TECHNICAL WORKSHOP ON STRENGTHENING REGULATORY FRAMEWORKS FOR PHARMACEUTICAL SYSTEMS IN THE PACIFIC

12–14 March 2018
Denarau, Fiji
MEETING REPORT

TECHNICAL WORKSHOP ON STRENGTHENING REGULATORY FRAMEWORKS FOR PHARMACEUTICAL SYSTEMS IN THE PACIFIC

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NOTE

The views expressed in this report are those of the participants of the Technical Workshop on Strengthening Regulatory Frameworks for the Pharmaceutical Systems in the Pacific 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 those who participated in the Technical Workshop on Strengthening Regulatory Frameworks for Pharmaceutical Systems in the Pacific in Denarau, Fiji from 12 to 14 March 2018.
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Keywords: Regional health planning / Pharmaceutical preparations – standards / Strategic Planning / Pacific Islands
## ABBREVIATIONS

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<tr>
<th>AEFI</th>
<th>adverse events after immunization</th>
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<td>PICs</td>
<td>Pacific island countries and areas</td>
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<td>TCM</td>
<td>traditional and complementary medicine</td>
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<td>WHO</td>
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SUMMARY

The WHO Regional Committee for the Western Pacific in 2017 endorsed the *Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce* (WPR/RC68.R7), which recognized the importance of strengthening legal and regulatory frameworks to ensure the quality and safety of pharmaceuticals to protect public health and to help achieve universal health coverage.

However, almost all Pacific island countries and areas (PICs) neither have national regulatory authorities nor mechanisms to regulate pharmaceutical products. Many countries have old and outdated pharmaceutical legislations, which inadequately address the scope of pharmaceutical regulation.

The Technical Workshop on Strengthening Regulatory Frameworks for Pharmaceutical Systems in the Pacific was held in Denarau, Fiji, from 12 to 14 March 2018. It brought together for the first time legal officers and heads of pharmaceutical departments from PICs to walk through legal and regulatory frameworks in order to understand: the role of each profession, scope of regulatory functions, shared country experiences, and identified areas for system strengthening at a national level and cooperation across the Pacific.

Twenty participants attended the workshop from 12 countries (Cook Islands, Fiji, Kiribati, Federated States of Micronesia, Nauru, Niue, Palau, Papua New Guinea, Solomon Islands, Tonga, Tuvalu and Vanuatu).

The meeting provided opportunities for the participants to discuss and recognize the importance of legal frameworks in the regulation of pharmaceuticals and medical products. Laws serve in general as the enabling mechanism for national regulatory authorities to establish their authority and sustain trust in the performance of their regulatory function.

Countries have acknowledged that a stepwise approach to strengthening regulatory systems, backed by appropriate legal frameworks and based on their context, is useful. Since the PICs are mostly importing countries, the core regulatory functions that would need to be prioritized based on a stepwise approach include the development of legal frameworks and the establishment of registration and pharmacovigilance functions.
1. INTRODUCTION

1.1 Meeting organization

The WHO Regional Committee for the Western Pacific in 2017 endorsed the Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce (WPR/RC68.R7), which recognized the importance of strengthening legal and regulatory frameworks to ensure the quality and safety of pharmaceuticals to protect public health and to help achieve universal health coverage.

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1.2 Meeting objectives

The objectives of the workshop were:

1) to discuss priority issues towards implementing the Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce, with a focus on identifying challenges and opportunities for strengthening legal frameworks to improve access to essential medicines, including traditional medicines, where appropriate;

2) to enhance technical and legal capacities for strengthening legislative, regulatory and administrative frameworks in countries to improve access to essential medicines; and

3) to develop short- and medium-term steps for strengthening legal frameworks to improve access to essential medicines, including coordination among countries in the Pacific and consideration for the establishment of a subregional mechanism for regulatory convergence and cooperation.
2. PROCEEDINGS

2.1 Opening session

Dr Martina Pellny, Coordinator of Pacific Health Systems from the Division of Pacific Technical Support, delivered the welcome speech on behalf of Dr Corinne Capuano, Director of Pacific Technical Support/WHO Representative to the South Pacific. Dr Luisa Cikamatana, Deputy Secretary of Hospital Services from the Ministry of Health and Medical Services in Fiji, welcomed the participants to Fiji.

