7th Pacific Heads of Health (PHoH) Meeting: 3 to 5 April 2019, Nadi Fiji

Agenda Item 4.1 – Background information to IP7- Strengthening primary health care towards UHC

1. BACKGROUND

Access to medicines, vaccines and medical products of assured quality, safety and effectiveness contribute to the attainment of universal health coverage and the healthy Island Vision.

Strengthening regulations is key to the achievement of this goal. It will enable countries to: 1) improve the availability of essential medicines as well as the network and integrity of supply chains; 2) better ensure quality and safety of medicines thus contributing to better health outcomes for the population; 3) protect the people from substandard and falisified medicines as well as harmful medical products and 4) facilitate the growth of the pharmaceutical sector, thus allowing the entry of a wider range of quality assured and affordable medicines that meet the needs of the populations;

The global trade of medical products and the increasing demand of medicines and medical products of the population puts pressure on countries to raise the level of regulations. Over the years, the PIC have faced many challenges including malpractices of suppliers and distributors and the introduction and marketing of products with false therapeutic claims. These practices harm the health and safety of the population. In addition, it is critical to ensure that medicines in the PIC are of assured quality, safety and efficacy in the light of the increasing burden of non-communicable diseases that requires prolonged treatment across large groups of populations and increasing cost to the health system,

The regulatory system of some countries in the Pacific have evolved to address these challenges while others remain to be constrained by resources, leading to an uneven level of regulation and variability of standards across the region. Having an effective and functional pharmaceutical regulatory system will prevent countries from receiving substandard and falsified (SF) medicinal products and ensure consistent access to safe and quality-assured essential medicines, vaccines and traditional medicines that are important in achieving Universal Health Coverage (UHC) and the Sustainable Development Goals (SDGs).

Regulations of medicines, vaccines and medical products are complex and resource-intensive. No country can undertake regulations on its own, and thus the need for cooperation and convergence across countries.

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 guide member states on actions to strengthen regulatory systems for medicines using the context of each country. The regional committee urge member states:

1. to use the Regional Action Agenda to guide the development of legal frameworks, policies, strategies and plans for regulatory strengthening;
2. to develop and strengthen capacity of the regulatory workforce and engage relevant stakeholders to monitor the impact and effectiveness of national regulatory systems for medicines and the health workforce;
3. to participate in regional convergence and cooperation initiatives to collectively strengthen the regulatory capacity of the Region and address public health issues; and
4. to share information on progress in implementing the Regional Action Agenda.[1]

The Pacific Island Countries and areas (PICs) have put in place some mechanisms for regualtions of medical products and initiated strategies to work together, such as sharing information on the quality of medicines in the joint website (www.medqualityassurance.org) initiated by WHO. In 2017, 12 countries (Cook Islands, Fiji, FSM, Kiribati, Nauru, Palau, RMI, Solomon, Samoa, Tonga, Tuvalu and Vanuatu) enrolled in this sub regional information platform to assist with procurement decisions. Through this information sharing mechanism, countries have been able to share information of suppliers or manufacturers that do not comply with regulations and produce sub-substandard and poor quality medicines.

Regulatory Convergence is the process whereby regulatory requirements, approaches and systems become more similar or aligned over time as a result of the adoption of internationally recognized technical guidance, standards and best practices. It has the potential to address regulatory challenges and create opportunities to raise the level of regulation across the region to address common public health concerns. Across the world, there are various substantial and long standing regional and global cooperation initiatives that support national regulatory systems through creating common standards and uniform

[1] Regulatory Strengthening, Convergence And Cooperation For Medicines And The Health Workforce, 2017

documents, and reliance of decision of participating members. The number of convergence and cooperation initiatives for the regulation of medicines has been increasing; they are grouped depending on their political, economic and social interest.[2]

2. ACTION TAKEN

In March 2018, a Technical Workshop on Strengthening Regulatory Framework for Pharmaceutical Systems in the Pacific was held in Fiji to discuss priority strategies in strengthening regulations in countries in the Pacific, guided by the Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce. This meeting 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). During the meeting, PICs confirmed their interest in exploring the possibility of establishing a sub-regional platform for regulatory system strengthening and cooperation for PICs, thus it was agreed to conduct a study to assess and map the overall situation. [3]

The study commenced in August 2018 and was completed by February 2019 (see attached to this information paper). A total of 11 countries participated (Cook Is, Fiji, FSM, Kiribati, Nauru, Palau, PNG, RMI, Tonga, Tuvalu, Vanuatu). Data were collected through literature search, online and face to face interview with chief pharmacists and other key stakeholders of participating countries. The main objective of the assessment was to provide the current status of medicine regulation and regulatory system in PICs and identify feasible options and ways to strengthen regulatory capacity in the Pacific, including collaboration at the sub regional level focusing on each regulatory functions such as licensing of establishments (importers, wholesalers, distributors, retailers); registration of products; market surveillance and pharmacovigilance and recall/withdrawal of products that do not meet standards.

