The network for regulation in medical products

Draft Report of the Annual Meeting of interim network for promoting cooperation for regulation of medical products in SEA Region, Bangkok, Thailand
17-18 August 2016
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Executive Summary

The annual meeting of the Interim Network for Promoting Cooperation for Regulation of Medical Products in the SEA Region was organised in Bangkok, Thailand, from 17 to 18 August 2016. The general objective was to promote next steps and hold the annual meeting of the interim network as agreed in the Regional Meeting for Promoting Cooperation for Regulation in Trade of Medical Products held in WHO-SEARO, New Delhi, India during 22-24 September 2015.

The specific objectives of the meeting were to:

- evolve an information sharing mechanism/prototype for the proposed Regional Network for Promoting Cooperation for Regulation;
- hold the annual meeting of the interim network; and
- formulate a report on the proposed network for the next Regional Committee.

The meeting was attended by 40 participants from all 11 Member States of the Region and technical experts. Ms. Yuwadee Patanawong, Director, Medical Device Control Division, Food and Drug Administration, Thailand chaired the meeting and Mr. Mohamed Rafieeq, Deputy Minister, Ministry of Health, Maldives was the Co-Chair. Mr. Dawa Tshering, Regulatory Officer, Drug Regulatory Authority, Bhutan was nominated the Rapporteur.

Outcomes

Participants adopted guiding principles for the establishment of the SEA regional network. They recognized the need to demonstrate value of the network through early successes. The proposed structure would initially be light and evolve as per the requirements. The Member states buy-in and effective decision-making would be achieved through the active participation of Heads of Agencies. An Initial Steering Group (ISG) will guide the network. There was also agreement on the need for setting up effective processes and oversight.

Participants supported the idea of convening the next meeting of the interim network in February or early next year, 2017 towards officially establishing the regional regulatory network. It was agreed that ISG comprising the Chair, Co-Chair, Heads of Agencies of India and Indonesia and the Secretariat would steer the Network till the next meeting.

Ms. Yuwadee Patanawong, Director, Medical Device Control Division, Food and Drug Administration, Thailand was nominated Chair and Mr. Mohamed Rafieeq, Deputy Minister, Ministry of Health, Maldives would be the Co-Chair of the ISG. The Drugs Controller General of India, Central Drugs Standard Control Organisation, India and the Head of the National Agency of Drug and Food Control, Indonesia were also nominated to the ISG. The WHO Regional Office for South-East Asia would continue to act as the Secretariat to facilitate the process.

It was decided that the network’s activities would initially focus on “quick wins”. Leading up to the next meeting of the interim network, a preliminary paper laying out the mission, scope and strategic objectives of the network will be prepared through the ISG. The ISG, with the help of the Secretariat, will also coordinate execution of the functions and deliverables network to enable
1. Introduction

The annual meeting of the Interim Network for Promoting Cooperation for Regulation of Medical Products in the SEA Region was organised in Bangkok, Thailand, from 17 to 18 August 2016.

This meeting was an outcome of the Regional Meeting for Promoting Cooperation for Regulation in Trade of Medical Products organized by WHO-SEARO in New Delhi, India from 22 to 24 September 2015. The Regional Meeting had resulted in strong and unanimous support from participants in setting up a regional regulatory network to promote affordable and quality inter country movement of medical products, in line with World Health Assembly Resolution, Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA), WHA 61.21, “Regulatory system strengthening for medical products”, WHA 67.20 and the South East Asia Regional resolution on International Trade and Health SEA/RC59/R9.

The Member States in region recognized that each country is evolving, developing and strengthening the regulatory mechanism to provide quality pharmaceutical products to achieve the goal of Universal Health Coverage (UHC) based on national norms and public health needs. In order to achieve their goal there is an immediate need to develop a regulatory network as most of the countries in the region have limited resources. A regional regulatory network will enable a platform for communication and meeting enabling cooperation and support to National Regulatory Authority (NRA) of each country for quality, safety efficacy of medical products in a timely and efficient manner.

It was hoped that the network would provide an opportunity for information exchange and sharing on policies, standards, procedures, process and products, to develop capacity through training and interaction between regulatory authorities within and outside the region, and to promote convergence and collaboration towards good regulatory practices and regional collaborative mechanisms.

Cooperation among Member States is becoming increasingly important due to the complexity of medical products (pharmaceuticals, biologicals, vaccines, diagnostics and medical devices), globalization and the threats to supply chains, and growing public expectations. Access to medical products is greatly influenced by regulatory requirements at national and international levels.

The formation of similar regional networks, sometimes defined by economic or political frameworks, is common in many other regions of the world such as the Americas, Africa, the Gulf, Asia-Pacific (APEC), ASEAN region and the EU. There is a void in the SEA Region. Hence, this initiative holds promise for encouraging convergence, the effective use of resources and the rapid exchange of information on products for the countries in the Region.

The need for a Network for Regulatory Affairs in SEA Region has been voiced from time to time. During the Sri Lanka national assessment of the World Health Assembly Resolution (WHA61.21), 2008 on Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA) this came up for consideration. At the Regional Meeting for Promoting Cooperation for Regulation in Trade of Medical Product conducted by WHO SEARO

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in New Delhi India September 2015, it was informed that the availability of medicines in some member states relies on medicine supplied from neighbouring countries in SEAR countries. Having a SEAR network would allow the SEAR countries to work together more closely and could share common goals by coordinating strategies and pooling resources.
2. Objectives

2.1 General objective

The general objective was to promote next steps and hold the annual meeting of the interim network as agreed in the Regional Meeting for Promoting Cooperation for Regulation in Trade of Medical Products held in WHO-SEARO, New Delhi, India during 22-24 September 2015.

2.2 Specific objectives

The specific objectives of the meeting were to:

- evolve an information sharing mechanism/prototype for the proposed Regional Network for Promoting Cooperation for Regulation;
- hold the annual meeting of the interim network; and
- formulate a report on the proposed network for the next Regional Committee.
3. Opening Session

3.1 Opening address

Dr Phyllida Travis, Director, Department of Health Systems Development, WHO Regional Office for South-East Asia, read out the Regional Director Dr. Poonam Khetrapal Singh’s address. She emphasized that access to quality medical products is crucial for achieving universal health coverage and in reaching the Sustainable Development Goal for health.