Following a round of introductions, Dr Socorro Escalante, Coordinator for Essential Medicines and Health Technologies at the WHO Regional Office for the Western Pacific, presented the meeting objectives and expressed her enthusiasm towards a productive meeting and looked forward to the establishment of the subregional regulatory platforms.

Mr Vali Karo, Manager of Pharmaceutical Service Standards at the National Department of Health in Papua New Guinea, was elected as the Chairperson and Ms Tuaine Elaine Marsters, Director of Pharmaceutical Board at the Ministry of Health in Cook Islands, as the Vice-Chairperson.

2.2 Pharmaceutical systems and regulation in the Pacific

Mr Asaeli Raikabakaba, Technical Officer for Essential Medicines and Health Technologies at the WHO Division of Pacific Technical Support, presented on challenges in ensuring access to quality and safe medical products in the Pacific. He acknowledged that quality and cost-effective essential medicines and vaccines that are intended to address the relevant health-care needs of the population play a crucial role in achieving universal health coverage. While he identified several prevailing challenges around substandard and falsified medicines, he likewise presented a number of strategic recommendations emphasizing effective cooperation and collaboration between medicine regulatory bodies and law enforcement agencies. He further recommended establishing a network among neighbouring PICs to ensure access to quality medicines.

Dr Socorro Escalante spoke on the access to medicines framework and medicines regulations. To ensure overall pharmaceutical system efficiency, she pointed out the areas of the framework that require regulatory interventions. Medicines regulation balances between safeguarding the quality, safety and efficacy of pharmaceutical products and the availability of these products for the public, especially in public emergencies. She highlighted that weak regulatory frameworks and lack of enforcement can lead to various bottlenecks that will limit access to essential medicines.

She shared the pharmaceutical legislation of each country within the Western Pacific Region and the registration status of products in the context of medicines, vaccines and biologicals, traditional and complementary medicines and medical devices. Smaller or less resourced regulatory authorities often rely on the approvals or assessments issued by the well-resourced regulatory authorities, in which is a much better option than no guidance at all, or poor-quality assessment.

Mr Eric Salenga, Technical Officer for Pharmaceuticals at the WHO Representative Office in Papua New Guinea, presented the country experience on regulatory reforms for pharmaceutical systems in Papua
New Guinea. Guided by the pharmaceutical profile of the country, which spent around US$ 80 million on medicines and other medical supplies in 2017, the current initiatives of the national pharmaceutical legislation for regulatory system strengthening are focused on in-country capacity-building to: test, assess and monitor the quality of products; inspect and license pharmaceutical establishments; ensure timely reporting and feedback on issues related to products safety and quality.

Mr Salenga mentioned the country’s approach towards the development of law reforms through extensive stakeholder consultations and meetings with the Senior Executive Management of the National Department of Health of Papua New Guinea.

2.3 Product regulation

Ms Uhjin Kim, Technical Officer for Pharmaceuticals at the WHO Regional Office for the Western Pacific, spoke on the products that need to be regulated in the Pacific. She explained the life cycle of a generic pharmaceutical product and highlighted the regulatory requirements and interventions. Regulations are based on identified risks; hence, regulatory approaches will differ on the product classification. Biologicals are subject to the same licensing procedures as other conventional pharmaceutical products, but the evaluation is done on a highly scientific and proven set of principles.

