EXPERT CONSULTATION
REGULATORY STRENGTHENING AND CONVERGENCE FOR MEDICINES

17–18 May 2017
Manila, Philippines

World Health Organization
Western Pacific Region
MEETING REPORT

EXPERT CONSULTATION
ON REGULATORY STRENGTHENING AND CONVERGENCE FOR MEDICINES

Convened by:

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NOTE

The views expressed in this report are those of the participants of the Expert Consultation on Regulatory Strengthening and Convergence for Medicines 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 Expert Consultation on Regulatory Strengthening and Convergence for Medicines in Manila, Philippines from 17 to 18 May 2017.
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Keywords: Pharmaceutical preparations – standards, supply and distribution / Health policy / Regional health planning
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<tr>
<td>APEC</td>
<td>Asia-Pacific Economic Cooperation</td>
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<tr>
<td>ASEAN</td>
<td>Association of Southeast Asian Nations</td>
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<tr>
<td>GMP</td>
<td>Good Manufacturing Practice</td>
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<tr>
<td>ICH</td>
<td>International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use</td>
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<td>NRA</td>
<td>national regulatory authority</td>
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<td>PIC/S</td>
<td>Pharmaceutical Inspection Cooperation Scheme</td>
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<td>TGA</td>
<td>Therapeutic Goods Administration (Australia)</td>
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<td>UHC</td>
<td>universal health coverage</td>
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<td>WHO</td>
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SUMMARY

Regulatory strengthening, convergence and cooperation for medicines and the health workforce has been adopted as an agenda for the 68th session of the World Health Organization (WHO) Regional Committee for the Western Pacific. In support of this agenda, the Regional Office for the Western Pacific is in the process of developing the *Western Pacific Regional Action Agenda on Regulatory Strengthening, Convergence and Cooperation for Medicines and the Health Workforce* to guide actions for WHO and Member States to strengthen their national regulatory systems as well as in considering their participation in regulatory convergence and cooperation as a means to push national regulatory strengthening.

Member States in the WHO Western Pacific Region have recognized the need to strengthen their national regulatory systems for medicines and to pay attention to the corresponding health workforce, along with a growing interest to participate in regulatory convergence as a means to achieve better regulatory outcomes in the interest of public safety.

The Expert Consultation on Regulatory Strengthening and Convergence for Medicines was organized to: generate advice from experts in the regulation field; provide recommendations for pathways to regulatory strengthening based on the context and needs of countries; and to ensure that regulations are effectively implemented and administered by competent authorities.

Experts working in the areas of medical products regulations and convergence participated in the meeting.
1. INTRODUCTION

1.1 Meeting organization

The Expert Consultation on Regulatory Strengthening and Convergence for Medicines was held in Manila, Philippines on 17–18 May 2017, with participants from national regulatory authorities in the Western Pacific Region, representatives from WHO headquarters and the Regional Office as well as experts involved in global and regional harmonization and convergence initiatives.

1.2 Meeting objectives

The objectives of the Consultation were:

1. to provide advice in formulating recommendations to Member States on areas where regulatory convergence is essential as well as to be better informed of the benefits, risks and the implication of convergence mechanisms in their overall regulatory environment; and

2. to advise the process of developing platforms that will support Member States to share information, conduct consultations and strengthen their capacity to participate in regulatory convergence initiatives.

2. PROCEEDINGS

2.1 Opening session

Dr Vivian Lin, Director of the Division of Health Systems in the WHO Regional Office for the Western Pacific, delivered the opening remarks on behalf of Dr Shin Young-soo, WHO Regional Director for the Western Pacific.

Dr Lin welcomed the participants and noted that WHO has been working to advance *Universal Health Coverage: Moving Towards Better Health*, the regional action framework, by supporting Member States to develop high-performing health systems that will deliver quality and safe products and services while ensuring efficiency, equity, accountability, sustainability and resilience. It is recognized that regulatory systems are a fundamental component of this process to improve service quality, ensuring equity and access and protecting the public interest. This is particularly true in relation to medicines and the health workforce. Effective regulation has to consider that people and products flow across borders and that many regulatory issues across countries are shared or related. A result trends towards regulatory convergence in the region and globally is notably identified. These processes of regulatory convergence present both opportunities and risks that need to be considered and managed by countries to safeguard access. Dr Lin noted that, even though the meeting focuses particularly on the medicines aspect of this framework, everyone is encouraged to keep in mind the broader agenda in the region in relation to regulatory systems strengthening and the achievement of universal health coverage (UHC). For this to happen, prioritization of strengthening and convergence to fill the gaps, the trade-offs involved in relation to regulatory convergence, and how to address the issues around sustainability and governance of convergence mechanisms should be considered.

