

Meeting Report

SIXTH WORKSHOP FOR NATIONAL REGULATORY AUTHORITIES FOR VACCINES AND MEDICINES IN THE WESTERN PACIFIC REGION



29–31 August 2017
Manila, Philippines



**Sixth Workshop for National Regulatory Authorities for Vaccines and Medicines in the Western Pacific Region
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WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC

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MEETING REPORT

THE SIXTH WORKSHOP FOR NATIONAL REGULATORY AUTHORITIES
FOR VACCINES AND MEDICINES IN THE WESTERN PACIFIC REGION

Convened by:

WORLD HEALTH ORGANIZATION
REGIONAL OFFICE FOR THE WESTERN PACIFIC

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NOTE

The views expressed in this report are those of the participants of the workshop for Sixth Workshop for National Regulatory Authorities for Vaccines and Medicines in the Western Pacific Region 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 Sixth Workshop for National Regulatory Authorities for Vaccines and Medicines in the Western Pacific Region in Manila, Philippines from 30 to 31 August 2017.

Contents

SUMMARY	1
1. INTRODUCTION	2
1.1 Meeting organization	2
1.2 Meeting objectives	2
2. PROCEEDINGS	2
2.1 Opening session	2
2.2 Session 1. Developments in the regulatory system strengthening	3
Session 1.1 Regional strategies in improving access to essential medicines	3
Session 1.2 Progress in strengthening regulatory systems in the Western Pacific Region	4
Session 1.3 Global updates on medical products regulation: WHO Good Regulatory Practices process and guidelines.....	5
Session 1.4 Updates on the development of WHO regulatory guidelines	7
2.3 Session 2. Regulatory co-operation	7
Session 2.1 Poster session	7
Session 2.2 Country experience: Added value and challenges of participating in a regulatory network.....	8
2.4 Session 3. Emerging regulatory issues in the Western Pacific Region	9
Session 3.1 Shortages and stock-outs a global concern	9
Session 3.2 The role of NRAs in response to public health emergencies	10
2.5 Session 4. Stepwise approach to strengthening regulatory systems.....	12
Session 4.1 Building capacities on clinical trials in countriesin the Western Pacific Region.....	13
Session 4.2 Breakout group work	13
2.6 Session 5. Regional Alliance restructuring and strategic planning	14
2.7 Session 6 Closing session	14
3. CONCLUSION AND RECOMMENDATIONS	14
3.1 Conclusions	14
3.2 Recommendations for Member States	15
3.3 Recommendations for the Regional Alliance	16
3.4 Recommendations for WHO	16
4. ANNEXES	17
Annex 1 Access to medicines framework	
Annex 2 Regional Alliance terms of reference	
Annex 3 Strategic objectives and workplan	
Annex 4 Prioritization matrix	
Annex 5 Regional Alliance Steering Committee meeting minutes	

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Abbreviations

AEFI	adverse events following immunization
ASEAN	Association of South East Asian Nations
CPP	Certificate of Pharmaceutical Product
DAV	Drug Administration Viet Nam
ELISA	enzyme-linked immunosorbent assay
EMT	Essential Medicines and Technologies
ECSP	Expert Committee on Specification for Pharmaceuticals Preparations
ECBS	Expert Committee on Biological Standardization
GBT	Global Benchmarking Tool
GMP	Good Manufacturing Practice
ICDRA	International Conference of Drug Regulatory Authorities
IDP	Institutional Development Plan
MFDS	Ministry of Food and Drug Safety, the Republic of Korea
MRA	Mutual Recognition Agreement
MOH	Ministry of Health
NCL	National Control Laboratory
NID	new Infectious Diseases
NIID	National Institute of Infectious Diseases, Japan
NRA	National Regulatory Authority
NPRA	National Pharmaceutical Regulatory Agency
PDMA	Pharmaceuticals and Medical Devices Agency
Ph Int	International Pharmacopeia
PIC/s	Pharmaceutical Inspection Co-operation Scheme
PIDM	WHO programme for International Drug Monitoring
PMMD	Pharmaceuticals and Medical Devices, Manufacture Division
QMS	Quality Management System
PV	pharmacovigilance
R& D	Research and Development
RAPS	Regulatory Affairs Professionals Society
RSS	regulatory systems strengthening
RASC	Regional Alliance Steering Committee
RAWG	Regional Alliance Working Group
SDG	Sustainable Development Goals
TGA	Therapeutic Goods Administration, Australia
UHC	Universal Health Coverage
UMC	Uppsala Monitoring Centre
VAEIMS	Vaccine Adverse Events Information Management System
WHA	World Health Assembly
WHO	World Health Organization
WHO CC	World Health Organization Collaborating Centers
WPR	Western Pacific Region

SUMMARY

Strengthening national regulatory systems to ensure access to safe, effective and quality essential medicines and health technologies is necessary to achieve universal health coverage (UHC) and the Sustainable Development Goals (SDGs).

Since 2011, the WHO Regional Office for the Western Pacific has been convening the Regional Alliance for National Regulatory Authorities as a mechanism for improving for collaboration and cooperation between countries in vaccines regulations.

The Sixth Workshop for National Regulatory Authorities for Vaccines and Medicines in the Western Pacific Region was held in Manila, Philippines from 30 to 31 August 2017. Eleven Member States participated in the workshop: Brunei Darussalam, Cambodia, Hong Kong SAR (China), Japan, the Lao People's Democratic Republic, Malaysia, Mongolia, New Zealand, Papua New Guinea, the Republic of Korea and Viet Nam. In addition, the Regional Alliance Steering Committee held a meeting on 29 August 2017.

In view of the need to strengthen the national regulatory systems of Member States more comprehensively, the scope of the Regional Alliance was broadened to include medicines, health technologies and traditional medicines.

The workshop provided a forum for sharing the progress of medical products regulations in the Region and updated the participants on recent developments of regulatory systems strengthening at the global, regional and country levels. Member States shared experiences in the performance of their regulatory functions as well as the gaps and challenges. Further, they discussed emerging issues that commonly affect Member States in the Region, such as shortage and stock-outs of medicines and vaccines, as well as the role of regulations in facilitating the entry of medical products during public health emergencies and in curbing antimicrobial resistance.

Prior to the two-day workshop, the Regional Alliance Steering Committee met to discuss the overall governance and operational mechanism of the Alliance. The Steering Committee proposed revisions of the terms of reference of the Regional Alliance, strengthened its own role as an executive board, and proposed the establishment of the technical working groups that would support scientific and technical matters as needed by the Member States. The strategic objectives and priority areas in the medium term were also endorsed and approved.

In addition, the draft Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation was unanimously endorsed by the Steering Committee.

1. INTRODUCTION

1.1 Meeting organization

The two-day workshop for national regulatory authorities (NRAs) in the Western Pacific Region was held in Manila, Philippines from 30 to 31 August 2017, participated by 11 Member States: Brunei Darussalam, Cambodia, Hong Kong SAR (China), Japan, the Lao People's Democratic Republic, Malaysia, Mongolia, New Zealand, Papua New Guinea, the Republic of Korea and Viet Nam.

On the first day, the participants were updated on the developments of regulatory systems strengthening at the global, regional and country levels. Member States also shared experiences in the performance of their regulatory functions as well as their gaps and challenges. The afternoon session provided an opportunity for Member States to discuss emerging regulatory issues in the Western Pacific Region.