She noted that with increasing complexity of medical products and supply chains, the implications of globalization and growing public expectations, there are new demands on national regulatory authorities and cooperation among Member States is becoming increasingly important for better access to medical products.

Dr. Singh reiterated that at the previous meeting in New Delhi in September 2015, Member States had supported the establishment of a network of national regulators to enhance information exchange and capacity-building with a view to encourage adoption of international standards, best practices and effective use of regulatory resources. In order to advance this agenda, it was also decided to meet annually until the network was formally established.

She pointed out that South-East Asia Region is a major supplier and consumer of medical products including drugs, vaccines and diagnostics. Furthermore, countries such as India and Bangladesh are significant suppliers of generic medicines, which dominate the regional market. In this context, she noted, a regional regulatory network is timely for ensuring access. The network could provide Member States a platform for timely and efficient cooperation between national regulatory authorities, facilitate their capacity development also provide an opportunity for information exchange on matters related to policy, standards, procedures, processes and products.

She recalled that during the deliberations in 2015, Member States made a number of recommendations to take forward regional cooperation relating to regulatory aspects. The Regional Office was requested to act as the initial secretariat of the network and it was recommended that the Regional Office consider inviting similar regional networks to share their experiences. She observed that the representative of one of the oldest networks in WHO, the Pan American Network for Drug Regulatory Harmonization (PANDRH) was present to share its experience as well as the experiences of other regional networks in the Asia-Pacific. This would enable discussions on what works and the practical aspects of establishing and running a network. She hoped that this in turn would help in establishing a clear vision, goals and initial activities for the network in the SEA Region in order to foster trust and enable reliance on and convergence of good practices.

Dr. Singh stated that access to affordable medicines and medical products is a major priority for the Regional Director of the WHO South-East Asia Region and supported by several WHO Resolutions. She expressed her desire that the consultation would lead to sustained collaboration among in the short and long term and also that the network established would be a vibrant one, addressing the specific needs and concerns of Member States of the Region.
3.2 Inaugural address

In his inaugural address, Dr. Boonchai Somboonsook, Secretary-General, Food and Drug Administration, Thailand stated that the present consultation was a continued effort from the meeting held in India during the previous year where SEA Region Member States’ regulatory authorities had gathered and provided important recommendations. It was recommended for Member States to contribute to the development of a network for the SEA Region for access to safe, quality medical products by learning from each other and other networks and to request the WHO Regional Office to continue to arrange annual meetings of the interim network until the official network was founded.

He said that these recommendations reveal that authorities in the Region are well aware of the imbalance between the roles and responsibilities of ensuring safe and quality medical products and the available resources to handle such tasks. He emphasized, therefore, the prime importance of having a forum for continued discussion in order to finally form a regional network for cooperation among the authorities.

Dr. Somboonsook stressed that we are here to form our cooperative and collaborative regional network. Presently, no one can work effectively and efficiently alone in very complex and rapidly changing global conditions. Only by teaming up among authorities in the region on common and shared priority needs can we achieve our important task. He explained this further through three “obvious things”:

First, he observed that we live in a trade-dominated environment where trade in goods, including medical products, has become the main agenda for almost all international forums. Thus to some extent the critical work of protecting public health through proper regulation of medical products has been adversely affected by regional or global trade rules. In particular, global harmonization of intellectual property rights through the TRIPS Agreement, especially of patents, has had an impact that potentially impedes public access to essential medical products.

He noted that although pharmaceuticals have long been the target for more stringent patent protection in free trade agreements, advanced by developed countries, medical devices have now become another target for stronger intellectual property rights and other protections in several trade negotiations. The Trans Pacific Partnership Agreement (TPPA) is an example of a trade agreement with such demands. He observed that it is becoming unavoidable for public health authorities to get involved directly or indirectly with these issues, despite it not being part of core strengths, in order to ensure protection of public health.

Second, Dr. Somboonsook highlighted the technical and technological complexities of medical product innovations, such as in the area of personalized therapies, and the challenges they pose for effective, efficient and suitable regulation of these innovations to ensure timely access for patients. Last, he noted that the number of medical product manufacturers has increased rapidly, both domestically and internationally. This poses challenges for regulatory authorities in
guaranteeing the quality, safety and efficacy of the medical products from these manufacturers and conducting inspections of facilities.

Given that on one hand the world is changing rapidly towards trade-dominated rules with respect to medical product innovation and that on the other hand regulatory authorities have limited resources including manpower, budget and knowledge, it is abundantly clear that each individual regulatory authority in the region would be unlikely to manage such huge tasks alone. He emphasized that a possible solution is for the regulatory authorities in the region is to collaborate and work together. Therefore, the regional network would likely lead to an answer for the proper regulation of medical products. Considering the great need of all regulatory authorities in the region, he remarked that it is was an idea whose time has come.

He encouraged the participants to actively and fruitfully brainstorm to come up with priority needs for cooperation or collaboration as well as efficient mechanisms to serve the network and expressed hope that the meeting would serve as a vehicle for continued support for Member States in the region to work together for regulation of medical products.

Finally, he conveyed his optimism that the term ‘interim’ would be removed from the name of the network for sustainable progress and advancement in the regulation of medical products in the region.
4. Proceedings

4.1 Background

Developing a Regional Regulatory Network - Annual meeting of interim network and expected outcomes

Dr. Manisha Shridhar, Regional Adviser (IPT), WHO Regional Office for South-East Asia, outlined the context and background for meeting. It is in line with the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, resolution WHA 61.21 (extended until 2022 through resolution WHA 68.35 in May 2015), Regulatory System Strengthening for Medical Products, resolution WHA 67.20 and the regional resolution on International Trade and Health, SEA/RC59/R9. The latter which sought to address the growing complexities of trade in medical products and influence of trade agreements on public health, was the precursor to the efforts to develop a regional regulatory network. The resolution urged Member States to improve the capacity of the National Regulatory Authorities and requested WHO to support Member States in this endeavor.