Mr Fumihito Takanashi, Deputy Director of the Office of International Regulatory Affairs of the Pharmaceutical Safety and Environmental Health Bureau at the Ministry of Health, Labour and Welfare in Japan, presented the regulation of medicinal products in Japan. He gave an overview of the legal structure of Japan that constitutes the Pharmaceutical and Medical Devices Act, which regulates and secures the quality, efficacy and safety of pharmaceuticals, medical devices, cosmetics and regenerative medicines. Quality standards such as Japanese Pharmacopoeia are updated and were last revised in 2017 for its 17th edition; the English translation is published on-line.

Dr Yu Lee Park, Technical Officer for Traditional Medicine at the WHO Regional Office for the Western Pacific, presented the regulation of traditional and complementary medicine (TCM). She shared updates in the development of policies to support safe and proper use of traditional medicine. She highlighted the importance of strengthening the regulations and standards for large and small-scale manufacturers and establishing systems for the qualification, accreditation or licensing of traditional medicine practitioners. Strengthened regulation and standards for traditional medicines should cover cultivation, collection and storage of raw materials, manufacture (Good Manufacturing Practice, or GMP), registration, post-marketing surveillance, laboratory testing and advertisement.

Mr Khay Ooi, Senior Analyst for Regulatory Practice and Analysis of Medsafe at the Ministry of Health of New Zealand, spoke on the medicines regulation in New Zealand. He outlined Medsafe’s different evaluation pathways for product registration, such as full evaluation, abbreviated evaluation and self-assessable changes to approved products. Several medicines expert committees are also involved in drug regulatory decision-making.

The current approach for TCM products in New Zealand is structured for pharmaceutical products. To regulate TCM products according to risk, the Natural Health and Supplementary Products Bill was drafted to provide a legal and product risk framework.
Meeting participants shared their thoughts on what medical products need to be regulated in their countries. The majority felt that all therapeutic products including medicines, biologicals, TCM, medical devices, blood products and veterinary medicines need to be regulated. Representatives from Papua New Guinea, Tonga and Tuvalu wanted to exclude blood products and veterinary medicines, whereas Kiribati and Palau wanted to exclude medical devices as well. Participants from Cook Islands, Nauru and Vanuatu expressed that they should focus on medicines and biologicals only with their limited capacity.

2.4 Market entry

Ms Uhjin Kim spoke on market entry regulation in the Pacific. Seven out of 14 PICs license their drug importers, wholesalers and retailers, four of which have included licensing of drug manufacturers in their legal provision, though not implemented. With regard to marketing authorization, three countries have legal provisions and require full registration prior to importation and marketing of medicines, while five countries have a partial approval system and six countries have no authorization process.

Mr John Tema, Principal Pharmacist for the Regulatory Affairs Division of the Ministry of Health and Medical Services of Solomon Islands, spoke on the country’s experience in licensing retailers and wholesalers. All pharmacy businesses, pharmacists and pharmacy officers are required to apply and renew their registration annually to the Pharmacy and Poisons Board. While regulatory actions may include a penalty, suspension or revocation of an existing registration, 15% of wholesalers and retailers are still operating without a license.

He mentioned that the Pharmacy and Poisons Act is under review and will be submitted to the parliament by 2018 or 2019. There is also a need to increase technical capacity and logistic support for the 14 newly appointed inspectors.

Ms Melenaite Mahe, Principal Pharmacist for the Central Pharmacy and Medical Store of the Ministry of Health of Tonga, presented on the country’s experience in product registration. She highlighted that the overall aim of Tonga’s National Drug Policy is to ensure all medicinal drugs available in the market are developed to prevent, cure and manage disease to the fullest extent possible. The National Drugs and Medicinal Supplies Committee is equivalent to a drug regulatory body that establishes and maintains the Essential Medicines List and determines the therapeutic goods to be purchased by the Ministry of Health.