Dr Socorro Escalante, Coordinator of the Essential Medicines and Health Technology Unit in the WHO Regional Office for the Western Pacific, then presented the meeting objectives and agenda.
2.2 Introductory sessions

2.2.1 Medicines regulation in the context of public health and UHC

Ms Uhjin Kim presented an overview on medicines regulation in the context of public UHC including financial, risk protection and access to quality health services. She gave examples of past failures surrounding the safety of established products in the market and those approved by well recognized agencies. Ms Kim further emphasized the role of UHC as part of the Sustainable Development Goals (SDGs) to ensure safe, effective, quality and affordable essential medicines and vaccines for all. Indications point to UHC moving towards better health systems, and increased relevance of regulatory authorities in medicines regulation and the global supply chain.

2.2.2 Achieving good regulatory outcomes: key regulatory functions and governance

Dr Samvel Azatyan presented an analysis of the disparities in access to medicines in low-, middle- and high-income countries, and how insufficient regulatory capacity and the lack of harmonized approaches for regulation of medical products impact on access. He highlighted the role of national regulatory authorities (NRAs), their main regulatory functions, principles of medicines regulation, and how the regulatory science is evolving with changing paradigms and realities in the face of more complex and sophisticated new products. WHO plays an important part in supporting countries to ensure access to safe, quality and effective medicines. He concluded that regulatory capacity-building is not a panacea without clear strategy and vision, and needs much better prioritization, coordination and collaboration when using so-called added value principles. There is no good regulation without good governance (accountability, transparency, fair and equal treatment of all regulated parties, etc.), and a proper regulatory outcome is not possible without proper enforcement of regulatory decisions. Prioritization of regulatory activities, work sharing, collaboration, networking and convergence could help to reduce the workload and to improve public health by improving overall regulatory performance.

2.2.3 Medicines regulations beyond national borders: Can regulatory convergence cover?

Dr Lembit Rago emphasized the importance of regulatory systems in access to medicines and UHC. Countries are facing old problems and new challenges. Collaboration, convergence and harmonization can be a solution to help countries address these challenges. He provided a clear presentation of the main initiatives for convergence in which Member States in the WHO Western Pacific Region are involved, including WHO, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Asia-Pacific Economic Cooperation (APEC), Association of Southeast Asian Nations (ASEAN), Pharmaceutical Inspection Co-operation Scheme (PIC/S), International Pharmaceutical Regulators Forum (IPRF) and International Generic Drug Regulators Programme (IGDRP), among others. He emphasized that as countries develop regulations they must be science based, respect international standards and best practices, and adopt an approach that focuses on what was not or cannot be done by others, while leveraging the work of other trusted NRAs and regulatory networks for remaining activities. Intelligent risk assessment and risk management should be integrated as part of regulatory review. Not all national regulators can do everything themselves in a timely manner, and decisions have to be made at the national level about which areas to focus on and build capacity in and which areas will rely on other regulators’ work. Dr Rago remarked on the need for good reliance and decision-making practices to help implement a risk-based approach. Harmonization and convergence alone cannot help, but can form a solid basis for the new regulatory paradigm to evolve in the future.
2.3 Experiences, gaps and challenges in medicines regulations

2.3.1 The case of Australia

Mr Michael Wiseman presented an overview of the Therapeutic Goods Administration (TGA) as well as its organization, mandates and participation in regulatory convergence initiatives. His presentation provided a brief overview of the TGA and the changes in the Australian regulatory framework, moving towards a risk-based approach. He emphasized that international regulatory cooperation is now a formal government policy of Australia, especially in the context of the country’s increasingly global medicine and device industry. The TGA’s efforts are addressed to avoid duplication of regulatory processes sharing other regulators’ evaluations and implementing best regulatory practices and policy thinking. The main constraints on collaboration experienced by the TGA were: differences in timing in receiving applications, confidentiality issues with industry/regulators, lack of technology to support collaboration, opportune access to information, no redacted reports, different languages and terminology in reports, initial increase in cost and work for regulators before collaboration becomes “business as usual”, and codified processes in regulations that can limit flexibility.

