Meeting Report

PACIFIC ISLAND MEETING ON SUBREGIONAL REGULATORY SYSTEMS FOR MEDICINES

28 February–1 March 2019

Suva, Fiji

World Health Organization
Western Pacific Region

Pacific Island Meeting on Subregional Regulatory Systems for Medicines
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WORLD HEALTH ORGANIZATION

REGIONAL OFFICE FOR THE WESTERN PACIFIC

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MEETING REPORT

PACIFIC ISLAND MEETING ON SUBREGIONAL REGULATORY SYSTEMS FOR MEDICINES

Convened by:

WORLD HEALTH ORGANIZATION
DIVISION OF PACIFIC TECHNICAL SUPPORT

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NOTE

The views expressed in this report are those of the participants of the Pacific Island Meeting on Subregional Regulatory Systems for Medicine and do not necessarily reflect the policies of the conveners.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for Member States in the Region and for those who participated in the Pacific Island Meeting on Subregional Regulatory Systems for Medicine in Suva, Fiji from 28 February to 1 March 2019.

CONTENTS

Keywords

Drugs, Essential – standards / Quality of health care / Universal coverage / Pacific islands

SUMMARY

In the Pacific, having an effective and functional regulatory system for medicines will ensure consistent access to safe and quality-assured essential medicines, vaccines and traditional medicines and will help achieve universal health coverage (UHC) and the Sustainable Development Goals.

A Pacific Island Meeting on Subregional Regulatory Systems for Medicines was held in Suva, Fiji from 28 February to 1 March 2019. The objectives of the meeting were:

(1) to present the findings of a feasibility study on regulatory cooperation to policy-makers and technical experts;

(2) to review concrete options for regulatory cooperation at country and subregional levels; and

(3) to consider short- and medium-term steps to support the possible establishment of a subregional platform for regulatory cooperation in the Pacific.

The meeting was attended by 27 representatives from 15 Pacific countries (Cook Islands, Fiji, Kiribati, the Marshall Islands, the Federated States of Micronesia, Nauru, Niue, Palau, Papua New Guinea, Samoa, Solomon Islands, Tokelau, Tonga, Tuvalu and Vanuatu). Representatives included two ministers of health, senior representatives from the ministries of health, and heads of the pharmacy departments responsible for the regulation of pharmaceuticals in their respective countries.

The meeting provided a forum for participants to discuss the results of a feasibility study and the proposed next steps to be undertaken jointly. Participants acknowledged the threat of antimicrobial resistance and other challenges faced in ensuring access to quality-assured, safe and affordable medicines and medical products as a foundation to achieve UHC. Participants confirmed the need to strengthen the national regulatory systems, including developing legislation and setting up structures to implement and enforce regulations, and agreed to consider using a subregional platform for regulatory cooperation in the Pacific.

1. INTRODUCTION

1.1 Meeting organization

In the Pacific, having an effective and functional pharmaceutical regulatory system will ensure consistent access to safe and quality-assured essential medicines, vaccines and traditional medicines and will help to achieve universal health coverage (UHC) and the Sustainable Development Goals.

Pacific island countries (PICs) have their own regulatory systems of varying capacity and level of development and have either no or limited regulations for medicines. Moreover, constrained human and financial resources have contributed to the limited functionality of national regulatory systems. Despite those challenges, several initiatives have been undertaken by PICs in the past, including development of national medicines policies, establishment of essential medicines lists and standard treatment guidelines and discussions for pooled procurement of medicines. Additionally, PICs have begun to collaborate on certain functions of a regulatory system for medicines by using a joint website (www.medqualityassurance.org) initiated by WHO. In 2017, 12 countries (Cook Islands, Fiji, Kiribati, Marshall Islands, the Federated States of Micronesia, Nauru, Palau, Solomon, Samoa, Tonga, Tuvalu and Vanuatu) enrolled in this subregional information platform to assist with procurement decisions.