On the second day, the participants discussed a stepwise approach in strengthening regulatory systems. The workshop ended with discussion on restructuring and strategic planning for the Regional Alliance for National Regulatory Authorities.

1.2 Meeting objectives

The objectives of the Sixth Workshop for NRAs for Vaccines and Medicines in the Western Pacific Region were:

- (1) to review the progress of recommendations from the fifth meeting and agree on further collaborative actions of strengthening regulatory systems for vaccines and medicines in the Region;
- (2) to clarify the roles of NRAs in ensuring the availability of vaccines and medicines for emergency use and shortages of global or regional significance;
- (3) to collect feedback by sharing experiences and challenges in the conduct of self-assessment using the WHO benchmarking tool and in the implementation of institutional development plans; and
- (4) to discuss options for convergence and cooperation for regulatory systems strengthening in the Region.

2. PROCEEDINGS

2.1 Opening session

Dr Socorro Escalante, Coordinator, Essential Medicines and Technologies, WHO Regional Office for the Western Pacific Region, delivered the opening remarks on behalf of Dr Shin Young-soo, WHO Regional Director for the Western Pacific. She highlighted the fundamental roles of the NRAs in ensuring the quality, safety and rational use of medicines. NRAs are also increasingly facing pressures

in the introduction of new technologies and the need to approve new medicines and vaccines in a timely manner in response to public health emergencies. Recognizing the complexity of medical products regulation, many countries in the Western Pacific Region are unable to implement all of the regulatory functions that are necessary for a fully functional NRA. Thus, it is necessary that countries undertake a stepwise approach to strengthening national regulatory systems, depending on their needs and context but emphasizing the need to adhere to science-based regulation and guided by international standards and best practices. She called for more resourced countries to help strengthen the regulatory systems in countries with fewer resources.

She urged NRAs and partners, through this Alliance, to work together to effectively strengthen regulatory systems in the Region and fulfil their roles in the achievement of UHC.

Following the opening remarks, Professor Chung Keel Lee was nominated and agreed as the chairperson for the workshop, Dr Atsushi Kato as the vice-chairperson and Dr Geraldine Gill as rapporteur.

Dr Jinho Shin, responsible officer for the workshop, presented the network's history and how it had evolved. He also gave an overview of the two-day workshop.

2.2 Session 1. Developments in the regulatory system strengthening

This session aimed to update participants on regional and global regulatory systems strengthening activities.

Session 1.1 Regional strategies in improving access to essential medicines

Dr Socorro Escalante first presented a brief overview of the access to medicines situation in the Western Pacific Region, particularly on the issues and challenges, with quality and safe medicines and vaccines still inaccessible to many people around the Region. Many countries in the Region have low pharmaceutical expenditure per capita, which results in the majority of the population bearing out-of-pocket payments when buying their medicines. Prices of some medicines are unaffordable to many patients. Stock-outs and shortages are another problem across the Region, especially in the Pacific island countries. Substandard and falsified medical products remain a threat that undermines the effectiveness of public health programmes. Antimicrobial resistance is becoming a more serious health threat. She highlighted that regulatory authorities have a crucial role in all these issues.

While countries are exerting efforts to find a solution to these issues, they are also placed in a very challenging situation such that the pharmaceutical sector is trade-oriented. Oftentimes, pharmaceutical production is not aligned with public health needs. Although policies and laws are robust in many countries in the Region, systems implementing and enforcing pharmaceutical policies and laws are very weak. Weak governance mechanisms in managing conflict of interest, information asymmetry and accountability still remain a challenge.

Given all the issues and challenges that countries are facing, she presented a framework (Annex 2) that can be considered in dealing with access to medicines. She emphasized that every issue and challenge should not be taken in isolation of each other; rather, they should be taken together as part of the whole pharmaceutical system either from the supply or demand side.

At the centre of all these issues and challenges sit the National Regulatory Authorities, which are mandated with enforcing regulations. She reiterated that regulations exist because of the following primary reasons:

- ensuring the availability of safe, effective and quality assured medical products;
- Safeguarding transparency and accountability of pharmaceutical sector;
- reducing information asymmetry: improving the decision-making for policy-makers and patients; and
- improving public trust in the health system.

As a way forward, WHO proposed three main strategic interventions:

1. Strengthen national pharmaceutical systems to improve access
 - Strengthen national regulatory systems
 - Improve availability, affordability and accessibility to essential medicines
 - Combat antimicrobial resistance
2. Strengthen regional platforms to support knowledge flow and capacity-building in countries
 - Strengthen the regional alliance of NRAs as a platform for regulatory strengthening, convergence and cooperation
 - Strengthen access to medicine network
 - Strengthen pharmaceutical systems through subregional platforms in Pacific island countries
3. Lead, convene and set an agenda to implement global and regional initiatives
 - Access to high-cost medicines in the Region
 - Western Pacific Antimicrobial Stewardship Initiative

Session 1.2 Progress in strengthening regulatory systems in the Western Pacific Region

Dr Shin presented the developments on regulatory systems strengthening (RSS) in the Region. He started by providing background about how WHO works to support countries in RSS. He presented various resolutions and frameworks that are part of WHO's mandate in exercising its duties towards the attainment of the Sustainable Development Goals (SDGs) and UHC.

He emphasized that regulatory systems are interlinked with many other programmes. For example, the Regional Framework for Implementation of the Global Vaccine Action Plan, which has as one of its areas of priority action strengthening NRA systems and facilitating relevant technology transfer to contribute to securing the global supply of quality vaccines. He explained the Global Vaccine Action Plan indicators to ensure the progress of vaccine regulatory systems. These indicators include the percentage of doses of vaccine used worldwide that are of assured quality and the number of adverse events following immunization (AEFI) reported per country per 100 000 surviving infants.

The regional implementation plan aims to strengthen pharmacovigilance by improving AEFI reporting from countries and linking with the global safety database (VigiBase). Vaccine Adverse Events Information Management System (VAEIMS) is a software tool developed for health facilities to report AEFI to a central database. It was developed under the Global Vaccine Safety Initiative (GVSI) by WHO and International Vaccine Institute (IVI) with technical guidance from the Uppsala Monitoring Centre (UMC) on E2B/ICH interoperability with the WHO global adverse

reactions database. VAEIMS is currently being piloted in Cambodia, the Lao People's Democratic Republic, Mongolia and Viet Nam.

He also discussed the overall progress of RSS activities in the Region, including the establishment of the Regional Alliance for NRAs for Vaccines and Medicines, which started with the first NRA workshop in Seoul in 2011 for vaccines only, noting that the scope has since been expanded to cover medical products. The Regional Alliance was started under the framework of the Global Vaccine Action Plan and a lot of progress has been made, including conducting a self-assessment to identify current status, strengths and gaps, and facilitating countries to develop and implement an institutional development plan (IDP).

The self-assessment has evolved and is now called NRA benchmarking. It is the core of regulatory strengthening and convergence, where systems are reviewed against benchmarking indicators to identify the performance maturity levels. He also reiterated that regulatory strengthening, convergence and cooperation rely on the Regional Alliance to serve as a platform for strategic planning and capacity-building.

