drugs and to expedite review and approval of new antimalarial drugs and diagnostic tools, such as simple point-of-care rapid diagnostic tests to establish the glucose-6-phosphate dehydrogenase (G6PD) status of individuals, in order to enable treatment of *P. vivax* malaria by established 8-aminoquinoline antimalarials (e.g. Primaquine).

At the request of APLMA, in 2014 the Australian Department of Health, through the Therapeutic Goods Administration organised and co-chaired a meeting of regional regulators, WHO and other players to develop a range of options for: improving the availability of, and access to, quality medicines and diagnostics (including newer and more effective treatments and tests); helping to contain the spread of artemisinin resistance; and strengthening regulators’ capacity to monitor the quality of products being supplied and to take action when substandard products are detected. The meeting made 12 recommendations across four key areas, which were subsequently endorsed by a plenary
meeting of APLMA and included in the advice to the East Asia Summit. Several of these objectives contribute to the 2015 APLMA Leaders Malaria Elimination Roadmap.

To initiate action on tackling some of these challenges, the **Roadmap priorities 2 and 3** focus on actions to provide universal access to high quality prevention, testing and treatment commodities. **Roadmap priority 6** outlines the need to accelerate access to state-of-the-art innovations in malaria elimination.

**Delays in obtaining regulatory approval for critical medicines and diagnostic tests have been one of the biggest barriers to access.** It is critical to develop ways to permit fast-track review and approval of new antimalarial medicines and diagnostic tools, without compromising on legal requirements and appropriate scrutiny of the products. This document proposes the establishment of a platform for designing and implementing innovative approaches, and for leveraging on existing mechanisms and progress made by the WHO, Stringent Regulatory Authorities (SRA) and regional regulatory mechanisms.

This approach aligns with the 2016-2030 WHO Malaria Global Technical Strategy Supporting Elements 1 and 2, which outline the need to Harness Innovation, Expand Research and Strengthen the Enabling Environment with National Regulatory Authorities (NRA) in a central role.

**Proposed Action: Establishment of a Regional Regulatory Partnership**

The APLMA Secretariat, the Australian Department of Health through the Therapeutic Goods Administration (TGA), the Asian Development Bank and the WHO’s Prequalification Program propose launching a **regulatory partnership.** This will be a partnership between regulatory authorities in the Asia Pacific to improve the efficiency and quality of the regulatory review for new antimalarial treatments and diagnostic tests. Because of the critical need for such products with vivax malaria, this will form the initial focus of the partnership.

The objective of the partnership is to **support rapid access to new antimalarial treatments and diagnostic tests** by

1) Expediting the assessment of breakthrough products, with an initial focus on *P.vivax* malaria, and
2) Strengthening regional regulatory capacity through enhanced post-market vigilance.

Regulators will do so by jointly identifying priority products for assessment, and launching bilateral and multilateral approaches for regulatory assessment and regulatory strengthening. A focus of this partnership will be through information and data sharing and collaboration on the product dossier review process.

The partnership will be co-chaired by the Therapeutic Goods Administration of the Australian Department of Health, with core members as the heads of National Regulatory
Authorities from the Asia Pacific. Regulatory experts from the WHO and other support organizations will also be closely involved. The APLMA Secretariat will provide support and secretariat functions for the partnership, which will include administration functions, facilitating the execution of outputs and tracking next steps. It is anticipated that members will meet biannually to identify priority issues, develop implementation plans and report on the progress of implementation in participating countries.

**Mechanism for Action: Key Outcome**

The meetings will be designed to *accelerate and strengthen regulatory approval processes* by launching bilateral and multilateral collaborations between Stringent Regulatory Authorities, National Regulatory Authorities and partners. It will do so by:

1) Identifying and prioritizing key antimalarial treatments and diagnostic tests for regulatory review and approval;
2) Developing a model for regulatory collaboration through the experiences and learnings from the WHO Prequalification Programme, African Medicines Regulatory Harmonization, ASEAN collaborative work streams, and other similar interventions; and
3) Providing the Regional Regulatory Partnership with appropriate support, planning, oversight and accountability.

This forum will provide members with the opportunity to *review progress, discuss challenges, set priority actions and announce new commitments*. Members will then collaborate outside of the partnership forum to develop and execute them. Detailed work plans will be developed for guiding ongoing work after the conference.