The participants in ‘Regional Meeting for Promoting Cooperation for Regulation in Trade of Medical Products (22-24 September 2015)’ decided to set up a regional network for strengthening cooperation in regulatory mechanisms as most of the countries in region have limited resources. Member States had supported the development of a platform for enabling cooperation and support to National Regulatory Authorities for quality, safety, efficacy of medical product by taking advantage of experiences of similar regional networks.

Member States requested WHO-SEARO to continue to with annual meetings of the interim network until the official network is established. Laying out the objectives of the meeting, Dr. Shridhar hoped that the meeting would fulfill the expectations set out.

SDGs and Universal Health Coverage: The role of regulatory systems

Dr. Phyllida Travis, Director, Department of Health Systems, WHO Regional Office for South-East Asia spoke on the role of regulatory systems in achieving the health-related goals of the Sustainable Development Goals (SDGs), particularly universal health coverage. She explained that SDG 3, “Ensuring healthy lives and promote well-being for all at all ages”, represents a significant broadening of the health agenda under the SDG framework in comparison with the Millennium Development Goals. In fact the central focus of the health-related SDG is achieving Universal Health Coverage (UHC).

UHC is achieved when all people receive the healthcare that they need and without incurring financial hardship. A study of the SEA Region done by WHO found that despite progress, around 130 million people still lacked access to one or more essential health services in the region. At least 60 million people are impoverished because of healthcare costs, in which out-of-pocket expenditure on medicines is a major contributing factor. Dr. Travis also described how the health needs in the SEA Region are rapidly evolving. For example, by 2020, the number of people aged 60 years and over will outnumber children under 5 years in the region.
Within the health agenda of the SDGs, regulation has an important role to play in ensuring access to medicines, vaccines and other medical products (Target 3.b). As per the 2010 World Health Report: Financing for Universal Health Coverage, three of the top ten sources of inefficiency were identified as linked to medicines. Furthermore, inadequate regulatory structures and mechanisms were found to be the common reasons underpinning these inefficiencies. Therefore, inadequate regulatory frameworks can pose a barrier to ensuring access to medicines.

Dr. Travis also described how medicines markets are changing globally and in Asia such as through the influence of trade agreements, the growing movement of medicines across borders, and greater demands on regulators in both importing and exporting countries. All these factors point to the need for better information sharing between countries.

4.2 Technical presentations

Practical experiences from regulatory networks – a global perspective

Mr. Michael Ward, Coordinator, Regulator Systems Strengthening, WHO-Headquarters, shared a global view of regulatory networks and spoke about several themes relevant to the deliberations about development of a network in the SEA Region. He described a new regulatory reality in which the degree to which National Regulatory Authorities (NRAs) fulfill their mandates in an effective, efficient and transparent manner has a direct impact on innovation, access and public health. NRAs must consider more modern and intelligent models of regulation to address challenges of resource constraints, increasingly complex technologies, globalization and public expectations. The increasing engagement in regulatory networks stems from a recognition that individual regulatory authorities, even the largest, cannot effectively manage these challenges in isolation. The underlying assumption is that regulatory networks are effective in improving the regulatory performance of participating members.

In fact, there are several considerations in establishing a well-functioning regulatory network and which are critical for achieving the desired outcomes. To begin with, a solid business case should be developed which articulates the problems to be solved and identifies goals and objectives that are meaningful and achievable. Next, the function of the network should be clarified, i.e., information-sharing, work-sharing, technical assistance or a combination of functions. It is also recommended to adopt a practical, incremental approach but with long-term goals. In such a scenario, early successes would be important to securing ongoing support towards fulfillment of the long-term goals. Another prerequisite is the presence of strong political support and/or a legislative foundation which for instance, could arise as a result of trade and economic efforts to increase the flow of good and services (e.g., ASEAN network).

It would be critical to avoid duplication of effort by leveraging the learnings from other networks, including with respect to harmonized standards, best practices and tools and the sharing of regulatory information. The concept of ‘interconnectivity’, which was recognized in the 14th ICDRA meeting in Singapore, seeks to build synergies and complementary actions between
regulatory networks. This is also increasingly a focus of heads of agencies such as International Coalition of Medicines Regulatory Authorities (ICMRA) when looking at investments. Good governance, including a well-functioning secretariat, is vital. Other factors to consider include appropriate resourcing and the diversity of the capacity and standards of the membership.

Dr. Ward provided an overview of the existing models of harmonization, convergence and other forms of cooperation at both regional and international levels such as ASEAN, APEC, DCVRN, ICH, IPRF, IMDRF, ICMRA, PIC/S, IGDRP, WPRO Regional Alliance. It is becoming increasingly apparent that intended objectives cannot be achieved unless products of harmonization and convergences are implemented in a consistent and intended manner.

Convergence and harmonization efforts are required but not sufficient factors in setting up conditions for enhanced collaboration and new regulatory paradigms. They should in theory diminish duplication by creating a “common language” for decision-making and facilitating cooperation, work-sharing and eventually reliance or recognition.

Summarizing the current situation in the SEA Region, Dr. Ward explained that there is great asymmetry in the size and capacity of regulatory agencies of countries, and their respective economies. Regulatory efforts are not part of a larger trade union as within ASEAN. Senior political support and resources for regulatory cooperation in the region are yet to be confirmed whilst some countries are part of ASEAN or other regional initiatives. However, it is a very active region in terms of manufacturing and trade of medical products and there is a growing recognition that a void exists in the region. In this respect, there is a great opportunities to learn from other networks and experiences of the WHO to take forward the proposed regional network.