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The meeting focused on discussing the results of a study conducted in 2018 on strengthening regulation of medicines and medical products. It was concluded that PICs could work together through a subregional platform to strengthen their regulatory systems and identify certain regulatory functions that could be done at country level and upon reliance with others. The detailed programme of activities is available in Annex 2.

1.2 Meeting objectives

The objectives of the meeting were:

(1) to present the findings of a feasibility study on regulatory cooperation to policy-makers and technical experts;
(2) to review concrete options for regulatory cooperation at country and subregional levels; and
(3) to consider short- and medium-term steps to support the possible establishment of a subregional platform for regulatory cooperation in the Pacific.

2. PROCEEDINGS

2.1 Opening session

Dr Corinne Capuano, Director, Division of Pacific Technical Support, World Health Organization (WHO), delivered the opening remarks on behalf of Dr Takeshi Kasai, WHO Regional Director for the Western Pacific (see Annex 3). Dr Capuano welcomed the regional participants and expressed her appreciation for the high-level presence from countries for this important topic.

The opening remarks were followed by Ms Martina Pellny, Team Coordinator of Pacific Health Systems, WHO Division of Pacific Technical Support, who presented the meeting objectives and agenda.

Dr Vivian Lin, Temporary Adviser, provided an overview of the Sustainable Development Goals (SDGs) and universal health coverage (UHC) in the context of medicine regulation. As a foundation, she gave an overview of the Western Pacific regional action framework, *Universal Health Coverage: Moving Towards Better Health*. The framework offers a menu of actions that countries can consider implementing, depending on their individual contexts, to improve the performance of their health systems along five key attributes, namely, quality, efficiency, equity, accountability, sustainability and resilience.

Dr Lin also shared that the WHO Regional Committee for the Western Pacific endorsed the *Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and Health Workforce* (WPR/RC68.R7) and the *Western Pacific Regional Action Agenda on Strengthening Legal Frameworks for Health in the SDGs* (WPR/RC69.R5) in 2017 and 2018, respectively. These action agendas emphasize the importance of regulation in achieving UHC and the SDGs in the Western Pacific Region.

2.2 Plenary: Introduction to medicine regulation and convergence of medicines

Over the past years and within the global context, regulation of medicines has become more comprehensive and complex to ensure the quality and safety of the products. This is how Dr Soccoro Escalante, Coordinator, Essential Medicines and Technologies, WHO Regional Office for the Western Pacific, introduced her presentation about regulation of medicines, regulatory mechanisms and its convergence. Regulation is not just about procurement. Regulation starts at product inception and carries on to the point when it is used by patients. It deals with market authorization, the establishment of essential medicines lists, the licencing of wholesalers and producers, and controls the quality of medicinal products for the benefit of the population. It is an important part of public health. Regulation of medicines ensures timely access to life-saving medicines and vaccines.

The Regional Committee resolution on regulatory strengthening, convergence and cooperation for medicines and the health workforce categorizes Member States into three types of countries, namely: (1) importing countries; (2) importing and producing countries; and (3) importing, producing and exporting countries. For importing countries such as PICs, the core regulatory functions needed to optimally ensure quality and safety of medicines were identified, including licensing of establishments, registration of medicines, quality assurance and market surveillance, pharmacovigilance, and recall and withdrawal. Since it is almost impossible for even strong national regulatory authorities to regulate and track all medicines, the global practice of cooperation and convergence with a regional approach would be useful for PICs as well.

Participants raised the issue of how procurement and regulation of medicines are interlinked. Good regulatory systems will ensure the efficient procurement of quality-assured, safe and effective medicine to enter the market of countries. One of the most essential WHO-recommended regulatory functions is called marketing authorization or registration. This means that products are reviewed for safety, quality and efficacy before they can be legally allowed to be sold and marketed in the country. With the establishment of a subregional platform for medicine regulation, participating Pacific island countries will be able to conduct marketing authorization and recommend favourably reviewed products to other countries. Over time, a comprehensive list of products that are used by several countries will be established. Once the same standards and products are registered, it will be easier for countries to pool procurement. Regulatory systems should be separated from the procurement system since there could be conflicts of interest. Regulatory convergence and cooperation would also help to tackle issues with oligopolies of wholesalers and distributors in the Pacific.