2.3.2 The case of Singapore

Ms Hui Keng Lee provided a perspective on the health system in Singapore with a brief description of the Health Sciences Authority (HSA), its vision and mission, and the regulatory principles for medicines regulation including legislations that support the regulatory mandate. The Singapore NRA has adopted the product life-cycle approach to regulation, working in collaboration with stakeholders, including the Ministry of Health, patients/consumers, manufacturers, importers, local agencies and certification bodies. A risk-based approach to product evaluation is employed. The main challenges are: keeping up with new scientific and technological advancement, keeping the regulatory capability and system up to date, supply chain issues, risk of counterfeits, balancing the gatekeeper and facilitator roles, limited human resources, need to prioritize and focus resources on value-added work, and small market size not commercially viable to register and market low-volume (but essential) medicines. The key elements identified as necessary to strengthen the current regulatory system in Singapore include: convergence of technical standards to minimize duplication of efforts and cost for industry, which could translate to potential benefits for patient access; collaboration through sharing of information, knowledge and expertise among counterparts to enhance regulatory effectiveness and preparedness and cooperation with trusted partners (e.g. joint review, joint inspection) to enhance efficiency.

2.3.3 The case of China

Dr Yanan Luo briefly spoke on the health system structure in China, the challenges of the overarching health reform, and how to implement the directive to ensure drug quality and to establish a scientific, efficient review and approval system for medicines. The important function of regulatory convergence for China is to improve regulatory capacity, break down the technical barriers to trade and participation in multiregional clinical trials, and implement the APEC Regulatory Science Center of Excellence (CoE) programme. At the same time, Dr Luo presented the programme to promote and advance the role of regulatory systems in public health and economic development, with China initiating a collaboration among stakeholders including the United States Food and Drug Administration (FDA), WHO, China Food and Drug Administration (CFDA), APEC members and industry. This initiative has resulted in: the strengthening of the review and approval system; drug classification adjustment; optimization of the review and approval procedure for generic drugs; improvement of the prioritized approval mechanism and acceleration of research and
development (R&D); launch of new drugs with clinical value and generic drugs in urgent clinical need; regulation of drug R&D; and the launch of self-inspection of clinical data.

2.4 Global initiatives: What outcomes have been met?

2.4.1 Global initiatives

Dr Samuel Azatyan gave a comprehensive overview of the major global initiatives on convergence, including the ICH, PIC/S, IPRF, International Coalition of Medicines Regulatory Authorities (ICMRA), IGDRP, the International Conference of Drug Regulatory Authorities (ICDRA) and several others. A key question was raised on the risk of duplication among these convergence mechanisms. In the current landscape, several initiatives have similar objectives, overlapping memberships, common problems and weaknesses. Finally, reflecting on WHO’s role, potentially facilitating harmonization was discussed in the plenary.

2.4.2 International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

Dr Yoshihiro Katsura presented an overview of ICH, a non-profit legal entity under Swiss law established in 2015. The objective of ICH is to accomplish technical guidelines such as the (electronic) Common Technical Document (CTD/eCTD) and Good Clinical Practice (GCP), the Medical Dictionary for Regulatory Activities (MedDRA), and over 60 guidelines on technical requirements that are implemented by regulatory authorities, with the Quality, Safety, Efficacy and Multidisciplinary (QSEM) principles. In general, the key elements of ICH’s success is the involvement of both regulators and industry, its science-based approach, consensus-driven use of common global tools, and close collaboration of parties with comparable regulatory and technical capability.

2.4.3 Pharmaceutical Inspection Co-operation Scheme (PIC/S)

Ms Helena Baiao presented a very broad perspective on the PIC/S objectives, its international expansion to be a global organization and its role in the development, implementation and maintenance of harmonized Good Manufacturing Practice (GMP) standards and quality systems of inspectorates in the field of medicinal products. Main achievements were presented, such as GMP standards and guidance documents, training competent authorities, and facilitating the cooperation and networking for competent authorities and international organizations. PIC/S currently includes 49 members of selected competent regulatory authorities, and organizations such as the European Medicines Agency (EMA), European Directorate for the Quality of Medicines and HealthCare (EDQM), United Nations Children’s Fund (UNICEF), WHO, Heads of Medicines Agencies (HMA), ICMRA, European Community, ICH, ASEAN and Organisation for Economic Co-operation and Development (OECD). Questions were raised regarding how PIC/S could provide support to less developed regulatory authorities in the world.