In this context, he described the efforts of WHO in developing guidance on Good Regulatory Practice (GRP) the scope of which would be medical products and the regulatory life cycle. This foundational, high level document will define GRP and relevant terms such as reliance and recognition, describe the principles and attributes of GRP that can be adopted irrespective of the size of the agency, lay out model processes and instruments for development of regulations and consider how it may be implemented by agencies. The guidance is envisioned to be relevant to all regulators, irrespective of resources of the system (centralized, decentralized, network). Further, it is foreseen that WHO will produce a series of guidances, including good reliance practices. He gave examples of guidances being produced or contemplated as part of a larger family of guidances to help guide regulatory authorities.

On the subject of reliance, Dr. Ward shared the outcomes of the second consultation on the WHO NRA benchmarking tool. There was recognition that reliance is increasingly important in helping to fulfill regulatory mandates and acknowledgement that a regulator may be considered ‘functional’ even if relying on others for certain regulatory functions. There was support for developing WHO guidance and tools to assist member states in promoting a sound, pragmatic and transparent approach to establishing suitable forms of reliance. It was also agreed that the WHO objective benchmarking/assessment tool must be able to evaluate the appropriateness of an authority’s reliance on another’s work.
Dr. Ward elaborated the concepts of reliance and recognition. Reliance by an agency is the streamlining or reduction of internal work such as by making use of the outcomes of another NRA to inform its own regulatory undertakings. Recognition involves making use of and recognizing the decision of another regulatory authority (e.g., mutual recognition agreements, unilateral recognition of certain authorities in certain regulatory areas). He stressed that under both scenarios, it is critically important to know that the regulatory authority is not giving up sovereignty. They may be part of a step-wise approach to building trust and leverage the outputs of certain regulatory authorities and institutions like WHO.

He provided insights on some steps that might be considered. First, establishing a baseline of the in-country or in-region situation (for example to assess the lay of the land in terms of capacities, standards, norms and approaches) could be undertaken to more precisely inform next steps. One mechanism to consider is the WHO rapid assessment toll to enable a rapid assessment of the regulators in the region, building off available information. This might also include further piloting of a competencies self-assessment (i.e., competencies of the staff and agencies to undertake and fulfill their functions) and evaluation of standards by building it into the regular NRA assessment tool.

Second, information platforms may be established like list serves to share alerts (PAHO model). The need for a modular platform for enhanced information exchange (such as in PAHO) may also be evaluated. Third, the capacity of NRAs may be built based on individual IDPs and common network goals, taking advantage of centres of excellence, twinning and formalized, planned schedules of rotation between agencies or even outside the region.

Fourth, advantage may be taken of outputs of trusted parties, notably through the WHO Prequalification decisions through the Collaborative Procedure and other pathways for facilitated registration and capacity building. Fifth, member states should contribute to and take advantage of the WHO Global Surveillance and Rapid Alert System.

He proposed several goals that a SEA regional regulatory network could consider. The overarching goal should be of regulatory system strengthening in accordance with resolution WHA 67.20. Additionally, the network could aim for convergence based on international best practices and standards and could explore enhanced forms of cooperation, leveraging lessons from other networks. It may also aspire to put into practice the concept of reliance as a pragmatic approach to regulation, based on enhanced knowledge and trust.

**Regional experience with regulatory capacity building, regulatory networks and reliance models**

Dr. Martin Eisenhawer, TIP-Vaccine Quality and Management, WHO Regional Office for South-East Asia discussed the mandate given to WHO under resolution WHA 67.20 for strengthening regulatory capacities in the world. The resolution noted that inefficient regulatory systems themselves can be a barrier to access to safe, effective and quality medical products.

He highlighted the benefits of a well performing NRA in that medical products are of assured of quality, safety and efficacy and are also made available to the market in a timely manner. The
NRA is an essential partner in the whole value chain for medical products, from R&D to delivery, and builds public confidence in medical products, whether locally produced or imported. It also contributes to the containment of Substandard, Spurious, Falsely labeled, Falsified, Counterfeit (SSFFC) medical products.

On the other hand, risks of an underperforming NRA include delayed access to medical products, use of potentially harmful products, potential delays in investigating cases of ADR/AEFIs and loss of the public’s confidence in the quality of medical products.

In the field of vaccines, a lot of efforts have been put into the region for building regulatory capacity and undertaking NRA assessments, he explained. This is because NRA functionality if a prerequisite for vaccine manufacturers to offer their products to the international market through WHO prequalification. India, Indonesia and Thailand have been declared functional NRAs on the basis of vaccine-specific aspects and their overarching systems. He noted that efforts of the WHO essential medicines department have also touched on NRA but that in the future the methodology will be combined within the harmonized tool developed by WHO headquarters that comprises both vaccines and medicines.

Dr. Eisenhawer described WHO’s work with regulatory institutions in the region. WHO has established a GLO training centre in Indonesia that can be used by other countries. The centre’s focus is on clinical trial authorization (CTA), GCP inspection (GCP-I) and clinical data evaluation (CDE). A GLO training center for lot release has been established in India and workshops have been conducted using the expertise present in India. WHO is also in the process of developing the cold chain training centers in India that already have a significant capacity and that have provided training for the region and other countries, to establish a mechanism to officially make them a centre of excellence.

Technical co-operations have been set up such as between Thailand and Bhutan to provide training and capacity building to Bhutan on functions such as development of quality systems, marketing authorization, lot release and laboratory access. A technical cooperation is also being set up between Nepal and Indonesia that will result in a MoU between the two countries.

Dr. Eisenhawer shared the experience of the SEAR Vaccine National Control Laboratory (NCL) network, which was established among national control laboratories involved in testing of vaccines in the SEA Region and also informally participated in by WHO Western Pacific countries.

The principles of the network are to address regional needs that are not covered by international solutions, gain mentorship by an international reference partner (NIBSC, London has served continuously as a mentor to the network), sharing of workload using existing expertise and information sharing.

The objectives of the network include the preparation of Regional Working Reference Standards (RWRS) for potency testing of vaccines. All member organisations are envisioned to participate in collaborative studies in the context of establishment of the RWRS. The results of the studies
are centrally recorded and may be used for the establishment of a Proficiency Testing Scheme, as a means to having external quality control and facilitating the exchange of information.

