Terms of Reference

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Introduction

Mosquitoes are considered the deadliest creatures on the planet - responsible for transmitting more than 17% of all infectious diseases,[1] and killing over 700,000 people a year through vector-borne diseases such as malaria and dengue.[2] A large proportion of this disease falls in the Asia Pacific region.[4] Among the 3.9 billion people at the risk of dengue, more than 75% reside in Asia Pacific.[5] Despite the progress made towards malaria control and elimination in the region, over 300 million people still to remain at risk.

Vector control tools (VC tools) are pivotal to the control and elimination of vector-borne diseases. They also have one of the highest returns on investment in public health. Vector control has taken an increasing share of investment within the neglected tropical disease portfolio[6], with funding for research and development (R&D) in vector control increasing from 35 million USD in 2017 to 56 million in 2018.[7]

Improved vector control is critical to eliminating malaria by 2030, consistent with the 2014 East Asia Summit commitment from leaders from 22 countries. While the malaria burden in Asia Pacific continues to fall, coverage to prevent transmission is a vital element of the 'last mile' effort. Malaria elimination in Asia Pacific will only be possible with the improved availability of, and accessibility to, existing and innovative VC tools that effectively reduce transmission, prevent resurgence and adequately respond to region-specific challenges.

Access to VC tools is also critical in other, non-elimination settings, such as Humanitarian Emergency settings, and are increasingly relevant in the current context of the COVID-19 pandemic. VC tools will also become more important in the future, considering climate change, possible changes in monsoon seasons, rising floods, and increased risk of Internally Displaced Persons and Refugees living in precarious conditions in zones prone to vector-borne diseases.

Overview of vector control landscape in Asia Pacific

Despite the gains achieved with cost-effective vector control interventions, multiple factors threaten future progress. In addition to the global challenges, Asia Pacific has its own set of region-specific challenges including social, behavioural and environmental factors that affect vector borne disease transmission risk.

Chief among these threats are insecticide resistance and residual transmission (including outdoor transmission). VC tools that have been tested and tried in Africa are not necessarily adaptable for the Asia Pacific region where the diversity of vectors and vector ecologies are greater. The tools that are currently available will not be sufficient to enable Asia Pacific countries to eliminate malaria and other vector borne diseases. New tools to prevent outdoor biting are also needed to protect forest workers and others who spend time working, but not necessarily sleeping in the forest, and therefore cannot use existing VC products effectively.

In addition to the technical challenges to effectively control vector borne diseases, policy and regulatory barriers have been consistently identified as barriers to the approval and introduction of new vector control tools in the region.[8] Given that vector control regulators in Asia Pacific often sit under the Ministry

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[1] World Health Organization

[2] World Health Organization, Global Vector Control Response, 2017-2030

[4] World Health Organization

[5] World Health Organization

[6] World Health Organization, Investing to overcome the global impact of Neglected Tropical Diseases, 2015

[7] World Health Organization, World Malaria Report 2019

[8] Raised by experts of the Asia Pacific Malaria Elimination Network Vector Control Working Group (APMEN VCWG), participants in the first consultative meetings of the VCAP platform, and the Innovative Vector Control Consortium (IVCC) landscaping team.

of Agriculture or Environment, rather than the Ministry of Health, public health VC tools may be evaluated under the framework for evaluation of agricultural pesticides. There are few examples of effective inter-ministerial collaboration for the registration and management of VC tools for public health use.

The pathways to scaling access to existing VC tools and introducing new ones, including through regulatory processes, are complex, lengthy and costly in many countries in Asia Pacific, as reported in the IVCC Market Access & Regulatory Landscape studies. In the Association of Southeast Asian Nations (ASEAN) alone, there are eight different registration schemes, and no examples of regional harmonised procedures for VC tools, even though relevant procedures exist for medicines.[10] Experts and industry partners have also noted the lack of transparency in regulatory pathways in some countries[11] including: i) disparity across the region, causing industry to navigate multiple pathways; ii) slow processes due to volume of reviews and the lack of any fast-track mechanism for products with public health benefits; and iii) lack of alignment with global best practices such as WHO PQ processes. Moreover, there is limited visibility for key decision makers and influencers in the regulatory process, including Director Generals of Ministries of Health or Agriculture, as country-specific focal points within regulatory bodies in Asia Pacific, which makes it challenging for manufacturers, disease program leaders, and global health partners to advocate to streamline regulatory reviews.