2.5 Regional initiatives: What outcomes have been met?

2.5.1 Regional initiatives

Dr Jinho Shin presented a broad overview of WHO’s activities in the Western Pacific Region, focusing on convergence efforts to support regulations of medicines and vaccines. He briefly described the regional initiative to assure quality and safety of vaccines and medicines, which includes NRA benchmarking and the establishment of the Regional Alliance for NRAs for Vaccines
in the Western Pacific. In addition, Dr Shin mentioned the collaboration among national control laboratories (NCLs) for vaccines and biologicals research and regulatory science, and the regional implementation of the Global Vaccine Safety Initiative for strengthening pharmacovigilance, the regional implementation of the Global Surveillance and Monitoring System for substandard and falsified medical products (substandard, spurious, falsely labelled, falsified and counterfeit medical products, or SSFFC), the role of the United States Pharmacopeial Convention promoting the quality of medicine, and the Asia Pacific Leaders Malaria Alliance (APLMA) in the fight against malaria. Other initiatives supported by the WHO Regional Office include in traditional medicines such as the Forum for the Harmonization of Herbal Medicines (FHH), strengthening quality assurance of traditional medicines in the Western Pacific Region, and the Good Agricultural and Collection Practices (GACP) for traditional medicines. Regulatory strengthening and convergence plays a basic role for achieving the overarching vision of UHC and the 2030 Agenda for Sustainable Development.

2.5.2 Asia-Pacific Economic Cooperation (APEC)

Dr Youngju Choi presented a perspective on the APEC initiative for regulatory convergence in the life sciences, briefly describing its organization and objectives for harmonization. The initiative covers development of guidelines and capacity-building to promote international harmonization of license approvals and safety management of medical products among APEC economies. The initiative provides support in three main areas: in-person training, online training and research. Dr Choi presented some data on training courses, content and attendance members. At the same time, it monitors the implementation of ICH guidelines (survey in 2014), with reports on the drug approval system guidelines from all 21 APEC members, to be published in 2018. Dr Choi remarked that the CoE programme is a sustainable platform for long-term efforts to implement the road maps that facilitate regulatory convergence. The APEC Harmonization Center is working with APEC member economies and other parties for regulatory convergence in the region and beyond (ICH, ICMRA, WHO, APEC Regulatory Harmonization Steering Committee).

2.5.3 Association of Southeast Asian Nations (ASEAN) Pharmaceutical Harmonization

Dr Salmah Binti Bahri presented an overview of the ASEAN Pharmaceutical Harmonization Initiative. It adopts the overall principle of “One Vision, One Identity, One Community” for an ASEAN Free Trade Area (AFTA). Dr Bahri gave a description of the ASEAN Consultative Committee on Standards and Quality Pharmaceutical Products Working Group (ACCSQ-PPWG) with the key milestone of the ASEAN convergence for pharmaceuticals and resulting ASEAN Common Technical Requirements and Dossier (ACTR and ACTD), and common technical guidelines for several other regulatory processes. Dr Bahri indicated in conclusion that ASEAN supports the movement towards convergence of regulatory requirements.

2.6 Plenary discussions

During the second day of meeting, plenary discussions were organized on the following topics.
2.6.1 Regulatory convergence: when and to whom does it matter?

In which areas of regulations and what stages of the medicines life cycle will convergence matter?

Convergence will add value in the following ways:

- Depending on which level of NRA maturity is considered and the needs for strengthening are prioritized.
- NRAs should perform an assessment to prioritize functions. Main functions to be considered for prioritization include marketing authorization and pharmacovigilance (notification and spread of information to start implementation). Other potential functions for convergence are: laboratory testing, GMP inspections, preclinical and clinical trials evaluation, and R&D.
- Prioritization of generics, vaccines and innovative products including all imported products.

The elements considered fundamental for the success of convergence are:

- adequately trained human resources in the field of regulatory science
- financial, political and sustainable support from governments and global and international bodies such as WHO, ASEAN, etc.;
- use of existing platforms with standards that are reliable and sustainable; and
- communication, reliance, trust and confidence building.

Pathways to convergence: How a country’s development context should be considered

A country’s development underpins the pathway for regulatory strengthening and convergence. NRAs at different levels of maturity require different strategies for convergence.

Convergence also requires costly and complex processes but is valuable in supporting national authorities to raise the level of regulations collectively in the region. Convergence mechanisms can be used to leverage support from more developed to less developed countries. On the other hand, less developed countries can contribute to the generation of information around challenges and needs. This information is important in the continuous improvement of national regulatory frameworks.

Pathways to convergence will start from information sharing, capacity- and trust building, and progressively move towards reliance and work-sharing. Reliance is recommended for less developed countries and with limited resources.

There are good examples of reliance initiatives such as between Canada and Australia who share results on GMP inspections, clinical evaluation and other functions. Singapore and Malaysia have also entered into a bilateral arrangement for reliance in GMP inspections.