Success could be attributed to several factors. The network started out informally with a technical orientation and through personal contacts. There was trust between the technical experts and a clear vision of the common goals. Local expertise and availability of a mentor contributed to the successes of the network.

Dr. Eisenhawer drew attention to the challenges faced by the network such as recognition at high political levels and the establishment of MoUs. In order for the network to be sustainable, maintaining financial and human resources are also challenging, including provision of an efficient secretariat. Another challenge is in regards to operationalizing of the network whereby one of the key next steps is to ensure that the standards products are also efficiently distributed.

Dr. Eisenhawer also gave several examples of convergence or harmonization efforts in different regions. In ASEAN, there are efforts for harmonized guidelines and mutual recognition agreements of GMP inspection. Efforts within APEC relate to good regulatory practices. The PIC/S member countries benefit from a common approach to GMP inspections and which are also internationally recognized. In the Western Pacific Region there is an NRA alliance that works on convergence and harmonization. He proposed four intersecting future scenarios – namely, the creation of more Centres of Excellence for NRA functions (e.g., for regulatory inspections), establishment of MRAs/MoUs between countries, out-sourcing to avoid duplication of work or establishing capacity where it is not necessary, and creation of a regulatory network as a means for achieving common goals.

In summary, Dr. Eisenhawer pointed out that all NRAs are short in resources and yet, regulatory expertise is present in the region. Building of and working with competent institutions is an important way forward. Networking between NRAs is becoming more and more necessary, of which work-sharing and international and regional reliance are important components.

**Regulatory system strengthening and collaborative network: the America’s model**

Dr. Murilo Dias, Specialist, Regulatory Affairs, Medicines and Health Technologies, WHO Regional Office for the Americas/Pan American Health Organization (PAHO), spoke in detail about PAHO’s approach to establishing the Pan American Network for Drug Regulatory Harmonization (PANDRH).

A key goal of the Medicines and Health Technologies Unit, PAHO is to “improve equitable and sustainable access to essential drugs and priority health technologies to prevent, diagnose, treat and relieve health conditions in order to contribute to the improvement of universal health coverage in the Region of the Americas” by supporting safe, effective, quality, cost-effective and rationally used medical products.

Based on this goal, PAHO approach is driven towards fulfilling the goals of 1) facilitating the development of context-specific national regulatory systems, 2) promoting regulatory
convergence and harmonization and 3) supporting the efficient use of resources by leveraging the work of others.

Dr. Dias explained that PANDRH was established in 1999 to promote regulatory harmonization, while strengthening the capacities of NRAs. It became an official network through CD41.R11 resolution in 2000. The network is framed on fundamental principles of participation, transparency, responsibility, effectiveness, efficiency, accountability and consensus as the basis of decisions. Its primary objective has gradually shifted towards strengthening of regulatory capacities and linkages with other projects.

PANDRH has been successful in developing 23 technical documents from 1999-2013. However, it has not been so easy for countries to adopt these references and incorporate them in policies.

Dr. Dias shared that with the approval of the Strategic Development Plan 2014-2020, the network has been reoriented in the new context of international regulatory landscape and the challenges of NRAs. Under the new strategy, there is a new governance structure that provides opportunities for health technology producers, NGOs and academics to participate as invited observers. A role has been created for National Regulatory Authorities of Regional Reference (NRAr) to provide leadership as NRA focal-points in strategic projects based on the priorities of the network.

Based on PAHO’s mandate under resolution CD50.R9 for “strengthening national regulatory authorities for medicines and biological”, a Regional Platform on Access and Innovation for Health Technologies (PRAIS) has been established. The platform is a means to promote interaction and technical cooperation among countries and also enables the dissemination of information and sharing of the results of functionality assessments through a bulletin.

The structure of the PAHO evaluation of NRAs involves three stages – preevaluation, assessment and assessment follow-up – with specific data evaluation tools. The PRAIS platform also contains an observatory for sharing of information with other NRAs (except protected and confidential information) and allows an NRA to access the correspondent data from other NRAs participating in the process. Since 2010, NRA assessments have been completed for 24 countries (i.e., 69% of PAHO members) with 4 regulatory authorities deemed to be NRAs of Regional Reference.

The NRAs of Regional Reference generate and share information between NRAs to facilitate decision making in national regulatory processes, promote greater integration in regulatory medicines to optimize assessment processes for medicines and other health technologies, strengthening and support strategic development of regulatory networks and regulatory exchange, participate and support evaluation of regional NRAs and facilitate access through PAHO to information on product registration and GMP inspections.

Dr. Dias elaborated that the regional initiative operates through establishment of institutional development plans, publication of regulatory countries profiles, prioritization of technical cooperation and identifying of strengths and partnerships/joint work plans with NRAs, and through prioritizing activities for harmonization and convergence. The path to achieving success is based on commitment and willingness reflected in voluntary agreements, use of an evaluation
methodology that promotes information transparency and involving countries in regional technical cooperation practices.

PAHO’s approach to promoting convergence and harmonization is based on the adoption of a systematic and robust priority setting mechanism of NRAs core regulatory functions. It also involves supporting the development of competency-based curriculum and a comprehensive development plan for staff and regulatory entities that reflect the region’s various realities and diversity and the implementation of global standards based on identified priorities.

Dr. Dias highlighted that PANDRH undertook a survey on current and future regulatory challenges in the Americas NRAs in 2013. The information collected from the NRA perspective can be combined with objective data from country assessments, specialist’s opinions to create new analysis of the technical areas to be prioritized.

In respect of PAHO’s goal towards supporting efficient use of resources by leveraging the work of other, the Regulatory Data Information System based on PRAIS and analysis of PRAIS observatory data are important mechanisms. It has also been possible to establish linkages with other relevant initiatives, forums and/or platforms.

He detailed the process through which data informational system facilitates combining the inputs of experts with data from the country profile and NRA assessments, to identify priorities for strategic projects for the network.