Dr Socorro Escalante spoke on regulatory convergence and cooperation. She explained why regulation is becoming increasingly complex. Regulatory systems vary widely in terms of the range of regulatory functions performed and the level of capacity. The Western Pacific Region has some of the most advanced national regulatory systems for medicines and medicinal products in the world, such as in Australia, Japan, the Republic of Korea and Singapore. As countries work together to effectively regulate, there is huge potential for the less developed countries to use these resources for training and capacity-building.

She explained that regulatory convergence in medicines is an established mechanism centred on development, adoption and recognition of standards, technical guidelines and trade facilitation. While there is an increasing trend in convergence initiatives, there is also potential duplication in some areas.
Ms Uhjin Kim presented on product registration and wholesale prequalification. In conventional regulation, the national medicines regulatory authority ensures that medicines are of required safety, quality and efficacy through pre-market evaluation, market authorization and post-marketing surveillance. In the PICs, where there are no medicines regulatory authorities, prequalification of wholesalers is common to allow import of pharmaceutical products through public procurement. While vaccines and medicines in the public sector are WHO prequalified, the private sector has poor-quality medicinal products.

Participants engaged in an exercise on the most feasible mechanism for market entry in the Pacific. Representatives from Fiji, Papua New Guinea and Tonga said that they would prefer product registration at a national level and that they are already working towards building capacity. Participants from Palau, Solomon Islands and Tuvalu said that they through product registration at a regional level would be more helpful for them as they have limited capacity. Representatives from Cook Islands, Nauru, Niue, Palau and Vanuatu wanted to continue to rely on the wholesaler prequalification system as they find that it is functional in scarce resource settings.

2.5 Post-market surveillance

Ms Uhjin Kim spoke on quality assurance regulation in the Pacific. The quality of pharmaceutical products can be influenced by different attributes. Due to small populations, low budgets and limited number of staff, quality assurance regulation across the Pacific has its challenges. Almost all of the countries conduct product inspection and quality control through visual assessment, but few keep retention samples and only Papua New Guinea has mandated quality analysis at the laboratory.

Dr Duncan Dobunaba, Executive Manager (Medical Standards) of the National Department of Health of Papua New Guinea, spoke on establishing the Medicines Quality Control Laboratory to ensure all medicines marketed in the country meet acceptable quality standards. It was inaugurated on 30 November 2017 as the first quality control laboratory in the Pacific. Papua New Guinea has developed its Medicine Quality Surveillance Framework that serves as a general guide to assuring the quality of medicines through practical and risk-based sampling and testing.

Dr Dobunaba shared the country’s plans to establish the Medicines Quality Control Laboratory as the national pharmaceutical quality control laboratory by meeting the requirements of the WHO Good Practices for Pharmaceutical Quality Control Laboratories (WHO Technical Report Series No. 957) and ISO 17025.

Mr Joe Junior Natuman, Assistant Senior State Counsel of the Parliamentary Counsel’s Unit in the State Law Office of Vanuatu, presented the legal actions on poor quality of medicines in Vanuatu. The Sales of Medicines Act from August 1966 provides the requirements on how to legally market the medicines. A person proven to have violated this Act could be liable to pay a maximum penalty of $A 500 or sentenced to one year in prison. He said that law reforms and new regulations should be developed to address the current issues in pharmaceutical regulation.

Ms Lisa Kerr, Director of Biomaterials and Engineering Section in the Therapeutic Goods Administration of Australia, spoke on the support for quality control testing for PICs that it provides with the Department
of Foreign Affairs and Trade of Australia. She shared the progress and future undertakings of the Pacific Medicines Testing Program for 2017–2021. The programme supports the quality assurance testing of planned campaigns with samples coming from the PIC central medical stores. The focus is on medicines to treat noncommunicable diseases, antibiotics, medicines nominated by the Therapeutic Goods Administration, and products with complaints or those that are subject of an adverse event. Country visits were made to seek information on the regulatory capacity, the available medicines and the problems with medicines in each country and to assist with the memorandum of understanding for health officials, finance officials, the Australian High Commission and partners to join.