He ended his presentation with some proposals on indicators to measure RSS progress: number of NRAs that underwent a periodic system gap assessment and strategic planning through the process of WHO self-benchmarking and IDP development, review and update; number of NRAs that meet WHO minimal capacity through validation by external experts (percentage of population covered by NRAs meeting WHO minimal capacity); number of NRAs that meet the WHO minimal AEFI reporting ratio; number of NRAs that share AEFI data with UMC VigiBase; number of NRAs that share ADR data with UMC VigiBase; number of NRAs that regulate clinical trials; and number of NRAs that publish a list of all licensed products.

Session 1.3 Global updates on medical products regulation: WHO Good Regulatory Practices process and guidelines

Dr Samvel Azatyan highlighted the role of medical products as a major instrument of public health and their effects on health and life expectancy. Unfortunately, equitable access to medicines is still a global challenge, especially in many low- and middle-income countries. Some of the reasons for the limited access to medicines involve the insufficient regulatory capacity in the countries and lack of harmonized approaches for the regulation of medical products.

Medicines RSS is another challenge faced by the countries. There are significant gaps in the regulatory capacity between countries: 30% of the 194 WHO Member States have limited capacity to perform all core regulatory functions, and 50% have variable capacity.

Regulators need to consider that regulatory science is evolving with time. The focus has changed from testing quality to understanding how quality is built into products or quality assurance, and from assessing efficacy and safety to assessing the benefit–risk balance. The basis of regulatory decision has also evolved in terms of specific scientific guidance to more general guidance. For most regulators, it is unrealistic to manage all functions in one national setting. Hence, there is need for collaboration with other countries. Countries should also consider determining exact competencies needed for regulators and harmonize core curricula for training.

He also shared that it is not true that the pharmaceutical industry does not want to be regulated. Rather, they are more interested in a more predictable environment for assessing their products. The industry also wants regulators to be regulated to ensure more predictable decisions by regulators.

Given all these challenges and realities, he encouraged regulators to consider good regulatory practices (GRP) as a solution to the problems. He shared critical drivers for GRP, with emphasis on the effective implementation of laws, policies and regulations. A WHO GRP guideline is being developed to provide guidance on how to set up a legal framework for medicines regulation. It is expected to be endorsed in October 2017 during the WHO Expert Committee on Specifications for Pharmaceutical Preparations (ECSP) meeting.

He also highlighted that GRP also considers international treaty obligations and regional agreements, including convergence and harmonization. He reiterated that convergence and harmonization do not affect national sovereignty or autonomy in decision-making. Using collaborative and cooperative mechanisms (such as joint assessments of marketing applications or sharing of inspection reports) do not imply collaborative decision-making. Joint decision-making is only possible when appropriate legislation exists (e.g. European Union). In all cases, the regulatory decision remains firmly in the hands of sovereign nations.

He also shared how WHO supports regulators through a holistic approach by developing evidence, maintaining knowledge and understanding the situation and needs of regulatory systems. He highlighted that the principal objectives of NRA benchmarking and capacity-building processes are to strengthen regulatory systems to a level corresponding with a well-functioning, stable system, and to promote regulatory cooperation, convergence, transparency, networking and work-sharing. He shared two initiatives that WHO has established: the Coalition of Interested Partners (CIP) to align the approach and activities of various technical assistance providers (donors, development partners, NRAs, foundations, nongovernmental organizations or NGOs). Centres of Regulatory Training Excellence (CoRTE) have also been established to further support RSS: in accordance with resolution WHA 67.20, NRAs identified/designated by WHO as meeting criteria for a functional regulatory authority will be able to give technical assistance to countries with less mature regulatory systems.

WHO also promotes regulatory convergence and harmonization between NRAs, which garners benefits throughout different sectors:

- **Patients:** quicker access to more affordable, quality assured medicines; assurance that available medicines are safe
- **NRAs:** increased capacity; more timely and cost-effective evaluation process; greater regulatory network sharing of best practice and experience
- **Manufacturers:** greater transparency; reduced regulatory burden; shorter time to approval and improved access to regional markets
- **National government:** health-care resources go further; improved public health outcomes through greater availability of quality assured medicines
- **Donor community:** greater patient reach for a given level of support.

Regulatory cooperation can take various forms, ranging from information sharing to work sharing, reliance, and recognition.

- Reliance will lead to reduction in work for NRAs (allows streamlining/reduction of internal work)

- Recognition means replacement of work for NRAs (rely on decision of other regulator).

He concluded that regulatory capacity-building, promotion of collaboration, convergence and harmonization remain WHO priorities and reminded everyone that there is no good regulation without good governance and proper implementation. Finally, the future of medicines regulation is in convergence/harmonization, collaboration and networking, with NRAs operating more as a functional network rather than as individual players, while the individual players focus on where they can give the best added value.

Session 1.4 Updates on the development of WHO regulatory guidelines

Dr Dianliang Lei in his presentation shared the importance of international standards and how WHO supports this programme. For WHO biological standardization, WHO has played a key role for over 60 years in establishing the WHO biological reference materials necessary to standardize biological materials as well as developing WHO guidelines and recommendations to assure the quality, safety and efficacy of biological products. These norms and standards, based on scientific consensus achieved through international consultations, assist WHO Member States in ensuring the quality and safety of biological products and related in vitro biological diagnostic tests worldwide.

He also shared the procedures in developing guidelines and how WHO works with partners such as its various collaborating centres (CCs) and committees who provide technical advice. Several guidelines were adopted by the pharmaceuticals committees (ECSP and ECBS) in 2016 and a current project is to be reviewed in 2017. He explained that the International Pharmacopoeia (PhInt), a collection of recommended procedures for analysis and specifications for the determination of pharmaceutical substances and dosage forms that is intended to serve as source material for reference or adaptation by any WHO Member State wishing to establish pharmaceutical requirements, is also being updated and will be available soon.

2.3 Session 2. Regulatory co-operation

This session discussed collaborative mechanism on strengthening regulatory systems, harmonization and convergence.

Session 2.1 Poster session

Country representatives provided an overview of their current systems and regulatory setup. In particular, they shared their respective national policy and governance, showing that all countries have existing legislation and policy. The presenters also shared their government structure and how it is anchored to the national government, with most operating under the health ministry except for the Republic of Korea where it is independent from the ministry. This session also provided a venue for Member States to share their strengths and challenges. Japan shared capacity-building opportunities in which other countries can participate and that are being offered by the Pharmaceuticals and Medical Devices Agency.

Session 2.2 Country experience: Added value and challenges of participating in a regulatory network

In the era where convergence and harmonization are in the spotlight of discussion, this session provided an opportunity for countries to learn from each other's experiences, especially on best practices.

a. Association of Southeast Asian Nations (ASEAN) membership – Cambodia

Mr Cheap Thonvuthy provided an overview of RSS activities (both planned and completed) in Cambodia, including the adoption of ASEAN harmonization in 2003 and their challenges.

b. Pharmaceutical Inspection Co-operation Scheme (PIC/S) membership – New Zealand

Ms Geraldine Hill shared New Zealand's experience as a member of the PIC/S. It is a technical organization with the mission to "lead the international development and maintenance of harmonised Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products". PIC/S aims to bring about competent, globally consistent auditing activities by NRAs to promote quality manufacture of medicines. It was established in 1995 as an extension of the European Pharmaceutical Inspection Convention and currently has 49 member NRAs.

Being a member of harmonization schemes such as PIC/S gives way to many benefits, including a reduced burden on individual NRAs to perform GMP inspections through the recognition of inspections performed by other NRAs. This is particularly beneficial for small NRAs with limited capacity to perform audits beyond their own borders.