He also described unique approaches for some sub-regions such as the Caribbean to set up a centralized process to prequalify and register medicines through reliance on NRAs of Regional Reference.

Dr. Dias provided a detailed orientation to the PRAIS platform, its vision and features as a repository of information and also discussed the challenges of designing and sustaining an optimal information sharing platform. Based on the need of countries to exchange confidential information he also shared the experiences of setting up secure Regulatory Exchange Platforms (REPs) which involved higher costs than regular platforms and also use of an high encryption process.

Finally, he touched up the Strategic Fund created by PAHO in 2000 to assist member states to procure essential medicines and basic public health products that meet international quality standards for the region.

Dr. Dias summarized important lessons derived from the experience of the regulatory network in the Americas. He emphasized that having a clear vision and goals are critical as is also recognizing diversity and common regional needs. The network should be based on consensus and transparency. It is important to build reliance among peers and promote extensive collaboration.

There should be continuous regulatory assessment of performance and sharing of information. There is also utility in tailoring regulatory models (e.g., sub-regional system for some regulatory functions). The network may support the capacity building in the region through the help of more
structured NRAs. Priority setting mechanisms are very important to establish strategic projects for strengthening the capacity of a sub-region or country. Lastly, creation of a data information platform for public, restricted or even confidential information can be useful in benchmarking and decision making.

**Network initiatives in the Asia Pacific**

Dr. Klara Tisocki, Regional Adviser for Essential Drugs and Other Medicines, WHO Regional Office for South-East Asia shared insights regional regulatory network operating in the Western Pacific region. Some of the common characteristics of effective regulatory systems are that they are science-based, risk-based, flexible and adaptive to evolving needs, streamlined and efficient, and harmonized and aligned with international standards. One way of increasing the efficiency of the regulatory authority is by leveraging the work of WHO and relying on trusted, “stringent” or “competent” NRAs and other regulatory networks.

Dr. Tisocki shared information about the existing medical product regulatory networks and initiatives in Asia, however, none of these networks have Asia Pacific-wide coverage. The Western Pacific Regional Alliance of NRAs for vaccines has a clearly articulated vision that WHO Member States in the Western Pacific Region will strive “to promote and support strategies and programmes to develop and strengthen NRAs” and “to ensure that all vaccines – especially those used in the national immunization programmes – are of assured quality.”

She explained that the structure was of a ISG with rotating chairpersonship and 5 working groups. The WHO Western Pacific Office served as the secretariat. With changes in the WHO regulatory system strengthening policy and new global benchmarking tools, some of the country assessments and institutional development plans (IDPs) need to be updated. There are also internal challenges in bringing about structural reforms for bringing together the vaccines regulatory strengthening work with medicines regulatory strengthening and the convergence of the two technical units within WPRO. Unfortunately, the working groups are not yet functional because of which no clear activity plans or outputs have determined. Lastly, the financing model needs to be made sustainable and not dependent on donor contributions and human resources need to be ensured for the secretariat for the active functioning of the network. Drawing from the experience of the network, an important lesson is what even with a clear vision and terms of reference, making a network work is not easy and could take a lot of time. She recommended setting realistic expectations of goals and what can be achieved through the network.

She proposed that the future of medicines regulation is moving towards collaboration and networking with regulators starting to function more as a part of a functional network rather than as individual players. Key elements that need to be in place for a successful network are a clear purpose, political support at the country-level to support the NRAs to take forward the regulatory strengthening process, planning of activities identified for the network, processes (e.g., for sharing information), and products that are beneficial to the members (e.g., information sharing platform, training plans, agreements with other countries to ease the burden of NRAs).
4.3 Consensus development – goals, structure and timelines of the Network

Following the technical presentations, participants engaged in detailed deliberations to identify common needs and the potential scope of the network. The concept papers provided by the member countries, experiences of other regional networks and inputs of experts guided the discussions.

Participants discussed the vision and scope of the network as well as the specific strategic goals that could be achieved. The priority needs that emerged were for information sharing between NRAs on policies, standards, procedures and regulatory outputs; development of the regulatory capacity of NRAs by fostering interactions between regulatory authorities within and outside the region and through improving competencies of NRAs in the region; and promotion of convergence towards good regulatory practices and development of regional collaborative mechanisms to rely on existing capacities and expertise in the region. Specific activities that would be practical and achievable in the short-, medium- and long-term to accomplish the objectives of the network were also recommended.

Reflecting on the lessons from the experiences of other regional networks, there was a consensus to take an incremental approach by defining the minimum activities for the network and expanding the scope and scale of activities in time. There was a robust discussion around the governance structures needed and attaining the highest level of political commitment to make the network a success.
5. Conclusions and way forward

Member States reiterated the need for a regional regulatory network in the SEA region to facilitate information sharing, creation of an enabling environment for greater cooperation and collaboration, the capacity building of NRAs and pooling of resources in the region.

Guiding Principles

Participants adopted guiding principles for the establishment of the SEA regional network. They recognized the need to demonstrate value of the network through early successes. The network’s governance and operating model must be fit for this purpose. Therefore, the structure that was proposed would initially be light and evolve gradually. Member country buy-in/commitment and effective decision-making would be achieved through the active participation of Heads of Agencies. A small Steering Group will guide and sustain efforts to institute the network. There was also agreement on the need for setting up effective processes and oversight.

Governance model

Participants agreed that the heads or delegates of the National Regulatory Authorities must be the decision makers. The designated focal points of each NRA would be responsible for participating in the day-to-day operations of the network. It was proposed that the annual meeting of the regional network would take place through the participation of Heads of Agencies and focal points with the purpose of holding discussions on the business of the network and on scientific and regulatory topics.

Participants supported the idea of convening the next meeting of the network in February 2017 towards officially establishing the regional regulatory network. It was agreed that initially a ISG composed of the Chair, Co-Chair, two other Heads of Agencies and the Secretariat would take decisions prior to the convening of the next (extraordinary) meeting.