Ms Uhjin Kim presented on the regional platform for information exchange on quality of medicines. She gave an overview of the Med Quality Assurance website (medqualityassurance.org) to support the regional information-sharing scheme and bring together prequalification information on suppliers, manufacturers and individual products. She also asked the participating countries to share and upload results of all quality testing of products, from visual inspection to laboratory testing and post-approval field reports, to serve as a guide for procurement and product recalls as necessary to other participating countries.

Meeting participants engaged in another round of live polling exercise to share their thoughts on barriers to active information exchange across the Pacific. Cook Islands, Kiribati, Tonga, and Vanuatu expressed they are too busy with their daily work and often forget to share information on product quality with other countries. However, Tonga has been most active on medqualityassurance.org. None of the countries said the website is difficult to use or information shared not useful. However, countries need nudges and reminders to be actively involved.

*2.6 Pharmacovigilance and promotion*

Dr Yu Lee Park spoke on pharmacovigilance and pharmaceutical promotion in the Pacific. She provided a comparative analysis of the systems across the PICs. She mentioned that five countries have pharmacovigilance regulation and five countries have a system in place. She also discussed the importance of regular data sharing between centres, causality assessment and reporting to the WHO Uppsala Monitoring Centre (Sweden), or through the WHO–UNICEF Joint Reporting Form on Immunization.

Ten countries have legal provisions for marketing and promotion of medicinal products. Eight countries require labelling on the products, while Samoa further requires information of the manufacturer or agent on the label.

Ms Teeteu Tekeaa, Clinical Pharmacist of the Ministry of Health and Medical Services of Kiribati, shared the country’s experience with pharmacovigilance and adverse events after immunization (AEFI). She specified that the fifth part of the Medicine Act of Kiribati covers the reporting of adverse effects and legal sanctions that will be imposed for those who fail to notify the relevant committee. The Expanded Programme on Immunization (EPI) is in charge of the procurement, distribution and reporting of AEFI. She mentioned that a system is in place to monitor AEFI, but no cases have been reported.
Dr Duncan Dobunaba presented the Medicines and Therapeutics Committee and Adverse Drug Reaction Sub-committee that have been established to improve clinical governance in Papua New Guinea. He referred to the policies and legislations backing pharmacovigilance. He also stressed that a good clinical governance mechanism to provide post-market surveillance/oversight of medicines at the implementation level can lead to improved patient care safety outcomes. He shared the country’s plan to establish the National Pharmacovigilance Committee to improve the system of detection, evaluation and reporting of any drug-related problem and their associated morbidity, mortality and costs.

Dr Socorro Escalante spoke on strengthening of pharmacovigilance systems in the PICs. She gave an overview of how pharmacovigilance works and showed the importance of reporting and how it may result in regulatory actions to further protect the public. She also emphasized that pre-market safety data are critical, especially for new chemical entities, vaccines and other biologicals, with respect to variations on registration data or label changes. She led the group through a simulation exercise with two cases to analyse.

Mr Apolosi Vosanibola, Acting Chief Pharmacist of Fiji Pharmaceutical and Biomedical Services of the Ministry of Health and Medical Services, presented on drug marketing and promotion in Fiji. He cited the current legislation that prohibits and controls advertising and promotion. As business is driven by profit, private sector strategies are always heavy on marketing. There is thus a need to control the advertisement and promotion of products to the public, including doctors and pharmacists. Though the country has a new law in place, implementation is being delayed since the guidelines are being drafted and state lawyers lack technical knowledge on the advertisement regulation.

Dr Yu Lee Park gave a summary on the marketing regulation of TCM in the PICs. Information on TCM products is very limited, and there are no restrictions on selling in pharmacies and other outlets. Member States with well-established systems for their own traditional medicines regulate traditional medicines as over-the-counter medicines but with different quality, safety and efficacy/effectiveness standards, or as new drugs. They can be sold with health claims based on clinical data or regulated as food supplements with no health claims.