Geographical or regional grouping such as ASEAN and the Pan American Network for Drug Regulatory Harmonization (PANDRH), with the support of the corresponding WHO regional offices, can support coordination of convergence and cooperation initiatives. It is important to facilitate learning and eventual strengthening of less developed national regulatory systems using convergence initiatives. ASEAN is an example of a successful convergence initiative that has provided benefits to less developed countries.
2.6.2 Examining the implications of regulatory convergence to countries

*In which areas do sovereignty and independence matter most?*

As a general principle, convergence and cooperation will not infringe on the sovereign right of Member States to make decisions, but rather, it will help inform independent decision-making processes, especially in countries where capacity for generation and assessment of information is not existent. All regulatory functions can be subjects of convergence but the final decision should be always under the responsibility of the NRAs in the countries.

*What are the trade-offs to be considered?*

Optimization of resources could be a trade-off as convergence and cooperation requires financial and human resources. Moreover, short-term benefits may not be appreciated, as the impact of convergence and cooperation can only be realized over the long term.

Countries with local pharmaceuticals production would need to invest more resources to improve the level of capacity of local manufacturers in order for them to meet international standards. Failure to meet standards will have a negative impact on production and trade.

2.7 Formulating recommendations for the Action Agenda

The principles for the Regional Action Agenda were established:

- Promotion and protection of public health: UHC is the overarching vision for health sector development and standards are universal.
- Governments are responsible for decisions. Sovereignty and independence are the drivers for reliance, convergence and use of references. Ultimately countries will make decisions based on the information generated through these mechanisms.
- Regulatory authorities should balance the assurance of safety and quality with facilitation of access to medicines.
- The development and strengthening of national regulatory systems should be based on the context and needs of countries, considering historical, political and economic environments.
- No regulatory authority, even in more developed countries, implements all regulatory functions by itself. Regulatory convergence and cooperation can support the exercise of regulatory functions in countries.

Proposed elements of the Regional Action Agenda are the following:

- **Strengthening**: A stepwise approach to national regulatory strengthening will be adopted and will start from the core functions that are most needed by countries.
- **Convergence**: Convergence will be encouraged and facilitated. Priority areas for convergence will be underpinned by the level of development, needs and context of countries as well as type of products. For products, a risk-based approach for prioritization will be considered.
- **Trust building**: A defining mechanism to build trust across countries and how WHO can support this should be established.
- **Pathways**: Four areas should be considered as pathways to strengthening regulatory agencies and promoting convergence: work-sharing, reliance, capacity-building and communication.
The following are the conclusions and recommendations on the elements of the Regional Action Agenda:

Strengthening
Regulations need to be supported by legal frameworks. Prioritization of areas to be strengthened will depend on whether countries are importing, producing and exporting, or a combination of these. A stepwise approach to strengthening that will be underpinned by the needs and context of countries may be considered.

Recommendation for Member States: Use existing standards, such as the WHO NRA benchmarking tool for self-evaluation.

Recommendations for WHO: Identify gaps and areas where capacity-building and transfer of technical competency can be undertaken, and promote mechanisms for a risk-based approach to regulations.

Convergence
The benefits of convergence must be extended to all countries.

Recommendations for Member States: Make a careful analysis of country needs in order to define the best strategies for convergence prioritizing functions and products needed and using available standards. Peer review is recommended between more developed countries.

Recommendations for WHO: Including at the regional level, WHO can play a significant role in generating trust in the analysis and dissemination of information across Member States. It can support NRAs by developing and disseminating guidelines such as the Guidelines for Good Reliance Practices.

Trust building
Recommendation for Member States: Participate in global and regional networks, sharing information, work-sharing, joint activities, and regular learning and training exchanges.

Recommendations for WHO: Develop incentives for trust among regulators, encourage staff exchange between regulators, and develop the Guidelines for Good Reliance Practices.

Pathways
Communication and increase of transparency between agencies, internally and externally, and promotion of common terminology are recommended for both Member States and WHO.

Recommendations for Member States: Encourage work-sharing and reliance, joint assessment and inspections, as well as capacity-building based on identification of country-specific needs with a risk-based approach.