However, being a member of PIC/S does not garner automatically mutual recognition agreement (MRA). PIC/S membership is an endorsement of an NRA as a credible regulator, but recognition of GMP certification by other regulators may not be automatic or immediate. It takes time for other countries to feel comfortable about accepting GMP certifications that are issued by new members.

c. PIC/S membership – Malaysia

Ms Noorul Akmar Mohd Nur described Malaysia's journey to gain PIC/S membership and the activities of the National Pharmaceutical Regulatory Agency as a PIC/S member

Prior to membership, a detailed assessment was undertaken to determine whether the Agency had the necessary competencies to undertake inspections of the standard required by PIC/S. The assessment included an examination of their inspection and licensing system, quality system, legislative requirements and inspector training.

The assessment culminated in a visit by a PIC/S delegation and inspectors to observe the GMP implementation and carry out GMP inspections, respectively. Malaysia became the 26th member of PIC/S on 1 January 2002, and passed PIC/S reassessment in 2015. Since becoming a member, the National Pharmaceutical Regulatory Agency has participated in the following PIC/S activities:

- Annual seminar
- Expert circle meeting
- Annual meeting
- Joint inspection
- Coached inspection
- Evaluation delegation

- Training of auditors
- Assessment and reassessment.

d. WHO Programme for International Drug Monitoring (PIDM) membership

Ms Soulyvanh Keokinnaly described the Lao People's Democratic Republic's experience with pharmacovigilance since 2008. The country became a full PIDM member in 2015. Being a member of WHO PIDM shed light on the agencies' work, especially in the strengthening of the pharmacovigilance system:

- More opportunities for education and training on pharmacovigilance
- Opportunities to collaborate in international and regional pharmacovigilance activities.
- Monitoring and data management through VigiFlow/VAEIMS¹
- Increased access to information including VigiLyze to view individual case safety reports from other countries
- Improving coordination and communication with internal and external stakeholders

2.4 Session 3. Emerging regulatory issues in the Western Pacific Region

This session provided an opportunity to reflect on the emerging issues in the Region and identify strategies and approaches to address them.

Session 3.1 Shortages and stock-outs a global concern

a. Role of NRAs in shortages and stock-outs of medicines and vaccines

Dr Jinho Shin presented global initiatives in addressing the global shortage of medicines and vaccines. He explained the reasons behind this continuing problem in the supply chain. These include insufficient or non-existent manufacturing capacity for products, problems with active pharmaceutical ingredients, financial constraints, problems with forecasting, challenges with supply chain management and serving areas that are difficult to reach. Financial constraints include limitations on national budgets as well as on patient out-of-pocket payments.

Currently, many countries, either regionally or globally, have no mechanism to report shortages. Prevention of shortages requires a systemic approach addressing production, approval, procurement and distribution. One of the possible solutions is in notification systems, and NRAs have an important role to play. He shared examples of country notification systems started by the Australian Therapeutic Goods Administration's Medicine Shortages Information (MSI) Initiative, the European Medicines Agency's Shortages Catalogue and the United States Food and Drug Administration's Drug Shortages Database. Such systems allow root-cause analysis. In the case of vaccines used in national immunization programmes, stock-outs are self-reported by countries annually.

He emphasized that, if the system is working well, shortages can be prevented. He shared the recommendations from the 2015 WHO consultation on addressing shortages and stock outs:

- Use risk management principles to identify and prioritize measures to ensure the continued supply
- Stakeholder involvement

¹ Use of VigiFlow full version requires a fee, but the limited version is available to NRAs without charge.

- During procurement, it is necessary to review systems and identify possible causes of shortages
- Adopt IT support with bar coding in supply chain management
- Observe ethical use and define priorities, for example oncology products in short supply
- Fair pricing
- Regulators should facilitate, prevent and mitigate supply interruptions by, for example, mandatory notification by manufactures and expedited inspections and reviews to incentivize manufacturing of good quality products of public health need
- In national reporting systems, it is necessary to standardize terms and harmonize reporting systems according to best practices.

b. Medicine Shortages Information Initiative – Australia

Dr Anthony Hobbs shared that the problem of shortages and stock-outs is a global concern. Even a mature regulatory system like Australia's Therapeutic Goods Administration still faces significant problems to address it. He shared Australian experiences on setting up a notification system as an important strategy to address the problem of shortages and stock-outs.

Australia has rolled out the web-based Medicines Shortage Information Initiative since 2014 that other countries in the Region may learn from. The Initiative was jointly set up by the Therapeutic Goods Administration and two industry groups (Medicines Australia and their member companies, and Generic and Biosimilar Medicines Association and their member companies).

It generates information that is helpful to the public, health providers and the industry itself in terms of shortages and stock-outs. The information is published and updated to keep health-care professionals informed of the situation and when it has been resolved.

He concluded by sharing critical issues that need to be dealt with to further improve the Initiative, such as being voluntary or to become mandatory, timeliness and accuracy of reporting, willingness to notify and the availability in the public market but not in private market.

In the discussion, participants raised issues about risks of sharing information. If not handled appropriately, the problem may escalate as there will be hoarding issues, market advantage, inflation of prices and other risks.

Session 3.2 The role of NRAs in response to public health emergencies

During public health emergencies involving communicable disease outbreaks, NRAs are pinpointed out by the government as the front line to address issues of quality, safety and effectiveness of medical products. This session provided an opportunity to learn from the current practices of Member States in response to public health emergencies.

a. Special approval pathway for medicines used in public health emergencies in Japan

Dr Fumihito Takanashi discussed how in a public health emergency the situation may call for immediate decision-making based on incomplete information (i.e. when the benefit–risk balance of a medicine or vaccine is uncertain).

He shared Japan's strategy in response to public health emergencies. There is legal basis included in the Japanese Pharmaceuticals and Medical Devices Act with a "Special Approval" provision (Article 14.3) that allows relaxation of some of the usual requirements when the following conditions are met:

- Pharmaceuticals for any urgent need to prevent the spread of a disease that may threaten public health, and for which there is no alternative intervention available
- Pharmaceuticals authorized in a foreign country with a regulatory system that is equivalent to that of Japan in terms of assessment of quality, safety and efficacy.

The Special Approval provision has been used in Japan for H1N1 pandemic influenza vaccines. He concluded that in developing strategies in response to public health emergencies, countries may consider the following:

- Legal basis of the special approval pathway where a part of the requirements is relaxed
- Specification of the products to be applied (i.e., situation and pre-approval from other countries)
- Readiness is required for every NRA.

b. Ministry of Food and Drug Safety strategies in response to new infectious diseases during outbreaks

Dr Jaehyun Lim presented the Republic of Korea's strategy in preparation for new infectious disease outbreaks, such as severe acute respiratory syndrome, novel influenza virus, Ebola virus, Middle East respiratory syndrome coronavirus and Zika virus.