The global vector control technology landscape is expanding with several new tools becoming available, and a dynamic pipeline of products in the R&D phase. With decreasing numbers of malaria cases in many countries, industry needs to sustain engagement in development of new tools to control and eliminate vector-borne diseases. The cost and time required to map and navigate country specific regulatory pathways may act as a disincentive for manufacturers to innovate. There are numerous benefits to streamlining the regulation of VC tools in Asia Pacific, as the market potential is greater if addressed at a regional level, rather than country-specific level. In addition, regionally consistent regulatory processes will reduce time and cost of registering new products. Engagement with disease program leaders may help regulators understand the benefits of timelier introduction of pesticides for public health use.

In response to the challenges outlined here, Unitaid and the Asia Pacific Leaders Malaria Alliance (APLMA) have partnered[13] to support efforts to improve access to VC tools tailored to the Asia Pacific context. More broadly, the partnership supports regional cooperation to improve health security, reduce the burden of vector borne diseases and eliminate malaria in Asia Pacific.

A summary of identified policy and regulatory challenges and an overview of proposed strategies and VCAP platform activities to respond to these challenges is available as Annex 1.

Background to VCAP

During the July 2017 APMEN VCWG meeting[14], national malaria program leaders and other participants identified the need for a leaders' organisation to engage senior officials in advocacy efforts to raise

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[10] Through platforms such as Regulatory Regional Partnership for Malaria Elimination, regulatory authorities for medicines and diagnostic devices in the nine Asia Pacific countries came together with disease programs and global health partners to review progress, discuss challenges, and set priority actions towards strengthening regulatory capacity for antimalarial medicines and diagnostic devices. The partnership harnessed the expertise of stakeholders in the regulation of medical products and leveraged technical assistance initiatives to expedite introduction of existing and new priority malaria treatments and diagnostic tests in the Asia Pacific market. The partnership was the springboard for the Regulatory Strengthening Program through which Australian Therapeutic Goods Administration builds regulatory capacity in 6 Asia Pacific countries.

[11] Statements gathered during the January 2018 consultation of manufacturers, disease programs and vector control experts in Bangkok, a consultation co-hosted by the Asia Pacific Leaders Malaria Alliance and UNITAID.

[13] MoU signed January 2018

[14] Asia Pacific Malaria Elimination Network Vector Control Working Group Meeting, Bangkok, July 12-14th 2017

awareness of, and commitment to, policy challenges related to vector control. A statement of action was issued to APLMA to take this forward (see Annex 2).

As a first step, a joint Unitaid and APLMA meeting on "Innovation and Access for Vector Control Tools" was held in Bangkok in January 2018 during the Prince Mahidol Award Conference (PMAC). The meeting was an opportunity to review challenges to VC in the Asia Pacific region including insecticide resistance and specific behaviour patterns of populations at risk, and to review potential solutions to these challenges from the perspective of leveraging senior officials to influence policy decision. Participants from industry, academia, Ministries of Health and global health organisations agreed that an ongoing, coordinated, and cross-sectoral approach, which involves engagement and advocacy with ministries beyond the Ministry of Health was essential to improving access to innovative VC tools adapted to the Asia Pacific context.

Improved information sharing on policy and regulatory challenges for VC tools, and better links to global evaluation processes and initiatives were identified as key needs. As an outcome of this meeting, Unitaid and APLMA proposed to jointly establish the Access to VC tools for the Asia Pacific region (Vector Control for Asia Pacific or VCAP) platform to complement the work of the APMEN VCWG and other VC research and programming initiatives by bridging technical recommendations with senior official influence, as well as policy and regulatory solutions.

The initial proposal for VCAP was developed in consultation with multiple stakeholders including APMEN, the World Health Organization, disease programs and regulators from Thailand, Lao PDR and Myanmar, the Innovative Vector Control Consortium and Innovation to Impact. Subsequently, VCAP was launched at the Malaria World Congress in Melbourne on the 2nd of July 2018.

Goal and Objectives of the Platform

The overarching goal of VCAP is to **support malaria elimination by 2030 in the Asia Pacific by accelerating the introduction and adoption of innovative VC tools**. VCAP supports efforts to accelerate the introduction of innovative VC tools with the potential to prevent malaria as well as other vector borne diseases such as dengue. The VCAP platform focuses on activities to achieve the stated objective, based on target audience needs. However, the platform will also be dynamic and able to adapt to new challenges and priorities over time.