Some participants mentioned having difficulty in regulating the costs of medicine and keeping them affordable for Pacific island populations. Dr Escalante agreed that it is a challenge and pointed out a number of tasks to undertake, such as negotiating with pharmaceutical companies and wholesalers, conducting cost-effectiveness analysis to compare costs of new and existing medicines, and comparing prices with the international reference prices of medicine. All of those tasks are challenging and need capacity-building, and this might be more feasible on a subregional level.

2.3 Plenary: Assessment of the medicine regulatory system in the Pacific

Mr Asaeli Raikabakaba, Technical Officer, Essential Medicines and Health Technologies, WHO Division of Pacific Technical Support, shared the study findings of the *Assessment of the Medicines Regulatory System in the Pacific*.

Mr Raikabakaba explained that PICs have their own regulatory systems of varying capacity and level of development and have either no or limited medicine regulations. Despite those challenges, several initiatives have been undertaken by PICs in the past, including development of national medicines policies, essential medicines lists and standard treatment guidelines. Additionally, PICs have begun to collaborate on certain functions of a regulatory system for medicines by using a joint website (www.medqualityassurance.org) initiated by WHO. In 2017, 12 countries (Cook Islands, Fiji, Kiribati, the Marshall Islands, the Federated States of Micronesia, Nauru, Palau, Solomon, Samoa, Tonga, Tuvalu and Vanuatu) enrolled in this subregional information platform. During the WHO Technical Workshop on Strengthening Regulatory Frameworks for Pharmaceutical Systems in the Pacific from 12 to 14 March 2018 in Fiji, PICs identified priorities and areas for collaboration, such as marketing authorization or registration, quality assurance, and recall and withdrawal. They also confirmed their interest in looking into establishing a subregional platform for regulatory system strengthening and cooperation and agreed to support a feasibility study.

Using surveys, interviews and literature reviews, the study assessed the current regulatory systems and explored options for regulatory strengthening in the Pacific. Eleven PICs (Cook Islands, Fiji, Kiribati, the Marshall Islands, the Federated States of Micronesia, Nauru, Palau, Papua New Guinea, Tonga, Tuvalu and Vanuatu) took part. The study revealed that there are regulatory systems in place in all PICs, but the level of development varied widely. All 11 PICs have laws that broadly mandate regulations of medical products; however, only a few cover the full range of all regulatory functions. The study suggested three options for how to proceed with regulatory strengthening: (1) setting up a

national regulatory system in each country, (2) relying on other countries with well-established national regulatory authorities, and (3) establishing a subregional platform.

A short discussion followed the presentation. In general, all country participants welcomed the study and recognized the importance of the topic. Cook Islands raised the issue of governance of a subregional platform and proposed that the Pacific directors of clinical services or a network of chief pharmacists could steer and govern a potential platform. Tonga wanted to hear from Papua New Guinea about how they ensure quality control in their laboratory – the only laboratory in the subregion that has the capacity to test medicines, and how they regulate access to the laboratory. Papua New Guinea answered that they are about to introduce an amendment to the legislation on medicine that is dealing with all legal issues related to the laboratory; this process is ongoing. Referring back to the earlier session, Papua New Guinea stressed that the regulatory system should be separated from any procurement activities since there are clear conflicts of interest and that transparency of the process is very important. Fiji shared their current development activities for improved regulation for medical devices, traditional medicine and complementary medicine. Fiji also commented on the study and suggested to focus on strengthening capacities in the area of regulation – and the important role that chief pharmacists have to play in this regard.

2.4 Plenary: Opportunities for convergence of medicines in the Pacific

Dr Escalante and Mr Raikabakaba presented on the three options and how to take the subregional platform forward. Each of the options were explained in detail, including their respective advantages as well as limitations and challenges. It was noted that the three options are not mutually exclusive, as options 1 and 2 both need some sort of collaboration at the subregional level, which is option 3.