He shared the Republic of Korea's emergency management system and procedures in collaboration with other relevant agencies such as the Ministry of Health and Welfare, Korea Centers for Disease Control and Prevention and others in prevention, preparation, response and recovery activities. He highlighted the regulatory pathway for rapid permission and the fast evaluation and approval system. He provided suggestions for public health emergency preparedness:

Global level:

- Strengthening international cooperation – to share information and advanced technologies via memoranda of understanding
- Issuing guidelines to evaluation new infectious diseases in a timely manner
- Research collaboration and education

National level:

- Secure budget to support research and development (R&D) on new infectious diseases
- Establish public health infrastructure to manage crisis
- Legislate to control public health emergency
- Strengthen cooperation between government, academia and the private sector

c. Expectation on regulatory systems for medical products in response to public health emergencies

Dr Jinho Shin shared how WHO works to support countries in response to emergencies. WHO should play a convening role in accelerating the development of appropriate diagnostics, vaccines,

therapeutics, and medical and information technology. He shared the lessons learnt during the Ebola crisis and strategic response plan.

He spoke on the challenges encountered from product R&D until it reaches regulators for review of quality, safety and efficacy. In particular during the Ebola haemorrhagic disease outbreak in West Africa, the challenges reported included difficulty in obtaining efficacy data in the face of declining case numbers, no immunological correlates of protection established, validation of enzyme-linked immunosorbent assay (ELISA) methods for measuring immunogenicity, data requirements for registration and acceleration of regulatory review.

2.5 Session 4. Stepwise approach to strengthening regulatory systems

Dr Socorro Escalante introduced the rationale of using a stepwise approach in RSS. Due to the varying degree of regulatory functions performed in terms of capacity and sophistication, NRAs cannot perform all functions at the same time. The Western Pacific Region has the most advanced national regulatory systems for medicines and medical products in the world, such as those in Australia, Japan, the Republic of Korea and Singapore. There is a huge potential for the less developed countries to avail themselves of these resources for training and capacity-building.

Raising regulatory capacity involves RSS and regulatory convergence and cooperation. A stepwise approach was outlined as follows:

1. **Country context:** Appropriate regulatory outcomes need to be determined for each country, based on the country's development stage, needs and pharmaceutical activity, and capacity and governance arrangements. This can be done through assessment.
2. **Legal framework:** Regulatory functions appropriate to each country's situation need to be determined with a clear delineation of mandate and roles. There should be a balance between the degree of restriction and the need to facilitate access to medicines, with special provisions for emergency access to medicines. Countries may refer to the legal framework of countries with more developed NRAs, and GRP and international standards may also serve as a basis.
3. **Core functions:**
 - Importing countries
 - Licensing of establishments (importation, distribution, retail)
 - Registration/marketing authorization
 - Market surveillance and pharmacovigilance
 - Recall and withdrawal
 - Importing and producing countries (core functions in addition to those for importing countries)
 - Laboratory testing and lot release
 - GMP inspections
 - R&D and clinical trials
 - Importing, producing and exporting countries (core functions in addition to those for importing and producing countries)
 - Certificate of Pharmaceutical Product (CPP)
 - Pre-qualification

She also discussed that RSS should be taken in parallel with regulatory convergence and cooperation, to provide a platform to collectively address public health concerns. It involves the development of legal frameworks, setting of standards, information exchange, capacity-building, enhancing regulatory reach across borders, and reducing the regulatory burden of individual NRAs. It also addresses public health concerns such as disease outbreaks, substandard and falsified medicines, and antimicrobial resistance.

Currently, cooperation between regulatory authorities tends to involve NRAs with comparable levels of maturity, and is based on stringent criteria for participation to enable trust and reliance. Countries with less mature regulatory systems are left behind, creating inequities in the degree of protection and safety of their populations.

The capability of countries with more advanced regulatory systems can be tapped, such support needs to be coordinated to maximize the impact for less resourced countries.

Session 4.1 Building capacities on clinical trials in countries in the Western Pacific Region

Dr Syed Shah presented on the role of NRAs in the approval and oversight of clinical trials. He started by sharing common challenges faced by many NRAs globally and regionally and suggested possible solutions and suggestions.

The regulatory framework for clinical trial oversight requires a clear legal mandate with identification of the responsible authority and definition of their duties and powers including the authorization and suspension of clinical trials. The legal provisions should ensure that clinical trials comply with Good Clinical Practice (GCP) and include the establishment of an independent ethics committee. Registration of all clinical trials in a publicly accessible registry helps to identify publication bias and ensures study objectives are not changed during the trial.

In the discussion, participants were invited to share their respective country's current situation in terms of clinical trial regulation. Many countries have a legal basis for regulations but acknowledged the challenges in implementation.

Session 4.2 Breakout group work

a. Marketing authorization

Participants were asked to identify issues and challenges, such as the source of potential risk(s) associated with registration and marketing authorization of medical products, and conduct risk assessment and risk categorization/prioritization by risk ranking matrix based on the likelihood and severity of the impact (consequences, results). A scenario highlighting the pandemic influenza outbreak was presented.

A root-cause analysis was conducted. Participants were able to identify internal and external issues from the mobilization of funding and expert resources, laboratory capacity strengthening and fast-track procedures. The participants identified two risks: delay in registering and safety of the product. After identifying causes, strategies were recommended in response to the pandemic influenza outbreak, including development of a contingency plan and capacity-building. In terms of product safety, active surveillance should be strengthened to improve data sharing globally.

b. Pharmacovigilance: How to conduct a risk assessment and how to select the best risk communication strategy

The group was presented with a scenario of a recent incident in South Sudan where 15 children died and 32 children were seriously ill, following immunization with a contaminated vaccine.

The root-cause analysis identified that the problem was not the vaccine itself, but resulted from an individual who had administered the vaccine using the same needle and syringe to all of the affected children. Additional problems identified were that children from the village had been involved in the administration of the vaccine and that the cold-chain had been broken for a period of four days.

Given the severity and unexpectedness of the AEFI, and the associated outrage, the risk was assessed by the group to be at the highest level on the risk assessment matrix. Consequently, the appropriate communication strategy was considered to be crisis communication: clear, compassionate, informative and transparent communication of accurate information.

The approach taken aimed to restore confidence in the vaccine and vaccine programme by highlighting that the failing was of one individual. However, it should be noted that to avoid a repeat of this situation, the system failings that allowed the situation to occur (for example, lack of trained vaccinators, inadequate supply of syringes and needles, and unreliable electricity supply) also need to be addressed, with accountability at a much higher level.

2.6 Session 5. Regional Alliance restructuring and strategic planning

Following the agreement from the fifth NRA workshop in September 2016 and as stipulated in the second edition of the Regional Alliance terms of reference, new terms of reference shall be developed.

This session provided a venue for the countries to discuss the outcome of the Steering Committee meeting in 29 August 2017. The draft Terms of Reference of the Regional Alliance for National Regulatory Authorities in the Western Pacific (previously called concept paper) were reviewed. A final draft will be circulated for consultation (Annex 3). After consensus was reached on the draft terms of reference, the participants discussed the strategic objectives (Annex 4) and priority areas of the network (Annex 5).

2.7 Session 6. Closing session

The workshop ended with reflections from each participant and a strong message on the need to continue collaboration with other countries.

3. CONCLUSION AND RECOMMENDATIONS

3.1 Conclusions

Updates on the work of NRAs

- (1) Updates on the developments of regulatory systems strengthening at the global, regional and country levels were provided. Member States shared experiences in the

performance of their regulatory functions as well as the gaps and challenges. The participants acknowledged that NRAs play a crucial role in shortages and stock-outs of medicines and vaccines. One potential solution is in information sharing through notification systems. However, care must be exercised in data management, as this may result in market advantage, inflation of prices and other risks. Surprisingly, most Member States have no clear regulatory pathway for medicines and vaccines during emergencies. Thus, more support is expected from WHO on this matter.

