I. Introduction: Steps leading to 2nd Annual Meeting SEARN

The Second Annual meeting of South-East Asia Regulatory Network (SEARN), Colombo, Sri Lanka, 21-23 March 2018 is a follow up of the First Annual Meeting of SEARN which took place in New Delhi, India, on 11 to 12 April 2017. In the First Annual Meeting all medical product regulatory agencies of the South-East Region decided to meet at least once annually. It was agreed that WHO-SEARO would provide initial secretariat assistance.

The WHO South-East Asia Region member countries launched South-East Asia Regulatory Network (SEARN) to enhance information sharing, collaboration and convergence of medical product regulatory practices across the Region to guarantee access to high-quality medical products. Regulatory authorities in several countries lack sufficient technical capacity, staff and resources to perform effectively. Even well-resourced authorities are hard-pressed to thoroughly evaluate new products and enforce existing regulations. Therefore, it is envisaged SEARN would be instrumental in encouraging collaboration, effective use of resources and rapid exchange of information on medical products for the countries in the South-East Region.

SEARN is the outcome of a series of consultations among Member states of the South-East Region that discussed collaboration for access to high-quality medical products. The discussions directly leading to SEARN are:

1. First Annual Meeting of South-East Asia Regulatory Network (SEARN) which took place in New Delhi, India, on 11 to 12 April 2017

II. Advocacy in WHO World Health Assembly (WHA) and Regional resolutions


In 2017 the Regional Committee of South-East Region reiterated the value of SEARN for ensuring access to quality drugs:

1. Hepatitis, SEA/RC70/7 requesting WHO to Support Member States in ensuring access to quality drugs for the treatment of hepatitis C at affordable prices through sharing of information on pricing, and facilitating negotiations through the South-East Asia Regulatory Network (SEARN).

II. Formation of SEARN: Role of Initial Steering Group (ISG)

An Initial Steering Group (ISG) comprising representatives from India and Indonesia, Maldives and Thailand was set up in Bangkok 2016 to guide the process till the first annual meeting. The main recommendation of Bangkok 2016 was to establish SEARN with Heads of National Regulatory Agencies playing a critical role and WHO-SEARO providing initial secretariat assistance. The ISG


3. Regional Meeting for Promoting Cooperation for Regulation in Trade of Medical Products WHO-SEARO, New Delhi, India from 22 to 24 September 2015.

Certain country deliberations on the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA) such as national GSPA assessment in Sri Lanka in 2015 recommended establishing a regional network for regulatory affairs.
approved a summary of discussion points/outcomes of the meeting held in Bangkok and provided a progress report to the First Annual Meeting of SEARN in 2017.

As desired by Member states, SEARN was launched by RD on 23 November 2016 and its scope was presented during the 27 November – 2 December 2016, 17th International Conference of Drug Regulatory Authorities in Cape Town, South Africa.

IV. Setting up of Steering group and Working groups

A Steering Group was set up in the First Annual meeting of SEARN in April 2017 to take the Network forward. The Steering Group comprises 3 members for continuity – India, Indonesia, Thailand, plus 2 other members – (Chair of the next meeting, Sri Lanka, and one member nominated by consensus – Bhutan, till the next meeting.

On 19 September 2017 the Members of the Steering Group (SG) met through WebEx. The following SG members participated: Prof. Asita de Silva, Chairman, National Medicines Regulatory Authority, Sri Lanka Chaired the meeting and the overview and progress was presented by Dr Manisha Shridhar. The technical discussions were made on the topics of “Regulatory Networks: Developing processes for Collaboration- AVAREF experience” by Dr Samvel Azatyan, WHO-HQ, “WHO Network for Technologies and reliance models by Dr Ute Rosskopf, WHO-HQ”, “Regulatory Challenges in the Safety of Medicinal Products in LMICs – Triple S (Smart Safety Surveillance) development” by Dr Raj Long, Bill & Melinda Gates Foundation and “Role of National regulators in translational programmes of i) vaccines, ii) point-of-care diagnostics, iii) clinical and product” by Dr Gagandeep Kang, THSTI. “Strengthening regulation of antimalarial products in the Asia Pacific region - the RRP was presented by Dr Marie Lamy and ‘An update from the Duke-NUS Centre of Regulatory Excellence’ was presented by Associate Director for Strategic Management, CoRE group, Mr Neo Cherng Yeu. Mr Stephane Guichard, guided the work on Quality assurance and labs and Dr Klara Tisocki presented on “Regulatory support for Anti-Microbial Resistance (AMR) in the Region and Dr Madhur Gupta on “Antibiotic consumption and use at National and state levels with specific reference to India”. Dr Razia Pendse, WR Sri Lanka gave the closing remarks for the meeting.