Recommendations for WHO: Facilitate connections between countries by encouraging work-sharing, implementing practical mechanisms to rely on references and sharing good practical examples; broadly promote communication and facilitate the use of existing platforms; provide financial support for training and encourage the use of standards and guidelines; and develop Good Reliance Practices, make available information and promote information sharing.
Additional recommendations on concrete actions were provided as follows:

- For countries with low resources such as Cambodia and the Lao People’s Democratic Republic, the first recommendation is to use WHO standards if available, considering these standards are adapted to the needs of less resourced countries. For vaccines, WHO has developed the best standards to support countries, but for other areas the standards could be insufficient to cover all functions. If no WHO standards are available, the recommendation is to implement whatever other standards are available. It is noted that there are enough standards for regulatory functions which have been developed by various international institutions, so it is strongly recommended to not develop new standards. The advantage of using international standards from recognized institutions is that the maintenance and calibration of these standards is resource- and time-consuming, often an underestimated activity. Using international standards renamed/relabelled with a local designation, although common practice in some African countries, is not recommended. Efforts should be focused on implementation of already available standards.

- WHO should make available to countries updated information on all WHO standards and guidelines. A remark was made on clarification of equivalence between WHO and PIC/S standards. Consensus was reached that implementation of the Good Clinical Practices standards is more complex as they require a high level of organization and systems which some countries may not have.

- Regarding capacity-building, the WHO NRA benchmarking tool was strongly recommended to provide information on gaps and focusing on priorities. As well, innovative ways to facilitate change and rotation of personnel should be considered, keeping in mind technical transfer, trust building and confidence. Capacity-building should be focused to identify gaps and implementation of mechanisms for evaluation. WHO continues to make efforts in promoting and developing the regulatory curriculum, providing recommendations for the implementation of common principles and expectations in terms of capacity and competencies for regulators around the world. Since staff retention is linked to capacity-building, it is helpful to give examples of countries such as Ghana which has implemented incentives for keeping experts interested in their regulatory jobs.

2.8 Final remarks

In the final remarks, Dr Vivian Lin indicated that there are many frameworks to guide the discussion of the meeting, one being emphasizing the close interrelationship between NRA strengthening and regulatory convergence. They are mutually beneficial in the support of countries, while recognizing specificities and making sure that this is not for the sake of regulatory convergence but to help countries to solve problems.

Additional discussion on traditional medicines will be requested considering their relevance in the Region.

Remarking the relevance of support to less resourced countries and the indicating that regulators should get a balance between technical and political aspects taking science in society.

Governments at very high levels are subject to pressure by industry, but at the same time they have made a commitment to UHC which has implications on regulation of quality and safety of medicines. This has an impact on trust in health systems – and consequently trust in the governments. Regulation is not about standards only, but has bigger implications.
The conclusions of the meeting will have an impact on the document to be presented in October to the WHO Regional Committee for the Western Pacific, after consultation with Member States. Therefore, the feedback on the document distributed will be of relevance for the Regional Committee and beyond.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

The discussions were initiated based on the principle that regulation can contribute to UHC by ensuring access to quality, safe and effective medicines, health services and workforce.

In order to achieve good regulatory outcomes, it is necessary for regulatory agencies to be able to implement core regulatory functions that are supported by clear legal mandates and governance mechanisms. Strengthening medicines regulatory systems is fundamental to guarantee access of the population to products of adequate quality and efficacy.

The discussions identified the main issues and challenges, indicating capacity-building is an important step to raise the maturity level of regulatory systems. New products development in the market represents a challenge for local regulatory systems and there are diverse approaches depending on whether the countries have local manufacturing or are only importing products.

Convergence initiatives might support the development of regulatory agencies as part of increasing demands due to globalization and trade. WHO has a relevant role in the facilitation of activities between NRAs to achieve convergence.

Member States are willing to participate in convergence initiatives without the implication of sharing decision-making processes. There is consensus as to sovereignty being the key driver of any harmonization or convergence process.

Many global convergence and harmonization activities are in place all around the world, including WHO, ICH, PIC/S, and regional ones such as ASEAN, PANDRH, and so on. This generates difficulties in the selection of the most appropriate one to support the development of systems with different levels of maturity. The main challenges are for less developed countries with very few reliable or non-existing regulatory functions.

The impact of regional or global regulatory initiatives for convergence was discussed. The clear indication is that some are successful in the implementation of their standards in some Member States, without added value from other initiatives. This provides less benefit for those less mature systems. The WHO prequalification was indicated as one example of convergence where WHO standards are used to identified medicines and vaccines of quality to be procured by countries.

Some bilateral examples of convergence such as the agreements between Australia and Canada have shown success, and others such as between Singapore and Malaysia are being developed.

