Meeting Report

THE FIFTH WORKSHOP FOR NATIONAL REGULATORY AUTHORITIES FOR VACCINES IN THE WESTERN PACIFIC REGION

28–29 September 2016

Manila, Philippines

World Health Organization
Western Pacific Region

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WORLD HEALTH ORGANIZATION

REGIONAL OFFICE FOR THE WESTERN PACIFIC

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Convened by:

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Manila Philippines
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NOTE

The views expressed in this report are those of the participants of the Fifth Workshop for National Regulatory Authorities for Vaccines 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 Fifth Workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region in Manila, Philippines from 28 to 29 September 2016

Contents

Keywords: Health personnel − education / Regional health planning / Vaccines − standards, supply and distribution

SUMMARY

National Regulatory Authorities (NRAs) for medical products are responsible for ensuring that all products used by health programmes in the country are of good quality, safe and efficacious. The critical role of NRAs in promoting access, affordability, appropriate use and assured quality of medical products (i.e. medicines, biologicals including vaccines, medical devices and diagnostic tools) has been recognized by multiple World Health Regulations resolutions.

These days, NRAs for medical products are faced with many challenges such as outbreaks of emerging and re-emerging diseases, dynamic changes of population structure in the surrounding environment, rapid innovations of new products coming into market, complexity of manufacturing and automation, international movement of raw materials, drug substances and drug products, diversified supply chains through public or private settings and regulation of promotional activities on multimedia, and pressure to speed up regulatory approval process for vaccines and medicines for health emergency use. Furthermore, NRA regulators are being exposed to pressure requiring the continuous improvement of the system in order to meet the needs of the public and the stakeholders in a transparent, accountable and predictable way. In line with these challenges, regulators can strengthen their system by participating in activities involving the latest global and regional regulatory strengthening policies and developments, and engaging in collaboration and networking to address these challenges.

The Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific meets annually to provide a forum for Member States to discuss issues in vaccines regulation commonly experienced in the Region.

The Fifth Workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region was held in Manila, Philippines from 27 to 29 September 2016. It was attended by representatives from 12 Member States, four technical advisers from WHO collaborating centres, and observers from the Japan International Cooperation Agency (JICA), WHO headquarters and WHO regional offices for South East-Asia and the Western Pacific. During the workshop, participants discussed WHO reforms on the regulatory system strengthening policy, methodology, global tool and pathway, in accordance with World Health Assembly (WHA) resolution 67.20.

The objectives of the fifth NRA meeting were:

1) to review progress against objectives of the Alliance;

2) to discuss and identify opportunities for the regional adaptation of newly proposed global policy on regulatory assessment; and

3) to review and identify options for collaborative actions for regulatory systems strengthening in the Region.

Prior to the NRA workshop, the Regional Alliance Steering Committee (RASC) gathered to plan a programme for the fifth NRA workshop, and to review the terms of reference including the scope and renewal of the RASC membership 2017–2020. The members reached

a consensus to expand the scope of the Regional Alliance to include not only vaccines, but also medicines and other medical products. A task force was set up to develop the third edition of the Regional Alliance concept paper. The participants have expressed high level of commitment to adopt the global benchmarking tool and discuss with their respective agencies on how to comply with the criteria.

1. INTRODUCTION

1.1 Meeting organization

On 27 September 2016, a day before the workshop, the Regional Alliance Steering Committee met to discuss the future of the Regional Alliance, the change of governance and the organization of the fifth workshop.

The Fifth Workshop for National Regulatory Authorities for Vaccines in the Western Pacific Region was held from 28 to 29 September 2016 in Manila, Philippines. Participants of the two-day workshop included representatives from 12 Member States (Australia, Cambodia, China, the Lao People's Democratic Republic, Malaysia, Mongolia, New Zealand, Papua New Guinea, the Philippines, the Republic of Korea, Singapore and Viet Nam), four technical advisers from WHO collaborating centres for evaluation and standardization of biologicals in the Western Pacific Region (Australia, China, Japan and the Republic of Korea), observers from Japan International Cooperation Agency (JICA), WHO headquarters and WHO regional offices for South East-Asia and the Western Pacific.

The first day was organized to update Member States on the latest global and regional regulatory strengthening activities and developments, and also to gather updates from Member States on their activities. The second day was designed to introduce participants with the global benchmarking tool that have scoring system for each of the indicators and sub-indicators and other features such as planning of activities.