[2] Regulatory Strengthening, Convergence And Cooperation For Medicines And The Health Workforce, 2017
[3] Technical Workshop on Strengthening Regulatory Frameworks for Pharmaceutical Systems in the Pacific meeting report 2018

The findings of the study were presented during the Pacific Island Meeting on Sub-Regional Regulatory Systems for Medicines held on 28 February to 1 March 2019. This meeting were attended by representatives from Cook Islands, Fiji, Kiribati, Marshall Islands, the Federated States of Micronesia, Nauru, Niue, Palau, Papua New Guinea, Samoa, Solomon Islands, Tokelau, Tonga, Tuvalu and Vanuatu, who included the Honourable Minister of Health from Palau and the Federated States of Micronesia, the Permanent Secretaries, Chief Executive Officers and senior representatives from the ministries of health and head of the pharmacy department responsible for the regulation of pharmaceuticals.

The analysis of the regulatory systems in PICs revealed the followings:

1. All eleven PICs that participated in the study have laws relating to pharmaceutical regulations and control of dangerous drugs and poisons but need to be reviewed and updated to improve alignment to international standards and practices and to better meet the needs of the PICs;
2. The most common regulatory functions that are covered by laws include registration of medicines, licensing of establishments, regulation of the pharmaceutical profession and reporting of adverse events;
3. Eight countries (8/11) have their national medicine policy that support and encourage participation in technical and regional cooperation commonly in the area of training and staff development, quality assurance and quality control, regional procurement, exchange of medicine information and information on suppliers;
4. Nine countries (9/11) have explicit provisions for collaboration with other regulatory authorities. The most common regulatory function that is open for cooperation/reliance mechanisms is medicines registration;
5. While laws are in place, implementation and enforcement vary across countries and highly depend on the technical, human resource and financial capacities of the regulatory authorities; and
6. Most of PICs may not be able to implement the full spectrum of regulatory functions on their own but could participate in regional convergence initiatives to collectively strengthen the regulatory capacity at both country and subregional level in order to address common public health issues.

The study also explored several options for regulatory strengthening that includes the: 1) setting up of national regulatory systems in each country, based on their needs and contexts; 2) reliance on other countries with well-established national regulatory authorities; and 3) the establishment of a sub-

regional regulatory platform to assist countries perform core regulatory functions that cannot be undertaken by countries on their own, especially in the context of constrained resources. The mechanism would be voluntary in the beginning and is not meant to replace national systems.

The proposed sub-regional regulatory platform could:

a) Serve as a mechanism recognized by PICs for cooperation in pharmaceutical regulations: The sub-regional platform will enable countries in the Pacific to cooperate in regulating medical products and enhance reliance mechanisms and/or joint or collaborative regulatory activities, and strengthen their own regulatory systems in the process.
b) Set up as a mechanism for information sharing and capacity development: coordinate information sharing and mobilize support from more stringent regulatory authorities for learning and capacity building for regulatory authorities in the PICs

3. CONCLUSIONS

The findings were discussed during the meeting and countries acknowledge the threats such as antimicrobial resistance and the challenging environment in ensuring access to quality assured, safe and affordable medicines/medical products and achieving universal health coverage. PICs share similar issues regarding pharmaceutical regulations and procurement policies but actions are limited due to the competing priorities, lack of financial and human resources and legislative frameworks. PICs also recognize that effective procurement needs a strong regulatory mechanism. PICs had also confirmed the need for strengthening of national regulatory systems, including development of legislation and setting up structures to implement and enforce regulations. There are challenges at the national level that needs operational interventions on a day-to-day basis that would need timely and sustained support from the sub-regional level. PICs recognised that a sub-regional approach will be valuable to support countries perform regulatory functions.

In conclusion, at the end of the meeting, participants agreed and recommend to:

1) Advocate political support for comprehensive regulatory strengthening at the national and sub-regional level;
2) Set-up the sub-regional platform to:

- Establish a mechanism for pharmaceutical governance to support the development of comprehensive regulations in the region;

- Through the Pacific pharmaceutical governance mechanism, explore regional and international regulatory platforms in collaboration with development partners, that could provide strategic support to the Pacific Regulatory System (PRS);
- Support countries to develop national regulatory systems backed-up by appropriate legislative framework, including identification of short, medium and long term priorities;
- Facilitate capacity building, setting of standards, information exchange, and short and long term human resources development
- 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
- Provide day to day guidance on pharmaceutical and regulatory issues.

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[4] Technical Workshop on Strengthening Regulatory Frameworks for Pharmaceutical Systems in the Pacific meeting report 2018

regulatory system in PICs and identify feasible options and ways to strengthen regulatory capacity in the Pacific, including collaboration at the sub regional level focusing on each regulatory functions such as licensing of establishments (importers, wholesalers, distributors, retailers); registration of products; market surveillance and pharmacovigilance and recall/withdrawal of products that do not meet standards.

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