The minimal regulatory functions to be implemented by less developed countries are: marketing authorization/licensing, monitoring safety (as preliminary function of more complex pharmacovigilance) and clinical trials, depending on the resources in each country. Prioritization was agreed: first generics, then vaccines, complex biologies, and finally products for export only.
The experts agreed that implementation, transparency, trust and reliance are essential values to enrich participation in the convergence and harmonization activities in order to get the most benefit from them.

3.2 Recommendations

3.2.1. Recommendations for Member States

Member States are encouraged to do the following:

**Strengthening**

1. Participate in the strengthening of core regulatory functions. For less developed countries, implement minimal basic regulatory functions such as marketing authorization/licensing and monitoring safety (pharmacovigilance), when feasible regulating clinical development.
2. Identify and use standards in place, mindful that no regulatory agency can accomplish successfully all regulatory functions.
3. Use the WHO benchmarking tool in the identification of gaps.
4. Use the standard platforms available. Avoid the creation of new standards considering that the maintenance and calibration of new standards is highly resource- and time-consuming.
5. Pay attention to the management of the supply chain, to maintain the quality of all other functions of the regulatory system.
6. Implement incentives for retention of trained staff.
7. Use a risk-based approach.
8. Implement the regulatory curriculum.

**Convergence**

9. Specifically identify appropriate convergence initiatives for each country to participate in and receive support in alignment with trade and regional associations.
10. Prioritize functions considering marketing authorization through mechanisms such as work-sharing and peer review for more advanced countries. For GMP inspection, use the recognized international standards available (WHO, PIC/S, ICH) to monitor safety (pharmacovigilance).
11. Prioritize products driven by the market in each country, depending on country needs and based on a risk approach, considering generics, vaccines, complex biologics and products for importation as the prioritization order.
12. Search for other opportunities for convergence and reliance on reference authorities, such as bilateral agreements, mutual recognition, work-sharing, peer review and others appropriate to each Member State’s situation.
13. Participate in capacity-building using the WHO benchmarking tool and other tools to promote the regulatory curriculum to ensure the quality of the regulatory workforce.
Trust building

14. Foster reliance on reference authorities and partners.
15. Promote activities with other agencies through work-sharing, peer review and bilateral agreements.

Pathways

17. Use work-sharing, reliance, capacity-building and programmes for staff exchange, depending on the geographical, political and economic situation, as pragmatic pathways for NRA strengthening and convergence.

3.2.2. Recommendations for WHO

WHO is requested to do the following:

Strengthening

1. Facilitate the identification of all WHO standards available to promote their use and implementation by Member States.
2. Promote the harmonized regulatory curriculum and guidelines development.
3. Validate implementation of regulatory functions by Member States, considering less developed regulatory systems.

Convergence

4. Develop Good Reliance Practices to support convergence and harmonization.
5. Seek out political support for Member States for regulatory strengthening.
6. Increase communication and dissemination of tools, guidelines and regulatory science among Member States.

Trust building

7. Ensure recommendations are equally implementable and applicable to all countries according to the equity principle.
8. Facilitate and promote interaction between regulators

Pathways

9. Use the WHO benchmarking tool for assessment of NRAs and facilitate the access to available tools.
10. Promote reliance between countries participating in convergence activities.
11. Facilitate the use of the existing platform.
12. Consider financial support for training and monitoring during standards implementation.
ANNEXES