1.2 Meeting objectives

The workshop objectives were:

(1) to review progress against objectives of the Alliance;

(2) to discuss and identify opportunities for the regional adaptation of newly proposed global policy on regulatory assessment; and

(3) to review and identify options for collaborative actions for regulatory systems strengthening in the Region.

2. PROCEEDINGS

2.1 Opening session

Dr Shin Young-Soo, WHO Regional Director for Western Pacific, opened the workshop. He reiterated the importance of successful immunization programmes in achieving health development goals according to the Global Vaccine Action Plan (GVAP) and advancing towards universal health coverage (UHC). As Member States move towards self-sufficiency in terms of providing and purchasing vaccines, they are faced with increasingly complex challenges. As such, there is a growing need for strong and sustainable NRAs to ensure access to vaccines that are effective, safe and of high quality, as well as other medical products. He urged Member States to use the meeting as a forum to discuss issues relating to regulatory challenges, to share experiences, and to work together to identify ways to strengthen regulations. He expressed his appreciation to all the participants and his hope for productive deliberations.

Professor Chung Keel Lee, Special Adviser to the Minister, Ministry of Food and Drug Safety, Republic of Korea was appointed as Chairperson; Dr Atsushi Kato, Director, Department of Quality Assurance and Radiological Protection, National Institute of Infectious Diseases, Japan as Vice-Chairperson; and Dr Yee Hoo Looi, Deputy Director, Health Sciences Authority, Singapore as Rapporteur. Professor Chung Keel Lee designated session moderators to further manage the discussion in each session.

2.2 Session 1: Update from WHO (Moderator: Dr Nagendram Nandapalan)

The objectives of the first session were to update Member States on global and regional regulatory system strengthening (RSS) achievements and the future direction of the Regional Alliance from the perspective of the WHO Secretariat, and to obtain feedback from Member States on the future direction of the Regional Alliance.

Session 1.1: Global update

Session 1.1a: Developments in regulatory system strengthening

Dr Samvel Azatyan provided an update on RSS activities in the global setting. He started by emphasizing the importance of safeguarding access to essential medicines and the role of regulatory systems underpinning the access every individual’s right to health. These days of rapidly changing environments, the regulation of medical products is challenging. Among these are new emerging economies, budget deficits in "old economies", and "emerging" regulators; changing research and development (R&D) industries (mergers, decreases in-house R&D staff, outsourcing); development of new technologies – from genome research to nanotechnologies and stem cell research to high-tech diagnostics solutions; and ongoing globalization of pre-clinical research, clinical research and manufacturing. At the same time, several cross-cutting factors are challenging the regulation of medical products, including:

"population" treatment versus more "personalized" treatment; declining numbers of new medicines and increasing R&D costs; increasing public concerns about safety; increasing concerns about access and price; and increasing demands for more transparency and patient involvement.

While facing these challenges, regulators may be unaware of the evolution of regulatory science; there are differences in good governance principles and regulatory systems on macro- and micro-level setups. There is also an unclear vision or policy regarding how to set up regulatory systems in response to globalization of regulatory science. There is no harmonized view on what exact competencies are needed for regulators and no harmonized core curricula for training. Moreover, regulators are faced with changing paradigms and realities, such as: 1) new products are likely more complex and sophisticated, demanding advanced health systems and "quality use"; and 2) the growing interest of the industry to a more predictable environment in regulatory evaluation of quality, safety and efficacy of innovative products.

Dr Samvel then explained how WHO is working in the area of medical products. The department of Essential Medicines and Health Products (EMP) works with countries to promote affordable access to safe, effective and high-quality medicines, vaccines, diagnostic tools and other medical devices, particularly promoting policies and technical capacities in low-resourced health systems, developing international standards for the manufacturing and regulation of health products, and providing guidance for health systems everywhere to deliver them safely and cost-effectively.

WHO works on strengthening regulatory systems by assessing national regulatory systems; identifying capacity gaps and providing support in development of institutional development plans; promoting good regulatory practices to facilitate decision-making; promoting regulatory cooperation, convergence and harmonization with other Member States; and supporting regulatory workforce development.