To operationalize the subregional approach, the study proposed short- and long-term options. The presenters explained that in the short term the subregional platform as a technical body or structure could be hosted by the WHO Division of Pacific Technical Support. In the long term, Member States may develop the platform into a Pacific regulatory authority or a shared regulatory mechanism attached to existing regional structures.

The platform would initially focus on four areas: (1) licensing of establishments, (2) marketing authorization or registration, (3) quality control, and (4) pharmacovigilance. The platform would support all core regulatory functions at national level and provide technical support, capacity-building and information sharing. With regard to the funding of such a platform, WHO and other development partners are able to support the establishment in the short term. In the long term, the study proposes other funding mechanisms such as Member State contributions and/or fees for services, which are used by other platforms in other regions.

A plenary discussion followed. Participants were interested to hear about similar regional approaches from other regions. The presenters stated that different models have been adopted across the world, and briefly highlighted regional platforms in the European Union and the Caribbean, which would be presented in more detail the following day. Dr Escalante emphasized the potential benefits that could come from a subregional approach. She explained that it was better to manage the risks in a collective way rather than managing them individually by country. The ownership of the approach was also discussed. Countries confirmed that a subregional approach would not duplicate or impose additional burden on existing national systems or on chief pharmacists in individual countries.

After the plenary discussion, Dr Lisa Kerr from the Australian Government's Therapeutic Goods Administration (TGA) delivered her presentation on a subregional platform in the Pacific from a stringent regional regulators perspective. Overall, she emphasized that she welcomed the discussion on a subregional platform for Pacific islands since regulation of medicine should be done globally and standards should be applied to ensure good quality of medicine. Dr Kerr then shared more information on TGA, Australia's regulator for medicine since 1990. She explained how TGA is organized, how it works to ensure regulation is enforced and how it ensures the quality of medicine. Dr Kerr also explained that TGA regulates medicines and medical product, but not the health workforce.

Dr Kerr also talked about the Pacific Medicines Testing Programme that is implemented by TGA and funded by Australia's Department of Foreign Affairs and Trade (DFAT). TGA tested 23 medicines from five PICs in 2017-2018 and implemented visual inspection trainings. For 2018-2019, they are planning to test around 80 products from 10 PICs. The testing is based on a memorandum of understanding between TGA and PICs and is free of charge for all countries. TGA has detected a number of challenges with regard to the quality of medicines that are circulating in the Pacific island countries and is working with them to improve this situation.

2.5 Panel: Preventing substandard and falsified medicines entering the Pacific

Panellists from Kiribati, the Federated States of Micronesia, Tonga and Vanuatu discussed how to prevent substandard medicines from entering their Pacific island countries. Most countries do not have the capacity to detect or monitor substandard and falsified (SF) medical products, but they acknowledge the WHO alert system. Panellists also stressed the need to exchange information on quality control and market control with other PICs. Some countries have samples tested in Australia upon request, but outside the DFAT-funded programme, the costs are very high for testing. They also noted that human resources capacity is a key challenge because of high staff turnover and lack of qualified pharmacists who are trained to recognize SF medical products.

Fiji shared that they recently modernized their medicines product act to meet the latest pharmaceutical developments, but the implementation of the act is still a challenge because not enough pharmacists understand regulation and its implementation. Samoa also agreed that regulation of medicines is an emerging issue in the country because it is difficult to control what the private sector imports, particularly from overseas companies. Other countries also emphasized the importance of wholesalers having a quality supply chain for their products, especially air-conditioned warehouses. Dr Escalante agreed and mentioned that quality assurance is challenging and expensive in all parts of the world, not just in the Pacific. Dr Yu Lee Park mentioned that it will be important to regulate traditional medicine products in the future. Currently, most traditional medicines are not registered when they enter the country and are sold in the private market without any quality control. She proposed as a first step to either share information via an online platform or to include it as part of the emerging subregional platform.