- (2) Participants acknowledged that a stepwise approach is necessary for regulatory systems strengthening, where marketing authorization and pharmacovigilance will be the starting points. Strengthening recall and withdrawal mechanisms were also identified as areas that require support.

Regional Alliance for NRAs

The Regional Alliance Steering Committee meeting focused on two issues:

- (1) The participating Member States expressed full support and endorsed the Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce (document for the WHO Regional Committee for the Western Pacific).
- (2) On the terms of reference of the Regional Alliance, the participating Member States:
 - upheld the role and relevance of the Regional Alliance in the Region;
 - approved/endorsed the terms of reference, which cover vision and mission, goals, strategic objectives, terms of membership, governance mechanisms and the role of the Secretariat and Member States who are participating in the Alliance (Annex 3);
 - agreed to expand the scope of the Alliance to all medical products;
 - clarified the roles of the Steering Committee and technical working groups, with the Steering Committee acting as an executive board and the technical working groups, established based on the needs of the Member State, dealing with the scientific and technical matters;
 - approved the strategic objectives (Annex 4) and priority areas in the medium term (Annex 5); and
 - proposed holding the Seventh Regional Alliance Workshop in Manila (thereafter Member States will be encouraged to host the meetings).

3.2 Recommendations for Member States

Member States may consider the following:

- (1) to practice a stepwise approach in strengthening regulatory systems in the context of their needs, resources and capacity with the Regional Action Agenda potentially serving as guidance in this process;
- (2) to regularly conduct benchmarking of regulatory performance against international standards and good practices and develop institutional development plans to address gaps and challenges;

- (3) to obtain political commitment and support in achieving good regulatory outcomes and through strengthening of regulatory systems and participation in the regional alliance and other relevant networks to improve cooperation;
- (4) to adopt international guidelines including WHO norms and standards and good regulatory practices; and
- (5) to collaborate with stakeholders and develop and implement strategies crucial for risk prevention, control and mitigation associated with medicine shortages and stock-outs, and emergency preparedness.

3.3 Recommendations for the Regional Alliance

The Regional Alliance is requested to do the following:

- (1) to serve as a platform for sharing information, convergence and cooperation in the Western Pacific Region;
- (2) to establish a pool of experts and institutions to support strengthening of NRAs with focused support to lesser-resourced countries; and
- (3) to work towards obtaining and building political commitment from Member States in the area of regulatory strengthening.

3.4 Recommendations for WHO

WHO is requested to do the following:

- (1) to continue supporting Member States in developing and implementing national priority actions on regulatory strengthening, convergence and cooperation to improve regulatory performance based on country needs;
- (2) to update Members States on norms and standards and other regulatory guidelines, and provide support for their adoption as necessary; and
- (3) to support the operations of the regional alliance and coordinate the implementation of its strategic objectives and priorities.

4. ANNEXES

Annex 1 Access to medicines framework

Annex 2 Regional Alliance terms of reference

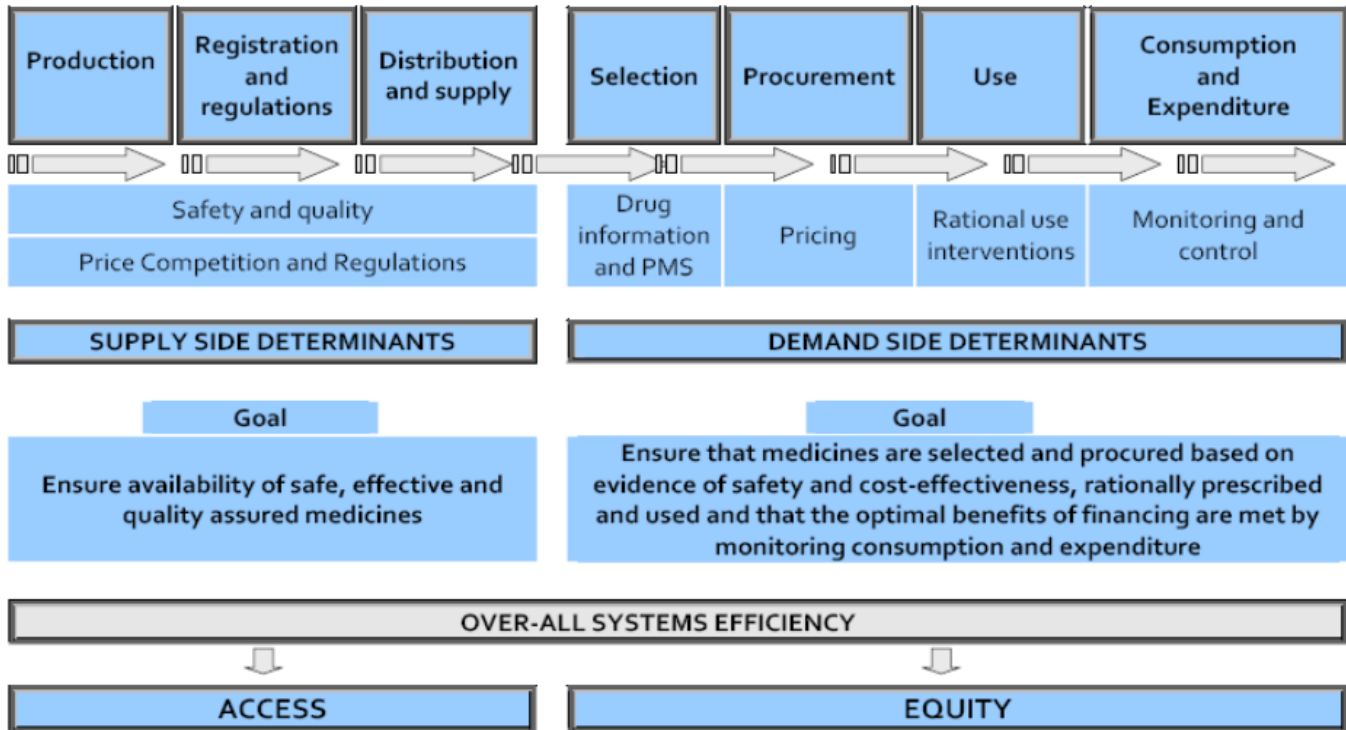
Annex 3 Strategic objectives and workplan

Annex 4 Prioritization matrix

Annex 5 Regional Alliance Steering Committee meeting minutes

Annex 1 Framework

Potential areas for intervention by the State Health Insurance



**TERMS OF REFERENCE
FOR
REGIONAL ALLIANCE FOR NATIONAL REGULATORY AUTHORITIES
IN THE WESTERN PACIFIC**

1. PREAMBLE.....2

2. VISION2

3. MISSION.....2

4. MEMBERSHIP2

5. GOVERNANCE.....2

5.1 THE GENERAL ASSEMBLY: 3

5.2 THE STEERING COMMITTEE: 3

5.3 TECHNICAL WORKING GROUPS 3

5.4 SECRETARIAT..... 4

6. CONDUCT OF BUSINESS4

1. Preamble

We the National Regulatory Authorities (NRAs) of the Member States in the Western Pacific Region, duly constitute the Regional Alliance of National Regulatory Authorities in the Western Pacific, and hereby commit to work together and cooperate to strengthen the regulatory systems in this region, thereby ensuring safety, quality and efficacy of medical products, promoting and protecting public welfare and contributing to the attainment of universal health coverage (UHC) and health for all.