He explained that workforce development was an often-neglected critical component of improving regulatory systems. In 2012, a multi-stakeholder working group, including the United States Food and Drug Administration (FDA), WHO, Pan American Health Organization (PAHO) Regulatory Affairs Professionals Society (RAPS) and International Food Protection Training Institute (IFPTI), met to discuss the minimal core competencies for basic-level food and medical product regulatory professionals in low- and middle-income countries (LMICs), i.e. knowledge, skills and abilities necessary for successful job performance, and to develop a curriculum framework to educate/train the regulatory workforce to the competencies. A gap assessment tool was also developed to identify gaps in employee training/knowledge and to prepare a professional improvement plan.

Dr Samvel recommended strategies to cope with these increasing demands:

- Avoid doing things that do not give added value.
- Concentrate on things that give added value.
- Be pragmatic and focus on priority issues most relevant for public health (risk–benefit approach).

- Increase effectiveness of internal operations.
- Ensure quality systems and international benchmarking.
- Cooperate with partners in order to increase regulatory capacity by elimination of duplicated activities.
- Facilitate with comparable standards and administrative requirements.

Dr Samvel wrapped up his presentation by reiterating that NRAs should continue to participate in regulatory cooperation, such as the current Regional Alliance for National Regulatory Authorities for Vaccines in the Western Pacific Region. He also encouraged the audience to participate in the 17th International Conference of Drug Regulatory Authorities in Cape Town, South Africa in November 2016.

Session 1.1.b: Regulation of vaccines in the context of development of international standards

Dr Dianliang Lei presented the role of WHO in biological standardization, the importance of biological measurement references and standards, and the development of WHO written guidelines and recommendations to assure the quality, safety and efficacy of biological products.

WHO commissioned the Expert Committee on Biological Standardization (EBCS) to establish detailed recommendations and guidelines for the manufacturing, licensing and control of blood products, cell regulators, vaccines and related in vitro diagnostic tests. The WHO norms and standards will assist Member States in evaluating the quality and safety of biological products in relation to in vitro biological diagnostic tests worldwide.

Dr Dianliang enumerated the list of measurement standards for biologicals that were developed from 2013 to 2016 and the list of written standards developed from 2014 to present. The revised Good Manufacturing Practice (GMP) guidelines for biologicals were adopted by the ECBS in 2015, under TRS 999 Annex 2, and are now undergoing implementation workshops. Dr Dianliang also spoke briefly of the written standards proposed to the 2016 ECBS meeting: 1) guidelines on regulatory preparedness for licensing pandemic influenza vaccines and the recommended regulatory pathways; 2) guidelines on Ebola vaccines that will provide guidance for NRAs on the full quality, nonclinical and clinical requirements for a license submission; 3) good regulatory practices for NRAs for medical products; 4) revision of flu recommendations, in which a new addendum entitled *Labelling Information of Inactivated Influenza Vaccines for Use in Pregnant Women* was proposed as Appendix 4 of WHO TRS 927 (this guideline will provide clarification and interpretation of the labelling information provided in the product insert of inactivated *Influenza* vaccines in order to facilitate maternal immunizations); and 5) post-approval changes for biotherapeutic products, which will guide NRAs to review changes to the products after licensure.

Dr Dianliang shared the following planned consultations and workshops scheduled on 2017:

- post-approval changes for bio therapeutics;
- safe production of polio vaccines in line the polio virus eradication progress, revision of TRS 926;
- GMP for biologicals for NRAs and manufacturers; and
- working group meeting on respiratory syncytial virus (RSV) vaccine.

All the documents are readily available on the WHO website (www.who.int/biologicals).

Session 1.2: Regional update

Session 1.2.a: Access to medicines in the Western Pacific Region

Ms Uhjin Kim presented an overview of the role of NRAs in ensuring access to medicines in the Western Pacific Region. Since 1978, WHO has been working extensively with Member States to improve access to medicines. Ms Kim explained the shift from Millennium Development Goals (MDG) to Sustainable Development Goals (SDG). She highlighted that one of the targets for SDG 3 is to achieve universal health coverage (UHC), including financial risk protection, access to quality essential health-care service and safe, effective, good-quality and affordable essential medicines and vaccines for all.

She shared data from *Health at Glance: Asia/Pacific 2016* to show that pharmaceutical expenditure is rising in the Region. She pointed out that ensuring easy access to medicines is a challenge for both low- and high-income countries. For high-income countries, the high cost of new health technologies is a growing burden, while low-income countries are experiencing limited access to medical products and high out-of-pocket expenditures.