The key outcome will be to *accelerate the time to market for high priority, high quality technologies for malaria elimination* without compromising the regulatory review process. While the focus of the partnership will be on malaria, there should be spillover impacts from streamlining and coordinating regulatory approval processes to medicines for other public health priorities, such as tuberculosis.

**Leveraging Australian Investment and Expertise**

Australia is widely recognized for showing exceptional leadership in malaria, a disease that kills over 50,000 people annually in Asia Pacific. Vivax malaria is of particular relevance given its impacts in Papua New Guinea, Australia’s closest neighbor. The overwhelming majority of cases of malaria detected in Australia have been acquired overseas, and about half of these are vivax malaria. Australia now has an opportunity to leverage its investment and expertise in support of the Roadmap.

Australia’s comparative advantages include world-leading academic and regulatory expertise. The Department of Foreign Affairs and Trade and the Department of Health have already made an important contribution to regional elimination. In 2014, the TGA convened
a first-of-kind meeting of regional regulators, where 12 concrete recommendations were delivered to the APLMA Task Force on Quality Medicines, which subsequently national Leaders agreed to at the 2014 East Asia Summit.

The Regional Regulatory Partnership would also build on Australia’s existing aid program support for an innovative Public-Private Partnership with Medicine for Malaria Venture (MMV) as a recipient of two grants (2013 and 2015-17). Australian universities have been closely collaborating with MMV on malaria drug discovery and development, ranging from high throughput screening to the challenge model to the discovery of new compounds.

The TGA’s involvement in the Regional Regulatory Partnership would provide strong support to the development of innovative regulatory strategies to accelerate access to life-saving public health commodities for malaria elimination and broader health security.

Regional Regulatory Partnership: Inaugural Planning Meeting – March 31-April 1, 2016 in Bangkok

The inaugural planning meeting of the Regional Regulatory Partnership will include senior executives from regulatory agencies, and achieve the following objectives:

1) **Establish the partnership and structure** for a Regional Regulatory Partnership in cooperation with other regional players

2) **Identify priorities** for intervention, with new products to address *P. vivax* malaria proposed as a first consideration

3) **Discuss lessons learned and existing models** from regional regulatory approaches and malaria control programs

4) **Outline the initial commitments**, both bilaterally and multilaterally, for joint regulatory assessment of new products and for regulatory strengthening

5) **Develop a detailed work plan and budget for prioritized actions**

6) **Explore potential sources of funding / support** for implementation of actions

Meeting Outcomes

Innovative regulatory strategies are set in motion to accelerate access to life-saving public health commodities (in particular medicines and diagnostics) for malaria elimination, specifically *P. vivax* malaria. One of the outcomes of the meeting should be an engagement strategy with appropriate ministries to work toward bi/multilateral agreements that facilitate regulatory cooperation to facilitate and accelerate access.

Participants to be invited should encompass a number of stakeholders, including:

a) **Medicines Regulators**: Therapeutic Goods Administration of the Department of Health (TGA) of Australia, Drug Control Authority of Malaysia, and National Medicines Regulatory Agencies of countries with high vivax malaria burden, including India, Indonesia, Myanmar, Thailand, Cambodia, Lao PDR, Vietnam, Papua New Guinea and Solomon Islands.
Regional and technical organizations: the ADB, Douglas, ASEAN Consultative Committee for Standards and Quality (ACCSQ) Pharmaceutical Product Working Group, WHO (including HQ, SEARO, WPRO), CoRE (Centre of Regulatory Excellence) Singapore, Medicines for Malaria Venture, PATH (and other directly relevant Product Development Partnerships working on vivax malaria technologies)
Appendix 4

Agenda:

Day ‘0’: 3:00-5:30 pm, March 30, 2016:

i) Pre-meeting for planning the conference, breakout sessions and fine tuning the agenda to be conducted jointly with Thai FDA, TGA, DCA (Malaysia), CoRE, MMV, PATH, WHO, ADB and APLMA.