Objectives

1. Increase timeliness of decision-making by policy makers on introduction of new VC tools
2. Identify opportunities to streamline regulatory pathways for introduction of VC products
3. Increase focus of manufacturer product introduction strategies on Asia Pacific countries

To achieve these objectives, VCAP will:

- Identify advocacy priorities, and design and implement advocacy strategies, to support the accelerated regulatory approval of VC tools in specific countries;
- Bring together senior officials, regulators of VC tools and disease program leaders in Asia Pacific on the same platform to discuss regulatory pathways, share best practices and existing challenges;
- Offer an entry point for global partners and partnerships to liaise with policy makers, regional and national stakeholders in the VC space in Asia Pacific and vice-versa;
- Identify opportunities for vector control regulators across the region to streamline and strengthen regulatory processes to facilitate the expedited review and introduction of VC tools;
- Share information with different stakeholders to address current information gaps acting as barriers to product introduction. As elaborated in Annex 1, for manufacturers a critical gap may be limited information on regulatory pathways in different countries; for regulators a critical gap

- may be limited information on best practices for VC dossier review; for policy makers a gap may be limited visibility on pipeline or on products are already available;
- Translate available data and research findings on VC tools into key messages for policy makers- to support accelerated decision making;
- Create awareness among senior officials, regulators and disease programs on the need for sustained vector control interventions, including in times of crisis or emergencies.

The list of proposed VCAP activities for period 2019-2020 can be found in Annex 3.

Expected outcomes and impact

The expected outcomes for the VCAP platform are:

- Increased collaboration among key stakeholders (Senior Officials, regulators of VC products and disease programs) for the introduction of VC tools in countries;
- Formation of a community of practice around the regulation of VC tools in the region;
- Increased awareness of challenges and best practices on the regulation pathways for VC tools;
- Increased efficiency in decision making due to better access to targeted information on new and existing VC products.

The expected impacts[17] of the VCAP platform are:

- Streamlined/consistent regulatory practices in the region;
- Shorter timelines for registration of new VC products;
- Faster policy adoption of new tools by the disease programs.

VCAP will conduct an annual survey with key stakeholders to evaluate the impact of the platforms' activities and refine the strategy and workplan of the platform going forward.

VCAP Scope of Work

Facilitating dialogue

The platform will facilitate active dialogues between VCAP stakeholders by convening side meetings at existing events e.g. the APMEN VCWG meetings, APLMA Senior Officials Meetings, the Prince Mahidol Award Conference, the Asia Pacific Conference on Public Health. VCAP meetings offer options for increased convergence and communication between regulators and work sharing across countries to facilitate the introduction of tools. VCAP will also convene events and moderate targeted discussions virtually, through online platforms, which will allow access to a wider array of participants.

Engaging Senior Officials

In line with APLMA's mandate to engage with leadership beyond health ministries,[19] VCAP will engage in policy level discussions with Ministries of Health, as well as agriculture, the environment, commerce or finance. VCAP will identify concrete messages to take forward, with the help of experts in the field. These targeted advocacy activities aim to contribute to a more enabling environment[20] for vector-borne disease elimination, with clearer registration pathways, identified contact points in relevant authorities, more streamlined decision-making processes, and more support for the introduction of innovations at senior official level.

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[17] These are not directly attributable to VCAP but is dependent on achievement of the intermediate impact

[19] APLMA engages with ministries of health, finance and interior in support of disease elimination efforts and strengthening of health systems.

[20] Clearer regulatory pathways, reduced timelines for introduction of vector control tools

Information sharing with target audiences

VCAP aims to fill recognised information gaps with specific target audience such as:

- Information on existing and new VC tools, approaches and categories that are of relevance to Asia Pacific- with Senior Official, disease programs and VC regulators;
- Best practices for the policy introduction of VC tools through case studies on regulatory pathways, with regulators of VC products;
- Information on regulatory pathways in countries - to inform manufacturers;
- Key messages from the region, with global health partners to feed into their advocacy efforts.

The information will be shared either through the website, webinars or in-person meetings. The list of proposed webinars can be found at Annex 4.