Ms. Yuwadee Patanawong, Director, Medical Device Control Division, Food and Drug Administration, Thailand would remain as the Chair and Mr. Mohamed Rafeeq, Deput Minister, Ministry of Health, Maldives would remain the Co-Chair of the ISG of the interim network. The Drugs Controller General of India, Central Drugs Standard Control Organisation, India and the Head of the National Agency of Drug and Food Control, Indonesia were nominated to the ISG. The WHO Regional Office for South-East Asia would continue to act as the Secretariat to facilitate the process.

Activities

It was decided that the network’s activities would initially focus on “quick wins” in the form of setting up systems for facilitating information sharing, developing capacity building through
participation in the Global Surveillance and Rapid Alert System and adoption of reliance by NRAs by taking advantage of WHO prequalification decisions.

**Necessary outcomes and next steps:**

Participants identified the necessary activities for taking forward the network such as defining the terms of reference for the network, its work plan and budget for mobilizing resources in the region, and getting political support from NRAs.

In the period leading up to the next meeting of the interim network, a preliminary paper laying out the mission, scope and strategic objectives of the network will be prepared through the ISG. The ISG, with the help of the Secretariat, will coordinate execution of agreed short-term functions and deliverables of the interim network to enable the official creation of the network for promoting cooperation for regulation of medical products in SEA Region in line with resolution WHA 67.20 and also prepare for the upcoming International Conference of Drug Regulatory Authorities in November-December, 2016 in Cape Town, South Africa.
Annex 1

Opening remarks by Dr. Poonam Khetrapal Singh, Regional Director, WHO South-East Asia

I warmly welcome you to this second meeting of the interim network for promoting cooperation for regulation of medical products in the SEA Region, in Bangkok. Access to quality medical products is vital for achieving universal health coverage and reaching the Sustainable Development Goal for health. Cooperation among Member States is becoming increasingly important for better access to medical products due to the complexity of medical products and supply chains, the implications of globalization and growing public expectations. There are new demands on national regulatory authorities in this increasingly complex environment.

At the previous meeting in New Delhi in September 2015, Member States decided to collaborate to help ensure access to quality, safe medical products to meet country needs. They supported the establishment of a network of national regulators to enhance information exchange and capacity-building with a view to encourage adoption of international standards, best practices and effective use of regulatory resources. They also decided to meet annually to advance this agenda, until the network is formally established.

As we are aware, the South-East Asia Region is a major supplier and consumer of medical products including drugs, vaccines and diagnostics. Generic medicines dominate the regional market and many countries such as India and Bangladesh are significant suppliers. In this context, a regional regulatory network is timely. This can provide our Member States with a platform for timely and efficient cooperation between national regulatory authorities, or NRAs, providing an opportunity for information exchange on matters related to policy, standards, procedures, processes and products, and help develop capacity through training to support harmonization and implementation of international standards and guidelines in the Region.

During deliberations in 2015, Member States made a number of other recommendations to take forward regional cooperation relating to regulatory aspects. Member States requested that the Regional Office act as the initial secretariat of this network. Member States also recommended that the Regional Office consider inviting similar regional networks to share experience. The representative of the Pan American Network for Drug Regulatory Harmonization, or PANDRH, one of the oldest in WHO, is here to its experience with us, and experiences from other regional networks in the Asia-Pacific will also be shared. This would enable discussions on what works well and what it takes to establish and run a network in the practical sense. This we hope would help in establishing a clear vision, goals and initial activities for the network in the SEA Region that will serve the aspirations of our people. We hope this will foster trust and enable reliance on and convergence of good practices.

Access to affordable medicines and medical products is a major priority for the Regional Director of the WHO South-East Asia Region. The goal of strengthening regulation for medical products is supported by several WHO Resolutions. I hope this consultation will mark a landmark contribution to collaboration and reap rich dividends for all Member States of our Region in the
short and long term and that the network we establish will be a vibrant one and address the specific needs and concerns of Member States of the Region.

I wish you all the best for a productive meeting and a pleasant stay in Bangkok.
Inaugural address by Dr. Boonchai Somboonsook, Secretary-General, Food and Drug Administration, Thailand

I am very honored to join you this morning for the inaugural address for the annual meeting of the interim network promoting cooperation for the regulation of medical products in the SEA Region. Our Permanent Secretary of the Ministry of Public Health, [Dr. …], would have really liked to join you for this important moment. However, with his prior scheduled tasks that could not be missed, he could not make it. Otherwise I strongly believe that he would have definitely joined you.

I have learned that this meeting is a continued effort from last year’s meeting held in India where SEA Region Member States regulatory authorities gathered and finally provided some important recommendations. Member States were recommended to contribute to the development of a network for the SEA Region for access to safe, quality medical products by learning from each other and other networks and to request the WHO regional office to continue to arrange annual meetings of the interim network until the official network is founded.

These recommendations clearly tell me that our authorities in the Region have been well aware of the imbalance between the role and responsibilities of ensuring safe and quality medical products and available resources to handle such tasks. It is of prime importance to have a forum for continued discussion in order to finally form a regional network for cooperation among the authorities. I am really delighted that the recommendations have been taken into account seriously and put into practice timely.

Someone has said, “if you want to go fast, you go alone; but if you want to go and grow stronger, we then go together”. I totally agree with such a statement. That is why we are here to form our cooperative and collaborative regional network.

Presently no one can work effectively and efficiently alone in really complex and rapidly changing global conditions. Only by teaming up among authorities in the region on common and shared priority needs can we achieve our important tasks.

Why do I think in this way? I have witnessed recent changes, that whether you agree or not, they have come long time. Let me explain to you three obvious things.

First of all, as you all may be well aware that during the last decade of the 20th century until now, trade in goods including […] medical products have become the main agenda for almost all international forums. It can be said that we live in trade dominated or driven environment. Certainly to some extent, our key work to protect public health through proper regulation of medical products has been adversely affected by regional or global trade rules.