Citing examples, she explained how weak regulatory systems could result in the proliferation of counterfeit and substandard medical products, which would not only result in treatment failure but also risk patient safety, contribute to drug resistance, increase economic burden and erode public trust in the health system.

Initiatives are available to help address these challenges. In 2015, the second meeting of Asia Pacific Network on Access to Medicines was convened to deal with pricing, procurement and reimbursement policies, and to promote evidence-based decisions using pharmacoeconomic evaluations. The network convened its third meeting on 22–23 September 2016 in the Republic of Korea. In 2009, a web-based system called PIEMEDS was created to collect and validate data on medicine procurement prices that are voluntarily shared by countries. The system promotes accessibility through price transparency.

Session 1.2.b: Regional update on regulatory system strengthening

Dr Jinho Shin provided an update on RSS activities in the Western Pacific Region. He presented updates on vaccine access, such that there are 23 communicable diseases that are preventable by vaccination and WHO recommends them for routine immunization. WHO Model List for Essential Medicines also registered them as essential medicines in 2015. As of June 2016, there are 143 vaccine products in 238 presentations prequalified by WHO. Production of new vaccines is expected to rise in the coming years. Manufacturers and NRAs in developing countries are increasingly contributing to the global supply of quality-assured, affordable vaccines. Some countries in Latin America and one country in Asia recently licensed a dengue vaccine – the first vaccine indicated to prevent dengue fever to be approved by NRAs.

New vaccines are increasingly the subjects of health technology assessment. Improving access to safe, effective, good-quality and affordable vaccines is an important action agenda towards achieving UHC.

He further explained that regulatory systems strengthening is facing a changing environment and is working under several WHO resolutions such as the Global Vaccine Action Plan and UHC. He further explained the position of RSS in achieving SDGs and UHC.

He also presented two strategies to support regulatory systems strengthening in the Region. First, a new WHO Global Benchmarking Tool was designed and released in 2015 to assess NRAs based on a "maturity level" scale. Second, in line with the development of WHO standards and guidelines, the implementation workshop of the recommendation to assure the quality, safety and efficacy of human papillomavirus (HPV) vaccines prepared from virus-like particles produced by recombinant technology is scheduled on November 2016 in Xiamen, China.

He described the challenges and opportunities for Member States according to three groupings: vaccine-producing, self-procuring and UN-procuring. While vaccine-producing countries should establish full scale of essential regulatory functions, UN-procuring countries needs minimal functions such as marketing authorization and vigilance. A country's grouping is helpful in strategizing WHO support..

Session 1.2.c: Vaccine pharmacovigilance update

Dr Ananda Amarasinghe, WHO Regional Office for the Western Pacific, presented an update on vaccine pharmacovigilance in the Western Pacific Region. He started by sharing an overview of vaccine pharmacovigilance in the Region, noting that countries rely heavily on spontaneous (passive) surveillance, especially in non-vaccine producing countries. The use of active surveillance is still limited, even though it is a requirement for vaccine-producing

countries as a part of regulatory requirement, and resources are scarce. Dr Amarasinghe emphasized that according to the new indicator for vaccine safety surveillance in the GVAP monitoring framework, a country has minimal Adverse events following immunization (AEFI)surveillance capacity if its **AEFI reporting** is with at least 10 AEFI cases per 100 000 surviving infants per year.

Globally, the Western Pacific Region is contributing sufficiently to AEFI reporting, based on Joint Reporting Form (JRF) data from 2014 and 2015. However, there is still a need to strengthen reporting. Seven countries and areas in the Western Pacific Region have no national system to monitor AEFI, and three countries and areas have no data at all.

The WHO Regional Office's support for vaccine and immunization safety is mainly focused on three areas: 1) capacity building on Pharmacovigilance/AEFI surveillance and response, (2) ensuring the safety of vaccines by strengthening regulatory capacity through NRA assessments and development of Institutional Development Plans (IDP), and 3) ensuring vaccine security by strengthening supply chains through the Effective Vaccine Management (EVM) initiative.

In line with the above-mentioned focus, regional efforts were initiated to support the countries. These efforts included the development of guidelines for immunization safety surveillance and vaccine safety communication, which are available on the WHO website. An Excel-based electronic vaccine safety database was also developed, which included WHO-recommended 25 core variables of AEFI reporting for both national and subnational levels. The WHO Regional Office has conducted NRA and EVM assessments followed by development of IDPs and training in several countries during 2015–2016.