Engagement strategies

Past

1. Global Launch at Malaria World Congress [July 2018]
2. Regional Launch APMEN VCWG and signup sheet, with break out session at APMEN VCWG to identify priorities to take forward to policy level [September 3-5th 2018 in Bangkok]
3. Engagement with manufacturers of VC tools at WEF Asia in Hanoi [September 11-13th]
4. First side-meeting of the VCAP platform at the APLMA / APMEN Malaria Week [April 2019 in Bangkok]
5. A focussed VCAP workshop with VC regulators and disease programs in conjunction with WHO Workshop on Pre-qualification process [November 2019 in Hanoi]

Future

6. Launch of VCAP Website and Membership [July 2020, online]
7. First VCAP webinar [July 2020, online]

Steering Committee

The VCAP steering committee (SC) oversees the strategic direction and progress of VCAP Including the scope of work and specific activities for that platform. The current members of this steering committee are: APMEN, APMEN VCWG, UNITAID, APLMA, UCSF, MoH Malaysia, BVBD Thailand, Thai Regulators (TFDA), WHO WPRO/ GMP, WHO PQ for VC, IVCC, I2I, BMGF, DFAT, USAID PMI, GFATM, Bayer Crop, Sumitomo Chemical, and Welltech Healthcare. In addition to the Thai regulator, VCAP will invite two more countries to join the Steering Committee in 2020: Malaysia, Viet Nam and/or India. VCAP scope of work will be informed and updated as we go along by the VCAP Steering Committee.

Linkages with other initiatives

APMEN Vector Control Working Group (VCWG)

Policy issues that are identified by vector control experts during VCWG meetings, are brought forward to VCAP. APMEN VCWG members also help to identify advocacy priorities for VCAP. The need to support the accelerated introduction of new and existing tools was largely informed by APMEN experts' advice.

In addition, VCAP bridges technical recommendations from the APMEN VCWG with leadership influence and policy solutions at the regulatory and ministerial level. VCAP provides a platform to identify common and more efficient pathways to register new tools, while APMEN helps with training disease programs on vector control. VCAP provides visibility on the pipeline of tools, based on the evidence from APMEN on the needs of programs and efficacy of available tools.

Indo Pacific Initiative

Australian Government's Indo-Pacific Centre for Health Security, part of the Department of Foreign Affairs and Trade (DFAT), awarded IVCC a 5-year grant for the development of a vector control product toolbox for the Indo-Pacific Region. As a part of this project, IVCC conducted landscaping studies in the region – to map technical gaps for vector control, evaluate regulatory pathways and explore market access routes. VCAP translates information from the technical landscaping studies into high level summaries best adapted for target audiences to increase visibility of the VC toolbox and clarify how these tools will support health security and elimination targets. VCAP elaborates on the findings from the regulatory landscaping studies and facilitates discussions between regulators and disease programs to identify solutions to access bottlenecks. For example, the November 2019 VCAP Workshop led by the WHO Pre-qualification team provided an opportunity to engage regulators and disease program leaders to discuss the findings of the landscaping studies.

This is an active document that will be revised regularly to adapt to the Networks' needs and demands

Annex 1: Summary of identified challenges and an overview of proposed strategies

Identified policy issues and gaps	Proposed solution	Activities
Regulatory issues		
In-country registration processes are often complex, costly and bureaucratic leading to unnecessary delays for VC products to reach communities that need them most. Source: Consultation January 2018; VCAP partner meeting September 2018; VCAP members survey.	Targeted outreach to Ministries of Health and Agriculture with a specific ask on procedural and/or legislative change to facilitate better enabling environment for access to VC tools. Countries targeted in 2020: India and Cambodia.	Outreach to the Indian Parliamentarians Network for Malaria and Ministry of Agriculture in India. - Written commentary co-authored with IHF - Call to action shared through the Indian Parliamentarians Network to streamline process for introduction of VC tools Outreach to Ministry of Health, Agriculture and Interior in Cambodia - Share Policy Roadmap for VC tools addressing outdoor biting among forest goers. - Highlight best practices from other countries on pathways for introduction of VC tools.
Pathways for new VC tools to access market are unclear. There is limited information on registration processes for VC tools in Asia Pacific countries This is a specific barrier for manufacturers which may lead to delay in regulatory submission or even no submission. There is also limited oversight among global health community on which authorities are responsible for registration of VC tools Source: VCAP members survey	Identify regulatory bodies responsible for the introduction of VC tools across Asia Pacific, within Ministries of Health/Agriculture or environment Targeted information sharing among manufacturers of VC tools on regulatory pathways	. Facilitate the exchange of information on registration pathways for Asia Pacific countries between VCAP members through meetings, online webinars, and online forum discussion boards. The website will list departments responsible for regulation of VC tools in different countries. In addition, with permission, the VCAP will list contact details of focal points within these regulatory bodies, which can be accessed only by VCAP members
Regulation of VC tools in the region is fragmented, with a lack of harmonized	Identify possible collaborative registration processes; promote benefits	Facilitate targeted information sharing (through Webinars and VCAP meetings) about collaborative registration processes from other regions or