Day 1: March 31, 2016:

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Potential Presenters (TBD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30-9:00am</td>
<td>Registration</td>
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<tr>
<td>9:00-9:30</td>
<td>Welcome remarks</td>
<td>Ben Rolfe, Executive Secretary APLMA</td>
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<td>Boonchai Somboonsook, Secretary General, Head of the Thailand Food and Drug Administration</td>
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<td>John Skerritt, Deputy Secretary, Department of Health, Australia.</td>
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<td>Raj Long, Senior Regulatory Specialist, Gates Foundation</td>
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<td></td>
<td>Douglas Ball, Consultant, Asian Development Bank</td>
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<tr>
<td>9:30-9:45</td>
<td>Overview of partnership concept and meeting objectives</td>
<td>Paul Lalvani, Senior Technical Advisor, Access to Quality Medicines</td>
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<tr>
<td>9.45-10:15</td>
<td>Overview of malaria in Asia Pacific: elimination efforts, drug resistance, public health challenge, main antimalarial technologies, with a focus on P. vivax</td>
<td>Chansuda Wongsrichanalai, WHO Malaria Specialist</td>
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<tr>
<td>10:15-10:35</td>
<td>Overview of ASEAN Regulatory Convergence activities</td>
<td>Dato’ Eisah Binti A Rahman, Senior Director, Drugs Control Authority, Ministry of Health, Malaysia</td>
</tr>
<tr>
<td>10:35-11:00</td>
<td>Summary of APLMA Access to Medicines Taskforce Regulators Working Group on Malaria report 2014 and key regulatory barriers</td>
<td>John Skerritt, Deputy Secretary, Department of Health, Australia.</td>
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<tr>
<td>11:00-11:15</td>
<td>Coffee break</td>
<td>N/A</td>
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<tr>
<td>11:15-12:15</td>
<td>Overview of case studies and models on joint regulatory collaboration (including regional efforts underway by ASEAN, ADB and others)</td>
<td>Milan Smid / Samvel Azatyan, Prequalification and Regulation of Medicines and Health products at WHO</td>
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<tr>
<td>Time</td>
<td>Session</td>
<td>Presenter</td>
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<tr>
<td>12:15-12:30</td>
<td>Centre of Regulatory Excellence (CoRE) role in regional capacity development and collaborative partnerships</td>
<td>John Lim, Executive Director, CoRE</td>
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<td>12:30-1:30</td>
<td>Lunch</td>
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<tr>
<td>1:30-2:30</td>
<td>Focus on vivax malaria</td>
<td>Stephan Duparc, Chief Medical Officer, MMV</td>
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<tr>
<td></td>
<td>• Background and challenges and importance of adding <em>P. vivax</em> as a priority</td>
<td>Nick Luter, Head of Market Access, PATH</td>
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<td></td>
<td>• The <em>P. vivax</em> pipeline and status of development</td>
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<td></td>
<td>o Medicines for <em>P. vivax</em></td>
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<td></td>
<td>o Diagnostics for <em>P. vivax</em> related tests (G6PD)</td>
<td>Chansuda Wongsrichanalai, WHO Malaria Specialist</td>
</tr>
<tr>
<td>2:30-4:00</td>
<td>Small group discussions on market authorization and accelerated review of priority products with applicability to vivax medicines and diagnostics</td>
<td><strong>Group 1</strong>: Boonchai Somboonsook, Secretary General, Head of the Thailand Food and Drug Administration and Michael Wiseman (TGA)</td>
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<td><strong>Group 2</strong>: Dato’ Eisah Binti A Rahman, Senior Director, Drugs Control Authority, Ministry of Health, Malaysia and Milan Smid (WHO PQ)</td>
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<td>4:00-4:15</td>
<td>Coffee break</td>
<td>N/A</td>
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<tr>
<td>4:15-5:00</td>
<td>Report back to plenary on small group sessions and priority interventions discussed</td>
<td>Co-chairs from Day 1</td>
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<td>5:00-7:00</td>
<td>Break</td>
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<tr>
<td>7:00-9:00</td>
<td>Cocktail reception (Venue to be announced)</td>
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</table>