2. Vision

All people in the Western Pacific Region will have access to quality, safe, efficacious medical products.

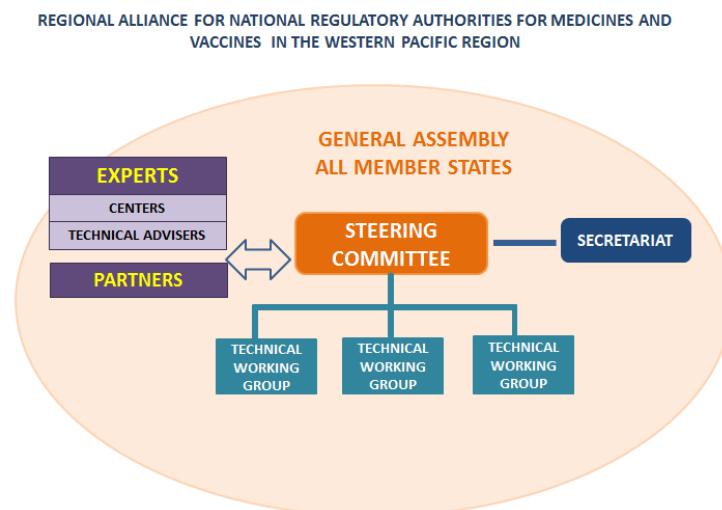
3. Mission

The Regional Alliance will strive to promote and support strategies to strengthen regulatory systems, providing an effective platform for regulatory convergence and cooperation in the Western Pacific Region.

4. Membership

Membership is voluntary and by Member States with duly designated representative who is the head of the National Regulatory Authority or his/her alternate.

5. Governance



The number of technical groups will be identified by the Steering Committee according to the needs of the Member States

5.1 The General Assembly:

Membership : The General Assembly shall be constituted by the Member States which are members of the alliance.

Role : The General Assembly shall:

- a. serve as the highest decision-making body of the alliance.
- b. appoint/designate members of the Steering Committee
- c. decide on the strategic workplan of the Alliance
- d. approve the creation of the technical groups upon the recommendation of the Steering Committee

Meeting : The General Assembly shall meet on annual basis. Ad-hoc meetings may be determined as necessary.

WHO Collaborating Centres, NRAs from other regions, partners can participate as observers. Invitation will be made by the Secretariat, upon authorization of the Steering Committee.

5.2 The Steering Committee:

Membership : There shall be a duly constituted Steering Committee composed of 7 members who shall be appointed by the General Assembly for a period of three years and maximum of 2 terms. In case of withdrawal of any member of the Steering Committee, a formal notification shall be submitted to the Secretariat and General Assembly. The General Assembly will then designate replacement. The Chairman will serve on a rotational basis among the countries and will be selected upon mutual agreement of the members of the SC.

Role : The Steering Committee shall:

- recommend policies and strategic directions of the Alliance to the General Assembly;
- oversee the implementation and or/operationalization of the work of the Alliance.
- propose technical working groups to be approved by the General Assembly
- advise the General Assembly on any other matters pertaining to its conduct of business, operations and strategic directions.

Meeting : The Steering Committee shall meet regularly every six months, a face-to face meeting and videoconference. Ad-hoc meetings may be scheduled as it deems necessary.

5.3 Technical Working Groups

Constitution and membership: : Technical Working Groups (TWG) will be established by the General Assembly upon the recommendation of the Steering Committee.

Role : The TWG shall provide expert advice to the alliance on specific areas of work across the domains of regulatory functions and product-specific issues.

- Meeting* : The TWG may determine the number of meetings as necessary.
- Reporting:* The technical working groups shall provide semi-annual progress report to the Steering Committee and annual report to the General Assembly
- Coordination and communication with secretariat* : All technical groups should coordinate their work plan and actions with the secretariat for smooth operations, ensure coherence and avoid potential conflict or delay in planning and conducting their duties. All harmonization (or technical) groups should also ensure that before communicating with external parties they have coordinated their actions with the secretariat

5.4 Secretariat

The WHO Regional Office for the Western Pacific, based in Manila, will provide secretarial support to the regional alliance.

Roles and functions:

- a. Provide technical and administrative assistance to steering committee and technical groups.
- b. Plan and organize face to face meetings, virtual meetings and annual workshops with the steering committee and also with the t groups if needed.
- c. Develop the program and agenda during meetings and annual workshop, coordinates with the steering committee
- d. Establish and update the roster of experts required for a defined area;
- e. Maintain institutional memory of regional alliance activities through archiving and relevant databases of information;
- f. Develop, manage and update the advocacy and information material of the Regional Alliance;
- g. Coordinate with Member States the regional alliance work plan; and
- h. Report about progress to Steering Committee Members

6. Conduct of Business

Meetings: The Steering Committee will meet every six months – 1) prior to the annual NRA workshop and 2) by teleconference. Adhoc meetings may be convened as the need arises..

Decision making: Agreement shall be reached through a consensus.

7. Strategic Objectives

Strategic objectives	Specific objectives	
1. Promote assessment of regulatory capacity and the concept of WHO minimal capacity to obtain commitments from the government and external partners.	1.1	Promote and assist in the assessments of NRAs or re-assessments of medicines regulatory authorities and identify pool of experts.
	1.2	Support the development and update of an NRA institutional development plan.
	1.3	Identify and coordinate regional needs for priority support
2. Help address challenges and gaps in regulation of medicines/vaccines and systematically implement institutional development plan especially to limited resource countries.	2.1	Conduct analysis of common and unique experience by member states by using the data obtained from NRA assessment and identify which gaps can be address in regional setting and/or country specific.
	2.2	Ensure quality management system functionality to monitor competencies and performance for the continuous improvement
	2.3	Obtain commitments from strategic partners in technical and financial areas.
	2.4	Strengthen regulatory workforce and enhance skills and competencies
3. Promote regulatory convergence, cooperation, reliance, and recognition of other NRAs decision.	3.1	Increase exchange of routine and critical regulatory information to support relevant and evidence-based decisions, as well as to ensure timely action in case of high health risk or threat.
	3.2	Promote and develop collaborative exchange mechanisms to learn about best practices and avoid duplicative work.
	3.3	Promote development of country policies consistent with WHO regional and international standards
4. Promote and coordinate application of regulatory science and support regulatory preparedness for health emergency	4.1	Promote use of WHO norms and standards and other international harmonized guidelines.
	4.2	Support in setting strategies to deal with health emergency situation like outbreak and other disaster induced health emergencies.

8. Resources

Activities of the NRA Regional Alliance including workshops, meetings and other activities within the work plan of the regional alliance will be supported by:

- a. World Health Organization
- b. Member States
- c. Partners and Experts

9. Management of conflict of interest

The Alliance shall establish a mechanism for management of conflict of interest for observers, experts and other entities who may wish to participate in the technical meetings of the Alliance.