Dr Amarasinghe concluded his presentation by citing areas for consideration in terms of vaccine pharmacovigilance, such as identifying reasons to overcome the issue of underreporting, strengthening AEFI investigations, using data at the subnational level, promoting evidence based on timely responses, and effective, timely communication and sharing of data and training, particularly at the subnational level

2.3 Session 2: Update from Member States (Moderator: Dr Chris James)

This session was designed as an opportunity for Member States to share experiences and lessons on the recent RSS activities and collaborating centres' recent activities.

Session 2.1 NRA strengthening

Seven countries, namely Cambodia, the Lao People's Democratic Republic, Malaysia, Mongolia, the Philippines, Singapore and Viet Nam, presented their respective NRA strengthening activities. Each country provided an overview of their agency, and shared their mission and vision, organizational structure and process flow. They also shared their process

for approval and licensing of medical products. Representatives from the Member States openly shared updates on IDP implementation, opportunities/strengths, challenges and future directions.

Mr Sokhem Hiem shared Cambodia's recent achievements in the regulation of medicines and vaccines. The private sector is required to submit a lot release certificate prior to the importation of vaccines. He pointed out that Cambodia is moving towards online product registration.

The Lao People's Democratic Republic, represented by Ms Soulyvanh Keokinnaly, acknowledged the support of partners such as WHO and the Global Fund, especially the support extended for the purchase of pharmacovigilance software and provision of in-country and overseas trainings. From this, staff will be able to further enhance their competencies. The Lao People's Democratic Republic is actively coordinating with stakeholders to make sure that the Pharmaceutical Law is understood at the subnational and district levels. Furthermore, the development of new regulation to define the institution involved in vaccine regulation is under way, and quality management system (QMS) tools are also under development.

Madam Noorul Akmar Mohd Nur shared the key achievements of Malaysia in the recent years. The National Pharmaceutical Regulatory Agency (NPRA) has received several recognitions by international organizations, such as Pharmaceutical Inspection Co-operation Scheme (PICS) membership, WHO Collaborating Centre for Regulatory Control of Pharmaceuticals, Mutual Acceptance Data (MAD) membership, ISO 9001:2008 certification, ISO IEC17025 certification, and working group for ASEAN Consultative Committee on Standards and Quality (ACCSQ). Despite these achievements, Malaysia is still facing unique challenges, such as numerous applications for post-approval changes, lack of guidance on handling temperature excursions for products not specified in WHO Guidelines on the International Packaging and Shipping of Vaccines , poor compliance with cold chain and lot release requirements, and increases in importation due to global shortage of pentavalent vaccines. Malaysia is looking forward to extending cold chain monitoring to hospitals, clinics and end users. There is a plan to conduct an independent laboratory quality control testing that will be necessary to become recognized as a WHO fully functional NRA.

Dr Choijoo Amarjargal presented the key accomplishments of Mongolia. There is an established online system called LICEMED for product registration, licensing and special permissions. There is also a Mongolian pharmacopeia, which was published in 2012. Mongolia is moving towards the enforcement of law and establishing QMS for all regulatory processes.

The Philippines was represented by Ms Maria Victoria Calub. The Philippine FDA has been certified as complying with ISO 17025:2005 and ISO 9001:2008, and is working to upgrade to ISO 9001:2015. Ms Calub shared the country's success in licensing a new vaccine despite

the limited resources available. The Philippines is expecting to establish a facility for vaccine and biological testing. Furthermore, the country is planning to establish a National Drug Advisory Committee.

Singapore was represented by Dr Yee Hoo Looi. The presenter shared the structure of Health Science Authority, Singapore (HSA) and provided highlights of a regulatory review that followed the WHO guidelines on good review practices (GRP). The presenter shared Singapore's experience with managing the review, the communication process with industries and other stakeholders, the review personnel involved in the evaluation, and how to conduct the review with emphasis on benefit-risk assessment.

Viet Nam was represented by Dr Le Thi Tuyet Lan. The Drug Administration of Viet Nam serves as the NRA for vaccines and was given full functionality status by WHO in 2015. The country is working hard to consolidate and sustain the NRA functionality in order to succeed in reassessment at the end of 2017.