regulatory processes for VC tools. This acts as a disincentive for innovators to target the Asia Pacific market. Source: IVCC regulatory landscape study	of harmonized regulatory pathways among regulatory authorities; broker partnerships between regulatory authorities and regional bodies that work on regulatory convergence. Advocate for greater consistency of approaches between different regulatory bodies in the region	other health commodity categories to a network of regulators, disease programs and manufacturers in Asia Pacific. e.g. joint regulatory reviews of new tools, harmonization of ASEAN regulation scheme. Outreach to ASEAN as a regional body working on regulatory convergence for health commodities including pesticides to identify options for convergence of regulatory practices in the region. Convene a network of stakeholders to facilitate work-sharing, the cross-border exchange of policy best-practices (Examples of Brest practices include; reliance on trial data generated by neighboring countries with similar epidemiological and entomological background; reliance on regional trial data. Develop case studies to outline regulatory pathways for VC tools in AP countries, share best practices that can be adapted by other countries. First case studies are on Thailand and Malaysia. Case studies are shared through meetings, webinars and the VCAP website.
Public health pesticides are evaluated with the same lens as are agricultural pesticides Source: IVCC regulatory landscape study	Evaluation of public health pesticides, specifically those to be used in mass distribution under malaria programs, should be prioritized.	One of VCAPs key advocacy messages for regulators, specifically in malaria endemic countries- will be to accord priority review to vector control products
VC regulators require more clarity on the WHO pre-qualification process to inform their own review processes. Source: IVCC regulatory landscape study; VCAP members survey.	Support WHO PQ team in disseminating information on their processes- to regulators in the region	VCAP facilitated a workshop by WHO for regulators in the region in November 2019. WHO shared information on the WHO Prequalification (PQ) process to regulators in the region. The website also has a short section on the WHO PQ process- which is linked to the WHO webpage for further reading. As per the needs expressed by the regulator, VCAP will facilitate workshops/webinars with trainings being delivered by WHO PQ team on safety, efficacy and risk assessments

Regulatory coordination challenges		
Limited peer-to-peer interactions and discussions between regulators of VC tools in the Asia Pacific region. This leads to a greater variety in regulatory processes in the region, limited sharing of best practices, little or no collaboration between regulators. Source: VCAP partner meeting September 2018	Facilitate a network of regulators, building on the findings of the IVCC regulatory landscaping study.	VCAP meetings provide a platform for network of regulators to interaction; get to know each other and exchange expertise on regulatory pathways. VCAP website provides a password protected forum which can be accessed by regulators in the region to discuss regulatory processes. VCAP website offers a members list with contact details of the relevant bodies responsible for the registration of VC tools in each country.
Need for more inter-ministerial collaboration to facilitate better access to VC tools that can support health security. Source: VCAP partner meeting September 2018	Promote intersectoral collaboration between different ministries including Ministry of Health and Agriculture.	VCAP meetings brokers brings together representatives from different ministries- disease programs (Min of Health), VC regulators (who often sit under Min Agriculture/Min of Environment) and Senior Officials (eg. Min of Health/Min of Finance/Min of Foreign Affairs/ Min of Interior) to discuss policy challenges with respect to introduction of VC tools and to agree on activities to streamline regulatory pathways Case Studies (e.g. on Thailand) highlights successful mechanisms for a whole of government approach to effect VC regulation
Need to increase the sense of urgency around the introduction of relevant VC tools to prevent transmission and contribute to the 2030 malaria elimination goal Source: VCAP partner meeting September 2018	Leverage APLMA's engagement with Senior Officials in the region to create a sense of urgency on the importance of better access to VC tools to support progress towards the 2030 elimination goal.	VCAP facilitates and contributes to targeted consultations with senior policy makers to highlight the importance of expedited introduction to priority VC products in the region to reach the 2030 malaria elimination goal. Policy Roadmaps are developed as an advocacy tool to highlight key processes for the introduction of VC tools, showing how an expedited review of these tools maps against elimination timelines and can accelerate progress.
Innovation gaps		
Need for better adapted tools to address the rising insecticide resistance and outdoor biting challenge in Asia Pacific.	Repackage information for senior officials to clearly explain what existing and new tools are relevant for the Asia Pacific region, what their purpose is, how they can help address outdoor biting and	VCAP facilitates targeted information sharing on new and existing products through VCAP meetings, online VCAP webinars, and the VCAP website. The Products page on the website highlights tools which can address challenges such as insecticide resistance and outdoor biting.