History of Revision

Rev 00	Initial Draft (drafted by secretariat from the survey on Regional Alliance expansion 2015)
Rev 01	Revised in January 2017 to include comments during the RASC WebEx meeting
Rev 02	Revised in June 2017 to include comments during RASC WebEx meeting
Rev 03	Revised in August 2017 to include comments during the RASC face to face meeting

Annex 3 Strategic Plan

<i>Strategic objectives</i>	<i>Specific objectives</i>		<i>Plan of action</i>		<i>Secretariat</i>
			<i>Regional Alliance</i>	<i>Member States</i>	
1. Promote assessment of regulatory capacity and promote the concept of WHO minimal capacity to obtain commitments from the government and external partners.	1.1	Promote and assist in the assessments of NRAs or re-assessments of medicines regulatory authorities (NRA assessment) and identify pool of experts.	<ul style="list-style-type: none"> - Review/debate/approve steps to harmonize indicators for different product streams - Review the progress on the status of benchmarking with harmonized global tool - Reporting of IDPs - Discuss collaboration and trainings - Set up workshops 	<ul style="list-style-type: none"> - Conduct self-benchmarking with - Develop/update IDP - Plan annual implementation of IDP - Share IDP to NRAs 	<ul style="list-style-type: none"> - Coordinate to develop steps to harmonize indicators for different product streams - Prepare progress report for benchmarking
	1.2	Support the development and update of an NRA institutional development plan.	<ul style="list-style-type: none"> - Update and maintain repository of country IDP - Reviewing existing IDP 	<ul style="list-style-type: none"> - Share IDP with RA - Political support 	<ul style="list-style-type: none"> - Coordinate repository process - Facilitate MS to report to RA and provide assistance and arrangement for trainings and assist in implementation
	1.3	Identify and coordinate regional needs for priority support	<ul style="list-style-type: none"> - Review/approve priority-setting - Provide political support 	<ul style="list-style-type: none"> - Implement country activities 	<ul style="list-style-type: none"> - Inform Member States of updated GBT factsheet
2. Help address challenges and gaps in regulation of medicines/vaccines and systematically implement institutional development plan especially to limited resource countries.	2.1	Conduct analysis of common and unique experience by Member States by using the data obtained from NRA assessment and identify which gaps can be address in regional setting and/or country specific.	<ul style="list-style-type: none"> - Foster opportunities for info-sharing (posters, newsletter) - Review/approve regional or country specific training plans - Information sharing, global training opportunity, provide funding 	<ul style="list-style-type: none"> - Participate in regional alliance - Continue country regulatory profiling and share with members - Provide root-cause analysis of gaps 	<ul style="list-style-type: none"> - Support RA and MS
	2.2	Ensure quality management system functionality to monitor competencies and performance for the continuous improvement	<ul style="list-style-type: none"> - Review/approve regulatory QMS tools 	<ul style="list-style-type: none"> - Implement QMS policy, principles and practices through self-audit and monitor the progress - Do SOPs, self-audit, self-assessment 	<ul style="list-style-type: none"> - Support RA and MS
	2.3	Obtain commitments from strategic partners in technical and financial areas.	<ul style="list-style-type: none"> - Review/approve regulatory partnership strategy 	<ul style="list-style-type: none"> - Identify and catalyse partnership - Support Regional Alliance by communicating 	<ul style="list-style-type: none"> - Support RA and MS

	2.4	Strengthen regulatory workforce and enhance skills and competencies	<ul style="list-style-type: none"> - Review/approve regulatory workforce strategy - Training of training for trainers 	<ul style="list-style-type: none"> - Define skills and competencies in regulatory systems and functions 	<ul style="list-style-type: none"> - Support RA and MS
3. Promote regulatory convergence, cooperation, reliance, and recognition of other NRAs' decision.	3.1	Increase exchange of routine and critical regulatory information to support relevant and evidence-based decisions, as well as to ensure timely action in case of high health risk or threat	<ul style="list-style-type: none"> - Review/approve indicators to monitor implementation for regional action agenda - Provide help to NRAs 	<ul style="list-style-type: none"> - Share experiences - MOU, MRA - Training for NRAs 	<ul style="list-style-type: none"> - Support RA and MS
	3.2	Promote and develop collaborative exchange mechanisms to learn about best practices and avoid duplicative work	<ul style="list-style-type: none"> - Review/approve proposal to share examples 	<ul style="list-style-type: none"> - Share experiences 	<ul style="list-style-type: none"> - Support RA and MS
	3.3	Promote development of country policies consistent with WHO regional and international standards	<ul style="list-style-type: none"> - Review/approve tools to monitor country implementation of consistency 	<ul style="list-style-type: none"> - Share experiences on policy development 	<ul style="list-style-type: none"> - Support RA and MS
4. Promote and coordinate application of regulatory science and support regulatory preparedness for health emergency	4.1	Promote use of WHO norms and standards and other international harmonized guidelines.	<ul style="list-style-type: none"> - Review/approve monitoring tools to measure country implementation 	<ul style="list-style-type: none"> - Harmonize national guidelines with international ones 	<ul style="list-style-type: none"> - Assist MS to implement international standards
	4.2	Support in setting strategies to deal with health emergency situation like outbreak and other disaster induced health emergencies.	<ul style="list-style-type: none"> - Review/endorse strategies for regulatory engagement and preparedness in public health emergencies - Regional Implementation workshop 	<ul style="list-style-type: none"> - Engage with multi-stakeholders in national disaster/emergency response - Participate in WHO implementation workshops where appropriate 	<ul style="list-style-type: none"> - Coordinate developing concept note on strategies for regulatory engagement and preparedness in public health emergencies - Facilitate country participation

Annex 5: Regional Alliance Steering Committee (RASC) Meeting, 29 August 2017, Manila, Philippines

The Regional Alliance Steering Committee (RASC) meeting was held in Manila, Philippines on 29 August 2017 and attended by representatives nominated from three member countries (Japan, Malaysia and Republic of Korea) and Technical Advisors for the Sixth NRA workshop.

Key findings of the meeting are as follows:

- 1) Discussed the role of the alliance in strengthening national regulatory systems in countries in alignment with the Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce. The framework received affirmative response from the members and endorsed. The Committee emphasized that the endorsement is only applicable to medicines and not to health workforce as this will be endorsed by another program area.
- 2) With regard to Regional Alliance role and relevance in regulatory systems strengthening in the region, the Committee:
 - approved/endorsed the terms of reference, which cover vision and mission, goals, strategic objectives, terms of membership, governance mechanisms and the role of the Secretariat and Member States who are participating in the Alliance
 - agreed to expand the scope of the Alliance to all medical products;
 - clarified the roles of the Steering Committee and technical working groups, with the Steering Committee acting as an executive board and the technical working groups, established based on the needs of the Member State, dealing with the scientific and technical matters;
 - approved the strategic objectives and priority areas in the medium term

A revised terms of reference was presented in the general assembly during the workshop for confirmation and endorsement. A further revision was made and a strategic plan was drafted and will be circulated to countries through official channels of communication.

The Committee also discussed the decision on the venue of the seventh workshop in 2018 which will be convened in WHO Regional Office Manila. The Secretariat is recommended to communicate and encourage the countries to host the meeting in 2019.

Recommendations

The Regional Alliance is requested to do the following:

- (1) to serve as a platform for sharing information, convergence and cooperation in the Western Pacific Region;
- (2) to establish a pool of experts and institutions to support strengthening of NRAs with focused support to lesser resourced countries; and
- (3) to work towards obtaining and building political commitment from Member States in the area of regulatory systems strengthening.

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