Notably, Member States are facing common challenges like financial sustainability, inadequate quantity and quality of staff, fast turnover of staff and change of management, limited capacity for law enforcement, lack of IT infrastructure, and lack of information management systems and communication with other stakeholders. Language is also a barrier for non-English-speaking developing countries since all references are written in English.

Dr Mitsuhiro Ushio stressed that in-country vaccine production should be encouraged, especially in countries with high population like the Philippines. Dr Jinho Shin confirmed that WHO supports local production, but it is not mandatory for public sector unless there is a high interest from the government. Hence a systematic analysis is necessary. Dr Martin Eisenhawer agreed that more encouragement for local production should be done as this would mean more vaccine security. He added that there should be an initiative to discuss vaccine security issues.

Session 2.2 Collaborating centre activities

There are four WHO collaborating centres for standardization and evaluation of vaccines and other biologicals in the Western Pacific Region. They are located in Australia, China, Japan and the Republic of Korea. The shared objectives of the WHO collaborating centres are to support WHO in developing international written standards and guidelines for regulatory evaluation of vaccines and biologicals, and to implement these into practice, development and use of international measurement standards and reference reagents for vaccines and biologicals.

The WHO collaborating centres have been participating in NRA assessments, providing trainings/workshops and technical advice to Member States. Each centre shared its work plan and contribution to WHO according to the terms and reference.

Dr Nagendram Nandapalan shared updates on the structure and staffing of Therapeutic Goods and Administration, Australia. He also shared the work plan for 2014–2018, proposed measurement studies and ongoing commitments, which include support to the Regional Alliance.

Ms Shen Qi shared what the National Institutes for Food and Drug Control, China has done during 2015–2016, highlighting a major contribution that involves technical support to Ebola vaccine guidelines and other important guidelines.

Dr Atsushi Kato, Japan, started by presenting an organization diagram showing the link between the NRA and National Control Laboratory (NCL). He shared many contributions and accomplishments of National Institute of Infectious Diseases, Japan as WHO collaborating centre, and expressed its high commitment to continue supporting the Regional Alliance.

Dr Jayoung Jeong, Republic of Korea, presented that there were six WHO guidelines that were supported in 2016 and seven in 2017. He also shared the process of reviewing the guidelines within the Ministry of Food and Drug Safety, Republic of Korea. For international standards, there were two standards in 2015 and four in 2016. A high level of commitment was also expressed to support the Regional Alliance.

2.4 Session 3: Regional adaptation of assessment policy (Moderator: Dr Atsushi Kato)

Following the release of the Global Benchmarking Tool in 2015, the next step would be to support the implementation. One of the main objectives of this workshop is for Member States to understand the WHO global assessment policy and tool and to identify ways to adapt the WHO assessment policy based on regional capacity.

Session 3.1 Overview of new policy and WHO global benchmarking tool

Dr Samvel Azatyan, presented an overview of the WHO benchmarking tool and pathway for regulatory system strengthening. He started by providing updates from the global context. He emphasized that effective regulatory systems are an essential component of health systems strengthening and contribute to better public outcomes.

In WHO headquarters, regulatory system strengthening is under the umbrella of EMP. Its direction is strategically aligned with the WHO reform agenda and several World Health Assembly resolutions, most notably resolution WHA67.20. Dr Samvel highlighted the role of WHO, which is to support Member States in the area of regulatory system strengthening, including: 1) evaluating national regulatory systems; 2) applying WHO evaluation tools; 3) generating and analysing evidence of regulatory system performance; 4) facilitating the formulation and implementation of IDPs; and 5) providing technical support to NRAs and governments.

Dr Samvel further explained the five steps of capacity-building: 1) development of NRA assessment tools, 2) assessment of NRAs, 3) development of IDPs, 4) providing technical support, training, learning and networking; and 5) monitoring of progress and impact.

The development of NRA assessment tools has undergone rigorous work; this includes collecting information from regulatory authorities and affiliated institutions. He explained the new features of the global benchmarking tool:

- integration of different medical product streams;
- enhanced ability for customization of the tool;
- comprehensive system-based benchmarking;
- adoption of maturity concept based on ISO standard;
- integration of Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) indicators;
- expanded benchmarking of regulatory QMS;
- categorization of the indicators enabling transverse benchmarking;
- link with predecessor tools;
- updating and expansion of regulatory guidelines;
- comprehensive guidance for benchmarking; and
- maintenance of functionality concept as part of eligibility criteria for WHO prequalification.