Need for tools that are better adapted for the main risk groups in Asia Pacific which are "mobile and migrant" and include forest goers, construction and mine workers, security personnel, border crossers, seasonal workers. Information on existing and new VC tools is disparate, hard to locate, and too technical for a non-specialist audience. High level information required on what tools already exist and what purpose for advancing health security in the region Source: Consultation meeting in January 2018; VCAP partner meeting September 2018; VCAP members survey, IVCC Technical Landscape study	insecticide resistance, and therefore contribute to the malaria elimination goal.	The products page will contain high level information on i) tools which are available/ registered for use in the region (both WHO PQ-listed and non PQ-listed) ii) tools which are already available in the market but not registered for use in any Asia Pacific country (only WHO PQ listed products) A webinar is being developed as part of *Malaria Gamechangers: a Health Innovation Series*, to discuss with and inform Senior Officials, regulators and disease programs on these new game-changing tools.

Annex 2: Statement by the APMEN Vector Control Working Group

Date: July 2017

Vector control in Asia Pacific

Participants to the Asia Pacific Malaria Elimination Network Vector Control Working Group (APMEN VCWG) meeting concur that the Asia Pacific Leaders Malaria Alliance (APLMA) has a key role to play as a high-level advocacy body to support vector control for the elimination of malaria by 2030 in Asia Pacific. APLMA is well positioned to relay the main message on the importance of vector control management, of Public Health entomology career pathways for sustainable surveillance and prevention of transmission and of improved targeting and access to vector control products. Two key recommendations arose out of the discussions during the APMEN VCWG meeting in Bangkok (July 12-14th 2017).

1. **Political commitment for entomology and vector control for malaria elimination and health security in Asia Pacific**

APLMA should advocate for greater political commitment for vector control for malaria elimination and health security. A cogent argument to support this advocacy is evidenced through countries that have successfully eliminated malaria in the region, such as Sri Lanka. These countries have Malaria Control Programs that are underpinned by strong vector control and entomology programs. The prevention of transmission, particularly among vulnerable populations such as mobile migrant populations in the Greater Mekong Sub-region, is a crucial component of the roadmap to elimination. Entomological surveillance is as important as disease surveillance within country and regional malaria elimination plans. A key to robust entomology programs is the training, recruitment and retention of entomologists within Public Health divisions or departments. The following international guidelines and frameworks support advocating for strengthened vector control programs:

- o   WHO Global Technical Strategy for malaria elimination[21]
- o   The Sustainable Development Goals[22] for strengthening health systems / access for MMPs
- o   The WHO Global Vector Control Response[23].
- o   The Regional Action Frameworks for malaria control and elimination[24] (WPRO and SEARO) e.g. WPRO framework objective 2.1 on interrupting transmission in resistance areas.
- o   WHO Guidance Note on Capacity Building in Malaria Entomology and Vector Control[25].

Beyond malaria elimination, APLMA should also advocate for a sustained integrated vector management approach to support regional health security against emerging and re-emerging vector borne diseases including Zika, chikungunya and dengue. This is particularly relevant in countries where dengue and chikungunya cause great economic and health burden and are high on the political agenda. Through the health security lens, it is also possible to engage with the Ministries of Defence and security forces who are often exposed to malaria in forested border areas[26].

2. **Improved access to Asia-specific vector control tools in Asia Pacific**

Vector control products have one of the highest returns on investment in public health. APLMA should advocate for equitable access to preventive health services, including vector control tools for vulnerable populations, within a framework of Universal Health Coverage (UHC). The first step is ensuring access to

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[21] http://www.who.int/malaria/areas/global_technical_strategy/en/
[22] http://www.un.org/sustainabledevelopment/sustainable-development-goals/
[23] http://www.who.int/malaria/global-vector-control-response/en/
[24] http://www.wpro.who.int/mvp/documents/mal_raf_2016/en/
[25] http://www.who.int/malaria/publications/atoz/who_guidance_capacity_building_entomology.pdf
[26] Note: Armed forces present in forest areas can also support in the delivery of services and commodities to hard to reach populations, through their available infrastructure

relevant vector control tools that meet the needs of populations and ensuring timely registration of the product for use in country.

    a.   Registration

Participants note the need to identify and to address the main bottlenecks and to strengthen regulatory systems to allow for faster access to WHO pre-qualified, quality vector control products in the Asia Pacific. APLMA should engage vector control product regulators and National Malaria Control Programs (NMCP) to promote understanding of the needs and priorities for these products. APLMA should also advocate for the harmonisation of national regulatory processes in the Asia Pacific to facilitate accelerated registration of WHO pre-qualified vector control products needed for malaria elimination. APLMA should support key partners in this space including the World Health Organisation Regulatory Systems Strengthening team.