2.6 Experience from the Caribbean

Dr Rudolph Cummings, Programme Manager for Health, Caribbean Community (CARICOM) Secretariat, presented the Caribbean Regulatory System (CRS), a platform for health regulation that is hosted by CARICOM. Early work on the Millennium Development Goals in 2001 opened up policy opportunities for a joint medical supply and regulatory system. The idea was further developed and discussed over the years. In 2010, a study was implemented that clearly identified the need for

improving availability and affordability of medicine, and the needed increase in quality, efficacy and safety of medicine in the Caribbean region.

With funding support from the Bill & Melinda Gates Foundation, the programme was piloted in some states with technical support from the WHO Pan American Health Organization. Some challenges were encountered in the initial stage of the implementation, such as minimal engagement of Member States, the different maturity levels of the national regulatory systems, and low uptake by manufacturers. However, most dossiers received were approved by the CRS and recommended to Member States for (voluntary) registration.

Dr Charles Preston, Adviser, Regulatory Systems Strengthening for Medicines and Other Health Technologies, WHO Pan American Health Organization then presented how the regulatory platform actually functions and the role of WHO to support the platform. Dr Preston mentioned several key enabling factors for the establishment of the regional platform in the Caribbean, including: the existence of a regional public health agency since 2013; regional cooperation on a drug-testing laboratory; and fruitful discussions on a regional platform and networking that had been ongoing for years. WHO Pan American Health Organization supports the regional platform, but technically CRS is hosted by the Caribbean Public Health Agency (CARPHA) under CARICOM. WHO Pan American Health Organization is currently consolidating the best practices and lessons learnt from the Caribbean regional experience and will come up soon with recommendations for the way forward. The CRS has been operating since April 2017, with 35 medicines recommended for registration, and more than 80 dossiers received so far. The CRS also issued over 160 reports of adverse events and SF medicines.

Participants showed lots of interest in both presentations. Most questions were aimed at the funding source for the CRS and its sustainability. The presenters explained that the initial activities of the CRS under CARPHA were funded by the Bill & Melinda Gates Foundation, but they are also exploring the possibility of fees for service for every dossier approved – to be paid by the pharmaceutical industry. Dr Cummings pointed out that trust was the foundation of building solidarity and sustainability. Dr Preston suggested using the regional platform to build capacity and virtual training on pharmacovigilance to increase sustainability. He also emphasized that there are other benefits to a subregional platform. The experience with the CRS platform in the Caribbean has shown that once there is a centralized entry point for registration, with one set of standards and a pooled market, global manufacturers not previously interested in small markets can be newly incentivized to sell their products there. This can translate into higher-quality generics at better prices. In the Caribbean, the prices of some products dropped by 8–25% when new manufacturers entered the market and offered the same molecules, doses and formulations for lower prices, while also maintaining quality.

2.7 Group work: Options for strengthening medicine regulatory systems in the Pacific

A group work session enabled participants to discuss in more detail the key regulatory functions that are needed at country level and subregional level. Country participants also worked on specific country support and a joint plan for the subregional platform with milestones. Countries were divided into five groups and identified common challenges: availability of medicine, limited resources and funding, capacity of staff, commitment from the policy level, legislation and regulation, and regulation of the private sector.

Priorities identified at national level were adverse event reporting, recall and withdrawal, and marketing authorization. Priorities identified for subregional level were registration and licencing,

quality control by laboratory testing, information sharing, capacity-building and collaboration with TGA and other partners.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

The regional meeting provided a forum for participants to discuss issues and share experiences as well as provide useful suggestions and recommendations on a proposed subregional regulatory system for medicines. Participants acknowledged the threat of antimicrobial resistance and challenges faced in ensuring access to quality-assured, safe and affordable medicines and medical products and achieving UHC. Pacific island countries share similar challenges regarding pharmaceutical regulations and their implementation, including: lack of financial and human resources, capacity of staff and legislative frameworks. Country participants confirmed the need to strengthen national regulatory systems, including developing legislation and setting up structures to implement and enforce regulations, and agreed to support the establishment of a subregional platform for regulatory cooperation in the Pacific.