Vividly from my experience, globally harmonized intellectual property rights, especially patents, contained in the TRIPS Agreement is a very good example of how the IPR rules have affected us in the way that potentially impedes public access to essential medical products. Although pharmaceuticals have been the target for more stringent patent protection in several free trade
agreements - agreements often led by the developed countries - medical devices now have become another target for intellectual property rights and other similar rights in several trade negotiations.

The Trans Pacific economic Partnership Agreement leaves you clearly with such a strong demand. In fact not only intellectual property rights but also other trade-related provisions of free trade agreements more or less have influenced the way we as public health people function. It seems that public health authorities have to get involved directly or indirectly with this issue despite it not being our core strength. Unfortunately it is unavoidable for us and we have to deal with it as best as we possibly can to make sure that our supreme code of public health protection is maintained. Such examples serve well on the certain aspect of how global trade rules can potentially force us to do something that we may have not done before. It is the way of life that I am sure everyone is aware of.

In fact not only the demanding of trade rules, but also the technical and technological complexity and advancement contained in medical product innovations do affect us directly. The science and technological advancement of medical products, for example towards personalised therapy, have surely caused a lot of headaches as we may not have scientifically competent scientists to handle this issue right now or even prepare ourselves for it.

Let me give you a concrete example. I am sure you may be aware of three-D printing technology that could be used to print a surgical knife for surgery or to manufacture a pharmaceutical at the patient bedside, for instance. How are we going to regulate these innovations effectively, efficiently and suitably to ensure timely and access to these innovation for patients? It might not happen now but it is surely to come.

I have always had this in my mind but I do not have an answer for that now. Can this to-be-formed network help me? It is your challenge.

In addition to the above example, let me get back to something much simpler and straightforward. The number of medical product manufacturers increased rapidly either domestically or internationally. How are we going to inspect their manufacturing facilities to ensure conformity with GMP standards? How can you guarantee the quality, safety and efficacy of medical products from those manufacturers?

The picture is clear that each individual regulatory authority in the region would be unlikely to manage such huge tasks alone. On one hand the world has changed rapidly toward trade dominated rules with respect to medical product innovation. On the other hand, regulatory authorities have very limited resources including importantly manpower, budget and knowledge. We all see this disproportion gap between what needs to be done and how we can achieve it meaningfully. I have faced the dilemma between scarce resources and big jobs to fulfill lying ahead. How can we fulfill our job responsibilities in regulating these products under the conditions mentioned above, effectively and sustainably?

I believe there are certain solutions to this question. One possible solution having emerged in my mind is to team up or work together among regulatory authorities in the region. Therefore, the
meeting of regional network or regional family of authorities would likely lead to a possible answer to properly regulate medical products. I hope that the regional network to be formed through this meeting has to find out an appropriate mechanism of ways to work together in the future. This meeting is coming at the right time. In the great need of all regulatory authorities in this region it is an idea whose time has come.

I am sure that you all will actively and fruitfully brainstorm to come up with possible key areas for priority needs for cooperation or collaboration as well as efficient mechanisms to serve for the network. In addition, I hope that you will please allow your thoughts, ideas or strategies that will used at the platform for all of you to work on.

This is a request that today’s meeting is very important and meaningful as it may serve as a vehicle for continued effort from all Member States of the region to move on and work closely together for better regulation of medical products. I really hope that the outcome of this workshop would have brought forth by our crystal clear thoughts, ideas and fruitful discussions will clearly […] us to look forward in the future with confidence of actively working together.

Today is a strong starting point and we will ignite a further chain reaction for progress and advance in the regulation of medical products in the region and worldwide. Despite optimism, the road ahead of us is very far and likely rough but I really believe that we all will never walk alone as we are committed to providing better protection of public health to our […] regional network.

Finally, after the meeting, I do expect the that term ”interim” before network will be dropped out and be replaced by something like “[...“I” or “permanent” so that we can be assured that all of our efforts and attempts will be sustained and carry on and on. I hope to see that all regional regulatory authorities can at last accomplish the ultimate goals of this important meeting.

My address to you today hopefully would fit your main theme for the formation of a regional network for regulation of medical products in the SEA Region.

As the host country for the meeting, I would like to warmly welcome you. I wish you all success with measurable progress in this milestone meeting and a joyful day in Thailand.
Annex 3

Agenda

1. Opening session
2. Introduction to Network
3. Existing Global and Regional Networks – potential applications/adaptations for SEA Region
4. Proposal for consideration of the Network – BAN, IND, INO, SRL
5. Country proposals
6. Consensus development – structure/timelines for the Network
7. Group work
8. Conclusions and recommendations
9. Closing session
Annex 4

List of Participants

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1. Ms Roxana Quader
   Additional Secretary (Public Health and WHO)
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   Dhaka

2. Mr Md. Golam Kibria
   Director (cc)
   Directorate General of Drug Administration
   Ministry of Health and Family Welfare
   Dhaka

Bhutan

3. Mr Dawa Tshering
   Regulatory Officer, Registration Division
   Drug Regulatory Authority
   Thimphu

4. Mr Pelden Chejor
   Officiating Drug Controller
   Drug Regulatory Authority
   Thimphu

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5. Dr Choe Hui Suk
   Section Chief
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6. Dr Kang Hui Jong
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   Ministry of Public Health
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7. Ms So Yong Sun
   Official
   Ministry of Public Health
   Pyongyang

India

8. Mr K L Sharma
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   Ministry of Health & Family Welfare
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9. Dr G N Singh  
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   Central Drugs Standard Control Organisation  
   Directorate General of Health Services  
   Ministry of Health & Family Welfare  
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Indonesia

10. Dra. Ratna Irawati, Apt, M.Kes  
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    Therapeutic Product Standardization and Household Health Supplies  
    National Agency of Drug and Food Control  
    Ministry of Health  
    Jakarta

11. Ms Dita Novianti S.A.  
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12. Mr Mohamed Rafeeq  
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    Ministry of Health  
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13. Ms Aishath Jaleela  
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16. Mr Bal Krishna Khakurel
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