After the international consultation on the development of the global benchmarking tool, several actions were taken from January to July 2016, such as validating the maturity level assignment and incorporating the comments received from the consultation. WHO has started piloting the tool in several assessments/self-assessments and initiated the drafting of related documentation (e.g. factsheets for indicators/sub-indicators, manual for benchmarking).

Session 3.2 WHO assessment policy: regional experience and discussion point

Dr Jinho Shin shared experiences in the Western Pacific Region with regards to the implementation of NRA assessment policy. In 2016, the WHO Regional Office conducted self-assessment validation in Cambodia and Mongolia. The two countries have completed several achievements from their IDPs to address gaps identified from the assessment.

One of the best experiences during NRA self-assessment and follow-up is it will bring together key national stakeholders in the regulatory field for vaccines and medicines.

Dr Jinho Shin shared several points for discussion in terms of NRA functionality and performance maturity level. First, regarding the regional verification of regulatory system performance, since Member States have different regulatory set-ups depending on the procurement status, it would be best to identify the minimal capacity according to product/functions, and clearly establish the reassessment frequency. Second, there is a need

to clarify the difference between laboratory access and laboratory testing, what minimum requirements an NRA needs to meet in order to be functional, if a memorandum of understanding is acceptable, a model template on the agreement of laboratory access between NRA and the third party needs to be established. Thirdly, there is a challenge in finding experts who are qualified for joint assessment; hence, an assessor's list should be established and shared. The participants asked when the global benchmarking tool will be available in the public domain. Finally, Dr Jinho Shin emphasized that NRAs are still looking forward for recognition upon meeting WHO standards.

2.5 Session 4: Activity I

This activity was designed to familiarize Member States with the features of the global benchmarking tool to enable them to develop IDPs and report afterwards.

Session 4.1 Demonstration of WHO global benchmarking tool

Dr Samir El Hemsy M.A. Abdel Wahab introduced the instructions and steps for using the tool. The tool has two modules, one for team leader and one for team member. The team leader module generates a PowerPoint presentation and full report, while the team member module does not have this feature. The TM module can be merged into TL module and the merged TL module can generate reports right after the assessment.

Dr Samir Wahab reiterated that it is important to check the latest version with the NRA team in WHO (country, regional office or headquarters) since they will able to support in the major changes from one version to another.

Session 4.2 Mock-up self-assessment

The participants were asked to install the global benchmarking tool onto their laptops. They were instructed to use the team leader module to conduct a self-assessment using their country data. At the end of the activity, they were able to generate a PowerPoint presentation, IDP and full report.

2.6 Session 5: Activity II

This activity aimed to provide Member States with a deeper understanding of the indicators and sub-indicators of the global benchmarking tool. Participants were given a factsheet that contains the individual benchmarking criterion. The fact sheet is a harmonized guidance from PAHO and other WHO resources which will guide assessors to clearly understand the scope,

rational and objective of each function and indicator/sub-indicator. It also details what information that is needed and what evidence needs to be reviewed and documented.

Dr Syed Shah, WHO consultant for regulatory systems strengthening, presented on the harmonized indicators and sub-indicators with emphasis on the evidence mapping and documentary evidence must be fully integrated with legal framework. He reminded participants that QMS is a critical aspect for consideration and encouraged them to take note of relevant questions:

1) What quality management models are available?
2) What context-specific quality management requirements must be met?
3) What are the specific tasks to be performed and who is responsible?
4) Who should carry out each task?
5) How can it be proven that a task was carried out correctly?

In a brainstorming exercise on regulatory framework categories, participants were asked to match eight common elements across national regulatory system and all regulatory functions with each of the 4 Ms (Man, Machines, Methods and Measures) using a turtle diagram. In another exercise, Dr Shah explained how to perform evidence mapping and asked participants what information and documents are needed under a specific indicator.

2.7. Closing session

The workshop ended with participants from Australia, Cambodia, China, the Lao People's Democratic Republic, Malaysia, Mongolia, New Zealand, Papua New Guinea, the Philippines, the Republic of Korea, Singapore and Viet Nam expressing their appreciation for the continuing support from WHO and their commitment to advocate the management of their respective organizations to use the global benchmarking tool.