New members for the current year for the Steering and Working groups were nominated- Bangladesh and Maldives – in place of Sri Lanka and Bhutan. These are in addition to the three permanent members India, Indonesia and Thailand. Key work plan activities were discussed and identified for each of the 4 Working Groups on SEARN. Another Working Group, 5. Medical devices and diagnostics was formed, keeping in mind the specific needs to the countries in the area, hence, now there will be five working groups in SEARN. The Second Annual meeting of focused on collaborative activities on work plan, terms of reference and next steps of SEARN SG and WG members. The Regulatory authorities agreed to:

- terms of reference (TORs) and functioning of the SG and WGs
- Establish a 5th WG on medical devices and diagnostics – to be coordinated by IPT
- Bangladesh and Maldives to take the place of Sri Lanka and Bhutan as revolving members of SEARN.
- Bill and Melinda Gates foundation will support developing a Vision document for SEARN
- A prototype for Information Sharing Platform be prepared by Centre for Development of Advance Computing (CDAC) – A scientific society of the

V. Deliberations and Recommendations from 2nd Annual SEARN meeting

The first day 21 March 2018 was Day 0 where all the Working Groups reviewed progress made and finalized their presentations to be made to the SEARN. The main SEARN meeting took place on 22 and 23 March 2018. Including WHO participants, there were a total of 61 participants in the meeting.

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Ministry of Electronics and Information Technology, Government of India

The following are agreed next steps to be taken up by the five WGs in SEARN:

**Working Group 1: Quality assurance and standards of medical products, including labs**
- Finalize priority list of medical products
- Mapping of lab capacity for testing medical products in SEAR
- Define the priority activities and focal point for each activity
- Develop protocols, SOPs, and define budget of the activities
- Ensure funds with approval of national authority, top management including WHO regional office.

**Working Group 2: Good Regulatory Practices including GMP, GDP, etc.**
- Self-assessment tools, benchmarking by countries
- Recommendations for minimum set information on GMP, GDP, GXP to be available on NRAs website
- Map needs for capacity development and identify training needs and regional or global learning / training opportunities for GRP etc. to have common understanding among SEAR members.
- Develop the strategic plan as well as a roadmap that consists of immediate term, medium term and long-term plan, with specific key indicators and targets, to measure working group performance and achievement.

**Working Group 3: Vigilance for Medical Products**
- Engage in Vigilance workshops for principles, practice and causality assessment in compliance with good pharmacovigilance practices, including haemovigilance and fostering reporting; Setting up of pharmacovigilance methods and reporting, tools and IT tools: Q4 2018 (leverage on PVPI India as WHO CC)
- Set up safety monitoring system for medical devices and in-vitro diagnostics Q1 2019
- Develop SEARN Vigilance Newsletter Q4 2018
- Workshop on Challenges, Solutions and Recommendations for Integrating Pharmacovigilance with National Health Programmes in South-East Asia Region – Q2/3 2019
- Workshop on Regulatory aspects of Pharmacovigilance, including Pharmacovigilance Inspections and role of Drug Regulators for enforcement- Q2019

**Working Group 4: Information Sharing Platform**
- A prototype for Information Sharing Platform be prepared by Centre for Development of Advance Computing (CDAC) – A scientific society of the Ministry of Electronics and Information Technology, Government of India and shared with present SG Chairman Prof Asita after deliberation in WG4 for placing before the new SG
- EU DEVCO funds for Information Sharing Platform be channelized accordingly
- Nodal person for gateway from each NRA for developing Prototype of Gateway provided by the NRAs.

**Working Group 5: Medical Devices and Diagnostics**
- Map medical device regulations, for every SEARN country by circulating questionnaire to know the current situation of each country;
- Map the capacity building needs by each country member of SEARN.
- Draft online questionnaire to be developed- by Thailand, Indonesia, India, and circulated in working group for inputs- by end April 2018
- Share the online questionnaire with the member states in the working group for filling it online- June 2018
- Engage in teleconference to agree on few capacity building activities in 2018-19- July 2018
- Each NRA/MOH to nominate focal points for working group on medical devices and diagnostics
- Explore possible Scope of capacity building for medical devices and diagnostics in SEARN
- Testing facilities for quality control of medical devices and diagnostics (IVDS)
- Review diagnostics and devices dossiers for regulators
- Engage for safety monitoring/vigilance for medical devices and diagnostics
- Engage for capacity building for GXP including GMP, GDP, GCP for medical devices and diagnostics
- Information sharing platform to support the above

**VI. Further recommendations:**

The participants agreed that effective collaborative mechanisms are key to SEARN activity. It is agreed that...
the SEARN structure needs to be light and nimble and to improvise as SEARN develops. Further aspects for activity are:

(i) Explore financial support for SEARN: from various institutional mechanisms, membership contribution may be thought of in the long term, in kind contribution from the countries may be considered, many donors would be interested in SEARN.

(ii) Deliberate through technical seminar on Antimicrobial Resistance (AMR)

(iii) Identify key deliverables before the next annual meeting of SEARN

(iv) Notify the date and place of next annual meeting.

The key guiding principle for SEARN is to take up activities where through collaboration the NRAs can achieve better results – savings in time, money, resources and speed up their work for medical products to enter the respective domestic markets.