2.7 Market exit

Ms Uhjin Kim presented on Recalls, withdrawals, penalties in the Pacific. She specified specific regulations and compared to the actual practice in the country. A number of PICs have implemented recalls and product withdrawals, penalties and sanctions were also imposed.

Mr Natano Elisala, Acting Director of Health of Princess Margaret Hospital at the Ministry of Health of Tuvalu, presented on the enforcement of pharmaceutical laws in Tuvalu. He emphasized the Pharmacy and Therapeutic Products Act of 2016, which repealed several pharmacy acts from 1948 and 1954. The 2016 Act covers regulation in sourcing and supply chain, wholesale or retail of therapeutic products, and other related activities. He described the legal mandate of the licensing authority, enforcement areas and penalties associate with violations.

He shared that Tuvalu lacks specific processes for enforcement and requires capacity-building for the enforcement bodies. The country plans to update and establish other regulations to provide specific
guidelines with regulatory actions, provisions to strengthen capacity and human resources, and training for law enforcement authorities.

Mr Andrew Francis Orange, Chief Pharmacist of Rarotonga Hospital at the Ministry of Health of Cook Islands, spoke on enhancing pharmacy services through regulation. He shared the country’s legal framework and set out the guidelines of the Ministry of Health Act of 2013, which establishes the government health services. He explained that the current regulation is cross-cutting, encompassing pharmacists and allied pharmacy professionals, operation of drug establishments, and assurance of quality, safety and effectiveness of therapeutic products.

2.8 Interactive session

Countries were given the opportunity to consult individually with other countries and experts of their choice for more in-depth discussion to address their queries and seek advice.

2.9 Legal frameworks

Ms Resel Elias, Nursing Program Coordinator and Pharmacist of the Department of Health and Social Affairs of the Federated States of Micronesia, presented the country’s experience with developing its Pharmaceutical Bill. With no specific legislation that regulates the pharmaceutical sector, there was need for a legal pharmaceutical framework. She shared the strategies that moved the draft Pharmaceutical Bill through introduction, deliberation and endorsement by the Congress. The country is now developing implementing tools, rules, policies and regulations.

Dr Socorro Escalante spoke on the role of legal frameworks in strengthening the pharmaceutical systems in the PICs. A legal framework is a broad system of laws, rules and governance mechanisms that enables and guides decision-making processes and the performance of a certain function. She outlined which regulatory functions need a legal mandate from product entry to continuing quality assurance and exit. She further highlighted that all administrative and executive instruments must fall under the ambit of the law.

2.10 Establishment of subregional regulatory platform in the Pacific

Mr Fumihito Takanashi presented Japan’s experience with international regulatory convergence and cooperation activities. Global regulatory cooperation has a nearly 40-year history, originating with the International Conference of Drug Regulatory Authorities in 1980. This was followed by diverse specific initiatives such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use founded by the United States of America, the European Union and Japan. Japan has been part of several multilateral initiatives and bilateral cooperation arrangements with various national regulatory authorities. This kind of participation in global cooperation has facilitated the improvement of regulatory performance.

Dr Socorro Escalante spoke on the proposed subregional regulatory platform for the PICs. The overarching goal is the access to medicines of assured quality, safety and efficacy for all people in the
Pacific by strengthening the regulations and legal frameworks for the pharmaceutical systems. It is critical that mechanisms exist for collaboration in pharmaceutical regulations and for capacity development to mobilize support from more stringent regulatory authorities for learning and coaching.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

The meeting provided opportunities for the countries to share strategies and challenges in establishing and strengthening regulatory frameworks for pharmaceutical systems. A cross-country analysis of pharmaceutical laws and regulatory functions in PICs prior to the workshop showed that most countries have outdated laws, which inadequately address the full scope of regulatory functions. Even countries that have recently developed or revised their laws have acknowledged the substantial gap between regulation and implementation. Countries have also expressed their need for support in reviewing or developing their respective national legislation to ensure that the core regulatory functions can be legally established and enforced.