**Day 2: April 1, 2016:**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:00-9:15</td>
<td>Session opening – agenda and objectives for the day</td>
<td>Paul Lalvani, Senior Technical Advisor, Access to Quality Medicines APLMA</td>
</tr>
<tr>
<td>9:15-11:30</td>
<td>Working session to explore architecture for collaboration between regional regulators, WHO and technical organizations on ideas discussed on day 1</td>
<td><strong>Group 1</strong>: Harry Rothenfluh (TGA) and Regulator from Indonesia (TBC)</td>
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<td><strong>Group 2</strong>: Dato’ Eisah Binti A Rahman, Senior Director, Drugs Control Authority, Ministry of Health, Malaysia and John Lim, Executive Director (CORE)</td>
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<tr>
<td>Time</td>
<td>Sessiondetails</td>
<td>Facilitator, Institution</td>
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<tr>
<td>11:30-11:45</td>
<td>Coffee Break</td>
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</tr>
<tr>
<td>11:45-12:45</td>
<td>Plenary session for reporting back on discussions</td>
<td>Co-Chairs from Day 2</td>
</tr>
<tr>
<td>12:45-1:45</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td>1:45-2:30</td>
<td>Round up: Overview of key discussion points and recommendations</td>
<td>John Skerritt, Deputy Secretary, Department of Health, Australia</td>
</tr>
<tr>
<td>2:30-5:30*</td>
<td>Discussions on leadership, architecture and next steps</td>
<td>Raj Long, Senior Regulatory Officer, Gates Foundation</td>
</tr>
<tr>
<td></td>
<td>• Leadership</td>
<td>Dato’ Eisah Binti A Rahman, Senior Director, Drugs Control Authority, Ministry of Health, Malaysia</td>
</tr>
<tr>
<td></td>
<td>• Governance</td>
<td>Milan Smid, Group Lead, Technical Assistance and Laboratory Services, WHO</td>
</tr>
<tr>
<td></td>
<td>• Commitments and declaration</td>
<td>John Skerritt, Deputy Secretary, Department of Health, Australia</td>
</tr>
<tr>
<td></td>
<td>• Priority areas for future investigation and work plan</td>
<td>Ben Rolfe, Executive Secretary, APLMA</td>
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<tr>
<td></td>
<td>• Budget and funding</td>
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<td></td>
<td>• Planning for next meeting</td>
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</tr>
</tbody>
</table>

* Coffee Break has been planned during 3:45 – 4:00 pm

**Day ‘3’: 9:30-12:00, April 2, 2016:**

i) The post-conference discussions (debrief) for assessing the outcomes of the meeting and planning for the next steps to be conducted jointly with Thai FDA, TGA, DCA (Malaysia), CoRE, MMV, PATH, WHO, ADB and APLMA.
Appendix 5

Country Malaria Profiles (WMR 2015):

Country malaria profiles from the WHO World Malaria Report 2015 can be accessed via Dropbox here.
Appendix 6

Presentations:

All meeting presentations can be accessed via Dropbox here.
Appendix: 7

Breakout sessions plan:

Day 1: 31 March 2016

Session 1: Market authorization and accelerated review of priority products with applicability to vivax medicines and diagnostics

Objective: To carry out interactive and effective group discussions between regulators and partners/donors.

Participants: The participants were divided into two groups headed by the following:

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
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</thead>
<tbody>
<tr>
<td>Boonchai Somboonsook (Thai FDA)</td>
<td>Eisah Binti A Rahman (Malaysia)</td>
</tr>
<tr>
<td>Michael Wiseman (TGA)</td>
<td>Milan Smid (WHO HQ)</td>
</tr>
</tbody>
</table>

Day 2: 1 April 2016

Session 2: Session to explore architecture for collaboration between regional regulators, WHO and technical organizations

Objective: To carry out interactive and effective group discussions between regulators and partners/donors.

Participants: The participants were divided into two groups headed by the following:

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harry Rothenfluh (TGA)</td>
<td>Dato’ Eisah Binti A Rahman (Malaysia)</td>
</tr>
<tr>
<td>Chansuda Wongsrichanalai (WHO WPRO)</td>
<td>John Lim (CoRE)</td>
</tr>
</tbody>
</table>
Appendix 8

List of Pre-Reads:

1. Asia Pacific Leaders Malaria Alliance Malaria Elimination Roadmap, October 26, 2015

2. APLMA Malaria Elimination Roadmap: Methodology and Background for Access to Quality Medicines


4. Regulatory framework for access to safe, effective quality medicines, Lembit Rägo, Hiiti Sillo, Ellen ‘t Hoen, Monika Zweygarth, Antiviral Therapy 2014