China will look forward to use the tool next year and suggested adding a feature that would allow countries to choose which medical product stream is assessed. Fiji expressed high commitment to discuss with the Ministry of Health on how to adopt the tool. The Republic of Korea expressed an interest for NRA assessment next year, and asked if it would be possible to invite responsible persons for both medicines and vaccines. New Zealand shared that the global benchmarking tool is timely since new regulation is under way; this will be an opportunity to consider the requirements and criteria stated in the tool. The Philippines also expressed interest in using the tool and complying with the requirements.

Dr Vivian Lin, Director, Department of Health Systems, WHO, closed the workshop by thanking representatives from Member States, technical advisers and all participants for the successful activity. She was delighted to hear about the development and adoption of the global benchmarking tool and the establishment of a task force to review the Regional Alliance concept paper.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

Member States in the Western Pacific Region reached a consensus on adopting the WHO NRA global benchmarking tool and pathway for regulatory system strengthening in line with the regional UHC action framework and the regional framework for implementation of GVAP.

Considering the results of the NRA survey in the Region, the Member States approved the stepwise expansion of the scope of the Regional Alliance for NRAs to include vaccines and all other medical products such as biotherapeutics, essential medicines, diagnostics, traditional medicines, medical devices and blood products.

Member States also reached a consensus on establishing a task force to review and amend the concept paper for the Regional Alliance for National Regulatory Authorities in the Western Pacific Region. The participants were asked to provide feedback on the draft third edition of the concept paper, implementing the RSS roadmap in accordance with World Health Assembly resolutions and Regional Committee resolutions on UHC and GVAP frameworks.

3.2 Recommendations for Member States

Member States are encouraged:

(1) to further develop, refine and implement regulatory strategic plan aligning with national action plans for 2030 Sustainable Development Goals (SDGs) agenda, UHC roadmap and GVAP framework;

(2) to apply the WHO global benchmarking tool in longer-term strategic planning and roadmap development;

(3) to keep regulatory standards up to date by harmonizing with recently developed international standards;

(4) to apply quality management standards to achieve greater credibility for decision-making, greater stability in operations, and have systematic planning, control, and improved quality in all processes throughout all regulatory functions and ensure a comprehensive approach for all; and

(5) to promote collaboration, reliance and recognition of regulatory decisions and practices among NRAs.

3.3 Recommendations for WHO Secretariat

WHO is requested:

(1) to collect the updated tool with the evidence of sub-indicators and maturity level of the regional NRAs and publish the implementation status of each of sub-indicator on the WHO Regional Office website, subject to agreement with the Member States;

(2) to support the establishment of a task force to review the draft Regional Alliance concept paper and to advise the appropriateness and application for regional adoption;

(3) to develop a dedicated, secure site to hold and share the central documents for the RASC and Regional Alliance members;

(4) to develop a transparent mechanism for the publication and sharing information such as an assessor's roster and RSS global benchmarking tool database (indicators, sub-indicators, maturity level and IDP progress); and

(5) to develop a mechanism for Regional Verification of Regulatory System Performance considering minimum maturity level for NRA functionality for each of product streams, where applicable.

ANNEXES

Annex 1. Abbreviations

AEFI	adverse events following immunization
DAV	Drug Administration Viet Nam
EMT	Essential Medicines and Technology
FDA Phil	Food and Drug Administration Philippines
GBT	Global Benchmarking Tool
GLO/VQ	Global Learning Opportunity for Vaccine Quality
GMP	Good Manufacturing Practice
HSA	Health Science Authority, Singapore
ICDRA	International Conference of Drug Regulatory Authorities
IDP	Institutional Development Plan
IFPTI	International Food Protection Training Institute
MFDS	Ministry of Food and Drug Safety, the Republic of Korea
NCL	National Control Laboratory
NIID	National Institute of Infectious Diseases, Japan
NRA	National Regulatory Authority
NPRA	National Pharmaceutical Regulatory Agency
PAHO	Pan American Health Organization
PICS	Pharmaceutical Inspection Co-operation Scheme
PMMD	Pharmaceuticals and Medical Devices, Manufacture Division
QMS	Quality Management System
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
TRS	Technical Series Report
UHC	Universal Health Coverage
WHA	World Health Assembly
WHO	World Health Organization

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