After the full analysis of regulatory functions, countries identified urgent needs. Many indicated product registration, quality assurance and pharmacovigilance as areas of focus. Countries also expressed the need to start product registration as the current mechanism of minimal quality assurance (i.e. prequalification of wholesalers) is inadequate.

Due to the increasing pharmaceuticals trade in the PICs, regulations need to be broadened to other products to include medical devices, veterinary medicines and TCM.

The importance of pharmacovigilance and controlling marketing and promotion of medicinal products was discussed. Especially with TCM products, there is over-advertising and therapeutic claims without evidence in some countries where importation of herbal medicines from overseas is growing.

3.2 Recommendations

3.2.1 Recommendations for Member States

Member States are encouraged to do the following:

1) Identify critical gaps in regulatory functions to strengthen national regulatory systems for medicines.
2) Review existing legal instruments to determine the need for additional legal frameworks to support the conduct of regulatory functions.
3) Advocate among policy-makers to enlist their commitment to strengthen legal and regulatory systems in their respective country.
4) Identify areas for collaboration with other PICs in the area of pharmaceutical regulation.
3.2.2 Recommendations for WHO

WHO is requested to do the following:

1) Provide technical assistance to Member States in strengthening legal and regulatory systems to better perform regulatory functions for medicines.

2) Continue to consult within WHO and with Member States and other stakeholders on the proposed establishment of a subregional collaborative mechanism for PICs.
ANNEXES

Annex 1. List of participants

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### Annex 2. Meeting timetable