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**Expert Consultation**

**Regulatory Strengthening and Convergence for Medicines**

Western Pacific Regional Office Manila Philippines

17–18 May 2017

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<tr>
<td><strong>Day 1 – Wednesday 17 May 2017</strong></td>
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<tr>
<td><strong>08:30–09:00</strong></td>
<td><strong>Registration</strong></td>
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<td><strong>09:00 – 09:45</strong></td>
<td><strong>Opening session</strong>&lt;br&gt;Welcome message&lt;br&gt;Dr Vivian Lin, Director, Division of Health Systems, WHO&lt;br&gt;Introduction of participants&lt;br&gt;Meeting objectives – Dr Socorro Escalante, WHO&lt;br&gt;Group Photo</td>
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<td><strong>09:45-10:15</strong></td>
<td><strong>Coffee break</strong></td>
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<td><strong>10:15- 12:00</strong></td>
<td><strong>Session 1 – Introductory sessions</strong>&lt;br&gt;Medicines regulation in the context of public health and UHC&lt;br&gt;Ms Uhjin Kim, WHO&lt;br&gt;Achieving good regulatory outcomes: key regulatory functions and governance – Dr Samvel Azatyan, WHO HQ&lt;br&gt;Medicines regulations beyond national borders: Can regulatory convergence cover? - Dr Lembit Rago, CIOMS&lt;br&gt;<strong>Discussions</strong>&lt;br&gt;Facilitator: Dr Maria Cortes&lt;br&gt;How best to achieve good regulatory outcomes&lt;br&gt;How can convergence support the process? Summary – Dr Socorro Escalante</td>
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<td><strong>12:00-13:00</strong></td>
<td><strong>Lunch</strong></td>
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<td><strong>13:00-14:30</strong></td>
<td><strong>Session 2 – Experiences, gaps and challenges in medicines regulations</strong>&lt;br&gt;The case of Australia- Mr Michael Wiseman, TGA&lt;br&gt;The case of Singapore – Ms Hui Keng Lee, HSA&lt;br&gt;The case of China – Dr Yanan Luo, APEC Health Science Academy, Peking University&lt;br&gt;<strong>Discussion: Pathways for achieving good regulatory outcomes?</strong>&lt;br&gt;Facilitator: Dr Maria Cortes&lt;br&gt;Legal framework and policy&lt;br&gt;Science&lt;br&gt;Governance&lt;br&gt;Summary: Ms Uhjin Kim</td>
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<td>14:30-14:45</td>
<td><strong>Coffee break</strong></td>
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<td>14:45-17:00</td>
<td><strong>Session 3 – Global initiatives: What outcomes have been met?</strong></td>
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<td>Global Initiatives - Dr Samvel Azatyan, WHO HQ</td>
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<td>International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)- Dr Yoshihiro Katsura, PMDA</td>
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<td>Pharmaceutical Inspection Cooperation Scheme (PIC/S)- Ms Helena Baião, INFARMED</td>
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<td>14:45</td>
<td><strong>Session 4 – Regional initiatives: What outcomes have been met?</strong></td>
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<td>Regional initiative – Dr Jinho Shin, WHO</td>
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<td>APEC- Dr Youngju Choi, MFDS</td>
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<td>ASEAN Pharmaceutical Harmonization –Dr Salmah Binti Bahri, MoH, Malaysia and Chair of ASEAN PPWG</td>
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<td><strong>Discussions</strong></td>
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<td>Facilitator: Dr Maria Cortes</td>
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<td>How existing initiatives contribute to strengthening national regulatory systems</td>
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<td>Summary: Dr Socorro Escalante</td>
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<td>17:00-18:00</td>
<td><strong>Reception and end of day 1</strong></td>
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**Day 2 – Thursday 18 May 2017**

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<th>Time</th>
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<tr>
<td>8:30 – 10:15</td>
<td><strong>Session 5 – Regulatory convergence: when and to whom does it matter?</strong></td>
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<td><strong>Plenary discussion</strong>: Which areas of regulations and at what stages of the medicines life cycle will convergence matter?</td>
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<td>Introduction: Dr Lembit Rago, Dr Samvel Azatyan</td>
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<td>Facilitator: Dr Socorro Escalante</td>
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<td><strong>Plenary discussion</strong>: Pathways to convergence: How a country’s development context should be considered</td>
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<td>Introduction: Dr Salmah Binti Bahri, Ms Hui Keng Lee</td>
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<td>Facilitator: Dr Maria Cortes</td>
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<td>10:15-10:30</td>
<td><strong>Coffee break</strong></td>
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<td>10:30 - 12:00</td>
<td><strong>Session 6 – Examining the implications of regulatory convergence to countries</strong></td>
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<td><strong>Plenary discussion</strong>: In which areas sovereignty and independence matter most?</td>
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<td>Introduction: Ms Helena Baião, Mr Michael Wiseman</td>
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<td>Facilitator: Dr Maria Cortes</td>
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<td><strong>Plenary discussion</strong>: What are the trade-offs to be considered?</td>
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<td>Introduction: Dr Yoshihiro Katsura, Dr Youngju Choi</td>
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<td>Facilitator: Dr Socorro Escalante</td>
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<td>12:00-13:00</td>
<td><strong>Lunch</strong></td>
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| 13:00-15:00 | **Session 7 – Formulating recommendations for the Action Framework**  
**Plenary Discussion**: Recommendations for Member States  
**Plenary Discussion**: Recommendations for WHO  
Facilitator: Dr Maria Cortes  
Summary: Dr Socorro Escalante |
| 15:00-15:15 | **Coffee break** |
| 15:15-17:00 | **Session 8 – Wrap up**  
Summary of recommendations for Member States  
Summary of recommendations for WHO  
Facilitator: Dr Maria Cortes  
**Closing** – Dr Vivian Lin, WHO |