3.2 Recommendations

3.2.1 Recommendations for Member States

Member States agreed on the following:

(1) Advocate political support for comprehensive regulatory strengthening at the national and subregional levels.

(2) Set up a subregional platform to:

(a) establish a mechanism for pharmaceutical governance to support the development of comprehensive regulations in the subregion;

(b) through the Pacific pharmaceutical governance mechanism, explore regional and international regulatory platforms, in collaboration with development partners, that could provide strategic support to the proposed Pacific regulatory system;

(c) support countries to develop national regulatory systems backed by appropriate legislative frameworks, including identification of short-, medium- and long-term priorities;

(d) Facilitate capacity-building, setting of standards, information exchange, and short- and long-term human resources development;

(e) support countries to formalize, strengthen and perform core regulatory functions such as: licensing of establishments; registration of products; quality assurance, post-marketing surveillance, pharmacovigilance, recall and withdrawal; and

(f) provide day-to-day guidance on pharmaceutical and regulatory issues.

3.2.2 Recommendations for WHO

WHO is requested to consider the following:

1) In collaboration with the Pacific Community (SPC), follow up on the recommendations for the proposed subregional approach to strengthen regulation of medicines, and submit the topic for consideration to the forthcoming Heads of Health and Pacific Health Ministers meetings.
2) Develop terms of reference for the proposed subregional platform.
3) Build linkages with the Caribbean Regulatory System (CRS) and other partners.

ANNEXES

Annex 1. List of participants, temporary advisers, observers and secretariat

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Annex 2. Meeting Timetable

Time	Thursday 28 February	Time	Friday 1 March
8:30-8:45	Registration	8.00:8.30	Registration
08:45-10:00	**1.1 Opening session & welcome address** • Opening prayer • Opening remarks – RD speech (7min max) • Welcome by host government (7 min max) • Group photo • Administrative announcements • Meeting objectives and participant introduction • Convergence of medicines & regulatory framework	8:30-10:00	**2.1 Experiences from the Caribbean (90 min)** • Perspective from a Caribbean island/ and CRS – what was the situation before CRS establishment, peer to peer view, political drivers & enablers that initiated the platform in the Caribbean, structure, role of each players, regulatory functions performed & benefits, resources, challenges & future plan, sustainability • Plenary discussion • Perspective from PAHO – role of WHO and other partners to support regional convergence, governance of regional platform • Plenary discussion
10:00-10:30	Morning Tea	10:00-10:30	Morning tea
10:30-12:30	**1.2 Introduction to medicine regulation & convergence of medicines (40 min)** • Plenary discussion/ understanding of technical terms – making sure all are on the same level of understanding **1.3 Plenary: Assessment of the medicine regulatory system in the Pacific (80 min)** • Sharing the assessment findings • Plenary discussion	10:30-12:00	**2.2 Group work: Options for strengthening medicine regulatory systems in the Pacific (60 min)** • . Group work per country: Key regulatory functions at the country level and for the sub- regional platform: Itemized specific country support and plan for the sub regional platform with milestones • Group work
12:30-13:30	Lunch	12:00-13:00	Lunch
13:30-15:00	**1.4 Opportunities for convergence of medicine in the Pacific (90 min)** • Proposed sub regional platform based on assessment findings in the Pacific – priorities and areas for collaboration • Plenary discussion • Perspective on a potential platform and development towards more convergence in the Pacific from a regional regulator/ Australia (based on the findings) • Plenary discussion	13:00-14:30	**2.3 Plenary: Feed-back from groups (90 min)** • Group feed-back: Itemized specific country support and plan for the sub regional platform with milestones • Summarize countries individual feed-back towards a subregional plan
15:00-15:15	Afternoon tea	14.30:15:00	
15:15-16.45	**1.5 How to prevent substandard medicines from entering the Pacific – issues & solutions? (90 min)** • Panelist from 4 countries to share case studies in relation to substandard medicines, their remedial actions and challenges encountered • Countries: Tonga, Palau, FSM & Vanuatu • Plenary discussion	15:00-16:00	**2.4 Plenary: Roadmap - Moving forward** • Meeting recommendations/ roadmap: endorsement by countries (for example agreement on establishment of platform/ agreement on steering committee for platform/ agreement on concrete roadmap)
16.45-17.15	Secretariat meeting	16.00-16.30	Secretariat meeting

Annex 3. Opening remarks of Dr Takeshi Kasai, WHO Regional Director for the Western Pacific

Honourable Dr Ifereimi Waqainabete, Minister for Health and Medical Services in Fiji;

Honourable Ministers and Representatives from the Pacific Countries and international development agencies;

Colleagues, ladies and gentlemen.