<table>
<thead>
<tr>
<th>Time</th>
<th>Mon 12 March</th>
<th>Time</th>
<th>Tue 13 March</th>
<th>Wed 14 March</th>
</tr>
</thead>
<tbody>
<tr>
<td>08:30-09:00</td>
<td>Registration</td>
<td>08:30-10:30</td>
<td>Quality assurance regulation in the Pacific – WPRO</td>
<td>2.5 Legal frameworks</td>
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<tr>
<td>09:00-10:00</td>
<td>1.1 Opening session</td>
<td></td>
<td>• The first medicines QC lab in the Pacific – PNG</td>
<td>• Country experience on legal reforms for pharmaceutical systems - FSM</td>
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<tr>
<td></td>
<td>• Opening remarks - WHO Division of Pacific Technical Support</td>
<td></td>
<td>• Legal actions on poor quality of medicines – Vanuatu legal Mobility break</td>
<td>• The value of legal framework in strengthening the regulatory functions in the Pacific</td>
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<td></td>
<td>• Welcome speech - Dr Luisa Cikamatana, MHMS, Fiji</td>
<td></td>
<td>• DFAT-TGA’s support on QC testing for countries</td>
<td>– Dr Socorro Escalante, WPRO</td>
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<tr>
<td></td>
<td>• Meeting objectives – Dr Socorro Escalante, WPRO</td>
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<td>– Dr Lisa Kerr, TGA, Australia</td>
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<td></td>
<td>• Nomination of Chair and Co-chair</td>
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<td>• Post-market surveillance for the sub-region and <a href="http://www.medqualityassurance.org">www.medqualityassurance.org</a> – Ms Uhjin Kim, WPRO</td>
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<td></td>
<td>• Participant introduction and icebreaker</td>
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<td>• Plenary</td>
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<td></td>
<td>• Group photo</td>
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<tr>
<td>10:00-10:30</td>
<td>Morning Tea</td>
<td>10:30-10:45</td>
<td>Morning Tea</td>
<td>2.6 Prioritization and country plans</td>
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<tr>
<td>10:30-12:00</td>
<td>1.2 Pharmaceutical systems and regulation in the Pacific</td>
<td>10:45-12:30</td>
<td>2.2 PV and promotion</td>
<td>• Group work</td>
</tr>
<tr>
<td></td>
<td>• Challenges in ensuring access to quality and safe medical products in the Pacific – Mr. Asaeli Raikabakaba, WHO DPS</td>
<td>• Pharmacovigilance and pharmaceutical promotion in the Pacific - WPRO</td>
<td></td>
<td>• Reporting back</td>
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<td></td>
<td>• Access framework and medicines regulations</td>
<td>• Pharmacovigilance and AEFI – Kiribati</td>
<td>2.7 Establishment of sub-regional regulatory platform in the Pacific</td>
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<td></td>
<td>– Dr Socorro Escalante, WPRO</td>
<td>• Pharmacovigilance in PNG</td>
<td>• Experience from international regulatory convergence and cooperation Activities</td>
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<td></td>
<td>• Mobility break</td>
<td>• Strengthening PV in the Pacific – Dr Socorro Escalante, WPRO</td>
<td>– Dr Takanashi Fumihito, MHLW, Japan</td>
<td>– Dr Takanashi Fumihito, MHLW, Japan</td>
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<td></td>
<td>• Country experience on legal reforms for pharmaceutical systems – PNG – Dr Eric Salenga, WHO PNG</td>
<td>• Marketing and promotion of medical products – Fiji</td>
<td>• Why the need for a regulatory platform in the Pacific</td>
<td>• Why the need for a regulatory platform in the Pacific</td>
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<tr>
<td>12:00-13:00</td>
<td>Lunch</td>
<td>12:30-13:30</td>
<td>Lunch</td>
<td>• Plenary discussion</td>
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<tr>
<td>13:00-14:30</td>
<td>1.3 Product regulation</td>
<td>13:30-15:00</td>
<td>2.3 Market Exit</td>
<td>• Plenary discussion</td>
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<tr>
<td></td>
<td>• What products need to be regulated in the Pacific? – Ms Uhjin Kim, WPRO</td>
<td>• Recalls, withdrawals, and penalties in the Pacific – WPRO</td>
<td>• Group work</td>
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<td></td>
<td>• Regulation of medical products in Japan – Dr Takanashi Fumihito, MHLW, Japan</td>
<td>• Can poor quality products be withdrawn from the market? – Samoa</td>
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<td>• Regulation of traditional and complementary medicines – Dr Yu Lee Park, WPRO</td>
<td>• Enforcement of the law – Tuvalu legal Mobility break</td>
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<td>• Medicines regulation in New Zealand – Mr Khay Ooi, MedSafe, NZ</td>
<td>• Enhancing pharmacy services through regulation – Cook Islands</td>
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<td></td>
<td>• Plenary discussion (Live polling)</td>
<td>• Plenary discussion</td>
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<td>• Products to be regulated in the Pacific</td>
<td>• Group work</td>
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<tr>
<td>14:30-14:45</td>
<td>Afternoon tea</td>
<td>15:00-15:15</td>
<td>Afternoon tea</td>
<td>2.8 Conclusion</td>
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<tr>
<td>14:45-17:00</td>
<td>1.4 Market Entry</td>
<td>15:15-17:00</td>
<td>2.4 Interactive Session</td>
<td>• Recommendations</td>
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<tr>
<td></td>
<td>• Market entry regulation in the Pacific – WPRO</td>
<td>• Meet the experts and countries</td>
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<td>• Closing remarks</td>
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<td>• Licensing of pharmaceutical establishments – Solomon Islands</td>
<td>• Q&amp;A</td>
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<td>• Product registration – Tonga</td>
<td>• Seek support</td>
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<td>• Mobility break</td>
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<td>• What regulatory convergence and reliance mechanisms could help countries – Dr Socorro Escalante, WPRO</td>
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<td>• Product registration or wholesaler prequalification? – Ms Uhjin Kim, WPRO</td>
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<td></td>
<td>• Plenary discussion</td>
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<tr>
<td>18:00-19:00</td>
<td>Welcome reception</td>
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