    b.   Innovation

Participants to the APMEN VCWG note the discrepancy between user preferences and the vector control tools available on the market. Current tools are ill-adapted to the South-East Asia context, particularly to the communities most affected by malaria in the region i.e. the forest goers, working at night, living and sleeping outdoors and therefore exposed to outdoor biting. There is a need for Asia-specific vector control tools adapted to the human behaviour and shelter ecology of vulnerable and at-risk populations. APLMA has a role in guiding and advocating for better adapted vector control tools that match user preferences. APLMA can also advocate at the country and regional level for the need to devote resources for research and development of better adapted vector control tools for Asia Pacific. APLMA should facilitate partnerships between academia and the private sector to support the development of better adapted tools.

APLMA may reach out to the following ministries in relation to vector control:

- *Ministries of Health e.g. statement to promote public health entomology as a career pathway for sustainable integrated vector management.*

- *Ministries of Agriculture e.g. on aggregating mapping data of plantations/ transmission zones and to facilitate streamlined pesticide registration.*

- *Ministries of Education e.g. to promote entomology as a training pathway*

- *Ministries of Public Works e.g. to encourage collaboration with private sector, companies hiring temporary workers, for infrastructure projects in areas of high transmission.*

- *Ministries of Finance e.g. to advocate for the reduction of taxes and tariffs for vector control products and for the "positive return on investment" for vector control for both malaria and for Aedes-borne diseases.*

Malaria Week and the Ministerial Meeting in December 2018 is one platform at which to raise the importance of vector control.

Annex 3: VCAP Activities 2019-2020

Network of Stakeholders for Access to VC tools

VCAP convenes a network of VC regulators as well as other VC stakeholders in Asia Pacific, with focal points for each country, to address policy regulatory bottlenecks for VC tools. Activities include;

- Identify collaborative registration processes that are relevant for the region. e.g. facilitating opportunities for joint regulatory reviews of new tools supporting the harmonization of ASEAN regulation scheme where possible.
- Collaboration with WHO PQ team to improve regulators' understanding of the evaluations conducted during the PQ process
- Facilitate targeted webinars on regulatory practices through online platforms, co-hosted by partner organisations and made available on the VCAP website (See Annex 3 for proposed Webinar topics)
- Develop regulatory pathway case studies: in consultation with regulators and VCAP SC members develop two case studies on pathways for the introduction of new VC tools (Thailand & Malaysia)
- Regulatory Action Plan: VCAP members review and prioritise challenges to the effective regulation of VC tools and agree on 2 priority activities to streamline regulatory pathways. As part of this exercise, relevant topics for webinars identified and prioritised for 2021.

Advocacy for the introduction of VC tools

VCAP facilitates targeted consultations with senior policy makers to highlight the importance of expedited regulatory approval , and subsequent introduction and use by disease programs for some of the priority VC products in the region.

- Priority 1: Regulation of VC tools in India: VCAP will engage with the Indian Parliamentary Network for malaria elimination and the Ministry of Agriculture (MoA) to discuss the importance of speeding up the introduction of urgent vector control tools in India- especially tools to address the rising challenges of insecticide resistance and outdoor biting among vulnerable populations. This advocacy activities will take the form of 1. A written commentary publishing in India with local partners 2. A brief for discussion among the parliamentary network 3. A bilateral meeting with the MoA requested through the parliamentary network. The message to Indian senior officials will highlight the delays in the process of registration as a missed opportunity to support India's progress to elimination. In collaboration with local partners in India, VCAP calls for specific policy changes to expedite the introduction of vector control tools.

Policy Roadmaps and Tracker are developed as advocacy tools targeting senior officials, to highlight key processes involved from production to use and to map the timelines for these processes against elimination timelines. The roadmaps will be used to advocate for better access to existing products as well as faster introduction of new types of products. As a continuation to the Asia Pacific landscaping studies, and in consultation with IVCC, findings from the studies and other country-specific evidence will be translated into the high-level Policy Roadmaps and accompanying Trackers for priority vector control products such as spatial repellents or insecticide treated clothing. The Roadmaps can be used for socialisation with senior officials including heads of regulatory authorities, through the VCAP platform.