Good morning and welcome to the meeting on Subregional Regulatory Systems for Medicines in the Pacific.

WHO Regional Director for the Western Pacific Dr Takeshi Kasai regrets not being able to join us due to previous commitments. He has asked me to send his regards and deliver these words.

Access to essential medicines is crucial to the achievement of universal health coverage and Sustainable Development Goals.

Access to safe, effective, and quality-assured essential medicines and other medical products including traditional medicines is ensured through an effective pharmaceutical regulatory and legislative system.

For Pacific island countries, strengthening the supply and management of essential medicines has been a priority since the Yanuca Island Declaration of ministers and directors of health for Pacific island countries in 1995.

This commitment was reiterated by the Rarotonga Agreement towards healthy islands in 1997 - and again at the meeting of the ministers of health in Koror, Palau in 1999 and in 2015.

Pacific Health Ministers are committed to the Healthy Islands vision. The vision emphasizes the importance of health service delivery and ensuring that children and adults can grow, learn, play and age with dignity. Combined with a focus on family and community values as foundation of Pacific culture, the Healthy Islands approach has strong links to Universal Health Coverage.

WHO provides technical support to Member States to develop national medicines policies and treatment guidelines, to strengthen procurement and supply chain management, quality assurance, regulatory system and rational use of medicines.

I commend Pacific island countries for their achievements in all aspects of pharmaceutical system strengthening.

The Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce – which was endorsed by the Regional Committee for the Wetern Pacific in 2017 – supports regulatory strengthening, convergence and cooperation in countries.

To follow up, a Technical Workshop on Strengthening Regulatory Framework for Pharmaceutical Systems in the Pacific was held in 2018 in Fiji. Member States expressed interested in establishing a subregional platform for regulatory system strengthening and cooperation.

It was agreed to do a study to identify step–by-step options for countries. These options range from building in-country regulatory capacity to sharing regulatory functions such as licensing of establishments, registration of products, market surveillance and pharmacovigilance and recall or withdrawal of products that do not meet standards.

Pacific island countries can benefit from this subregional regulatory cooperation. It can help to address common public health concerns during health emergencies and minimize the risk of receiving substandard and falsified medicines.

All in all, our efforts have been successful. But challenges persist.

Small populations spread across thousands of square kilometres of ocean face a multitude of obstacles to the establishment of effective regulatory systems for medicine.

These challenges will become much more significant as the double burden of noncommunicable and communicable diseases - along with health emergencies caused by natural disasters and antimicrobial resistance - increase the demand for essential medicines.

There are also other critical issues we need to address. With constrained human and financial resources, countries are struggling to ensure quality of imported medicines.

While traditional and complementary medicines are widely used but not regulated and integrated into current health systems.

There is a need to identify practical and sustainable solutions for the Pacific to strengthen pharmaceutical systems to ensure quality, availability, safety, efficacy of medicines.

We hope this meeting will provide such an opportunity for policy-makers and technical experts from the Pacific island countries to discuss steps and strategies based on the study and in the context of each country. In this way, we can strengthen the regulatory and legislative frameworks for pharmaceutical systems collaboratively.

WHO will continue to provide support on strengthening of pharmaceutical regulatory and legislative system in the Pacific.

I would like to express my sincere gratitude to the Government of Fiji for hosting this important meeting. I would also like to thank our partners and technical advisors for contributing to the presentations during the meeting.

I wish you all a productive discussion and look forward to your deliberations.

Thank you.

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