- Priority 2: Roadmap and tracker for introducing new VC tools in Cambodia: to highlight the key advocacy issues and timelines relevant to accelerating the introduction of new VC tools. The roadmap provides a high-level overview of the policy and related processes leading to the efficient introduction of VC tools. The tracker developed will map the timelines for these processes against the country elimination timeline. The roadmap and the tracker will be jointly used to advocate with senior officials for the timely introduction of tools with potential to contribute to the elimination goal. The tools will be developed in consultation with multiple stakeholders and shared among the members of inter-ministerial National Task Force for malaria elimination in Cambodia.

VCAP website development and launch

The VCAP website is designed to complement VCAP meetings as a digital platform to facilitate:

- Increased interaction between VCAP members: The website includes an online discussion forum to facilitate regulator-to-regulator as well as regulator-to-national disease program manager dialogue- to improve alignment between regulators and disease program leads regarding prioritized insecticide products with potential public health benefits.
- Access to high level27 information on vector control tools for Asia Pacific: The website hosts high level information regarding currently available vector control products registered in the region, with clarity regarding the WHO PQ status and registration status in AP countries. Information on tools which are WHO PQ-listed and available in the global market, but not yet available in the region, is also shared through the website. The information provided focuses on how these products can support the 2030 malaria elimination goal.
- A webinar series: The website hosts webinar series for VCAP target audience on topics related to the main objectives of VCAP
- Sharing of case studies on best practices on regulatory pathways: Through case studies published on the website, best practices on regulatory pathways in AP countries are be shared with the VCAP members.

The VCAP website will be linked to sections within complementary websites or online materials produced by ORENE (the APMEN Vector Control Working Group website), IVCC, Innovation to Impact (i2i), WHO and manufacturers. The VCAP website is being developed and updated according to the availability of information, in line with confidentiality agreements and in collaboration with key stakeholders and the VCAP Steering Committee.

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[27] Information shared via VCAP is the key information pieces/resources relevant to addressing regulatory barriers to VC market introduction

Annex 4: List of proposed webinars

Purpose of the Regulatory Strengthening Activities

- Share expertise and best practices
- Streamline and harmonize regulatory processes
- Explore opportunities for joint review of products

Topics

1. **Why vector control matters to Public health and Disease Elimination:** An introductory Webinar targeting vector control regulators from outside of public health and the challenges of VB diseases in the region. Proposed topics for discussion:

   - Introduction to disease landscape
   - Importance of vector control tools
   - Remaining challenges- insecticide resistance, outdoor biting etc.
   - Need for new tools in the region
   - An opportunity to introduce the Webinar series that will follow

2. **VCAP website Launch and introduction to the VCAP Products Page:** A discussion on why it is important to look at products beyond bed nets/ IRS. Evidence backed by the IVCC technical landscaping report findings.

   - Focus 1: New and existing tools to address insecticide resistance
   - Focus 2: New and existing tools to address outdoor biting in AP
   - Focus 3: Novel tools to consider e.g. Insecticide paints or Insecticide Treated Materials (Malaysia)
   - Conclusion: What regulators, disease leaders and global health professionals can do to support accelerated introduction of these new tools?

3. **Expedited pathways for review and approval of innovation VCPs and regional collaborative mechanisms:** What can we learn from the drugs/ diagnostics world?

   - Focus 1: The SRA route: is there a waiver for SRA approved tools
   - Focus 2: The WHO Pre-Qualification route: examples of expedited registration processes for WHO PQ-ed tools
   - Focus 3: Examples of collaborative mechanisms from Africa (e.g. Zazibona/ EAC)
   - Focus 4: Fast tracking the introduction of a new tool: The Singapore NEA model
   - Focus 5: Collaborative registration procedures: ASEAN Harmonisation efforts and sharing and adapting lessons learned from SEARCH, SADC, CILSS in Africa to vector control in Asia Pacific

4. **Cross-agency collaboration for more effective regulation of VCPs for PH use:** Why collaboration with different ministries for vector control is important?

   - Focus 1: The Thailand example
   - Focus 2: Cross-ministerial expert committees or working groups for VC products

5. **Testing the validity of VCPs in Asia Pacific: Sharing expertise to speed up trials phase**

   - Focus 1: Benefits, costs and risks associated with local trials
   - Focus 2: Presentation on Malaysia case study (Focus on acceptance of regional trial data)
   - Focus 3: Case of Myanmar where due to the lack of efficacy testing facilities, reports of trials conducted following international protocols are accepted

- Discussion co-led with APMEN as a network to share expertise.

6. **Webinar on vector control projects in Asia Pacific**

- Project Bite by UCSF team
- IVCC's NATNAT programme in Papua New Guinea

7. **Workshop on risk and exposure assessments** [For regulators only]