

Implementation of the Initiative for Coordinated Antidotes Procurement in the South-East Asia Region

Training Workshop Report

30-31 March 2022
Virtual Training Workshop



iCAPS



REGIONAL OFFICE FOR

World Health
Organization

South-East Asia

Implementation of the Initiative for Coordinated Antidotes Procurement in the South-East Asia Region (iCAPS) Training Workshop Report

Virtual training workshop

New Delhi, India, 30-31 March 2022



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Executive summary

The initiative for Collaborative Procurement in South-East Asia Region (iCAPS) seeks to support public health systems in the Region to secure the supply of essential antidotes both in emergencies and on a regular basis through multi-country collaboration. Since the effective implementation of iCAPS requires close collaboration between key stakeholders and participating countries, there is need for a systematic approach to procuring and managing the supply and distribution of quality-assured antidotes and assuring appropriate use.

The training was conducted to provide clear guidance to countries on coordinating and responding to poisoning emergencies. Participants from country procurement agencies, country poison center and National Regulatory Authority (NRA) were nominated to participate in the virtual training workshop.

This training provided clear guidance on the processes that need to be followed to ensure coordination and timely response in cases of poisoning in the South-East Asia Region. The two different response pathways available in response to poisoning were clearly outlined. These are the emergency response pathway and the planned joint annual procurement pathway.

Participating countries shared their current enablers and opportunities available to support scaling up of the initiative and ensure access. The countries face limitations and challenges due to the nature of antidotes, market failures, high cost of production and low volume requirements. This has led countries to face difficulties in sourcing quality assured products at affordable cost. Countries in the Region with small markets expressed their unique opportunity to immensely benefit from the pulling of resources.

The participants committed to start the discussion in their respective countries to start benefitting from the initiative. The Thai Working Group committed to support countries in procuring the antidotes and providing technical support on poisoning management. WHO South-East Asia Regional Office undertook to continue providing technical support to countries that need assistance in accessing antidotes.

1. Background

Improving access to safe, efficacious, quality, and affordable medicines remains a critical focus of the South-East Asia Region. The Regional Committee Decision (SEA/RC70(3)) agreed to develop intercountry cooperation, on a voluntary basis, that include initiating a collaboration on the procurement of antidotes for improved access to limited supplies of medicines for life threatening conditions.

The Initiative for Coordinated Antidote Procurement in the South-East Asia Region (iCAPS) is working towards improving access to essential antidotes and helping in preventing premature deaths due to poisoning. iCAPS helps to secure the supply of these life-saving medicines in the SEA Region through coordinated procurement and the emergency response with support from Thailand's national antidote programme.

Antidote shortages are a problem globally, and even worse in low- and middle-income countries. It is challenging to strike a balance between maintaining a sufficient, well-distributed stockpile and supply of antidotes and not losing money on unused, expired medicines that become waste. Concerted efforts to coordinate supply may effectively address these issues, aggregating demand and coordinating quality assurance systems.

This systematic approach for antidote procurement will improve procurement efficiency by aggregating demand, reducing costs, and coordinating quality assurance.

Participating countries will access the available resources and experience to support capacity building to improve awareness about poisoning and its prevention and train health professionals in the management of poisonings and appropriate use of antidotes

The virtual two-day training provided guidance to iCAPS national focal persons, national poison centers and medicine regulatory agencies on how to access essential antidotes through iCAPS and increase awareness on the epidemiology, prevention and management of poisoning including the rationale use of essential antidotes.

The iCAPS operational [manual](#) and [tools](#) were developed to provide clear guidance on the processes that need to be followed to ensure coordination and timely response in cases of poisoning in the South-East Asia Region.

2. Objective

The aim of the virtual training workshop was to provide guidance to the SEA Member States on the developed processes of ensuring collaborative procurement of essential antidotes in the Region through iCAPS and support countries in responding to poisoning emergencies.

Specific Objectives

- (1) Discuss on the process developed to improve access to essential antidotes and secure supply through collaborative procurement.
- (2) Develop and improve the capacity of Member States in the prevention, control, and management of poisoning.

- (3) Review and learn how Thailand has significantly improved availability of essential medicines for poisoning (including antidotes, anti-venoms, and other anti-sera) through improved procurement and distribution system.
- (4) Estimate the preliminary annual antidote needs from each country and develop a risk-based distribution and stock control system for antidotes in the Member States.
- (5) Learn procurement processes and cycles from participating Member States. Agree and adopt measures needed based on different context to guide countries in accessing essential antidotes through iCAPS.

3. Session – Day 1

Opening Remarks

The meeting was opened by Ms Uhjin Kim, Regional Advisor: Essential Drugs and Other Medicines, WHO Regional Office for South-East Asia.

Ms Uhjin highlighted that poisoning is a global public health problem and causes significant injury-related deaths. In 2019, 2 million deaths around the world were attributable to selected chemical exposures and the majority of deaths occurred in low- and middle-income countries. SDG target 3.9 aims to substantially reduce the number of deaths and illness from hazardous chemicals and air, water, soil pollution and contamination. To achieve this target and to reduce the number of preventable deaths, access to essential antidotes would be critical. When used in a timely and appropriate manner, combined with good supportive care, they could save a patient from death or long-term sequelae, and in doing so reduce the burden on the health system.

The virtual two-day training provided guidance to iCAPS national focal persons, national poison centers and medicine regulatory agencies on how to access essential antidotes through iCAPS and increase awareness on the epidemiology, prevention and management of poisoning including the rationale use of essential antidotes. The training would also provide an opportunity to learn procurement processes and cycles from the participating Member States to agree on the best approaches to procure essential antidotes through iCAPS mechanism. WHO remains strongly committed in supporting our Member States in the region to reduce incidences of poisoning and ensure that essential antidotes are accessible to all.

The challenge in antidote availability and epidemiology of poisoning

Dr Uma Rajarathnam, Regional Advisor: Air Pollution, Environment and Chemical, WHO Regional Office for South-East Asia highlighted that reducing exposure to hazardous chemicals is essential to achieving the Sustainable Development Goals. The rise in noncommunicable diseases is also attributed to the increase in exposure to the toxic chemicals due to injuries are caused by unintentional poisonings and suicide attempts. Trends in South-East Asia show that poisoning is on the rise and 85% of cases are unintentional.

The WHO Model Essential List of Medicines 2021 included 15 antidotes, and these should be always accessible to the population in sufficient quantities. However, in the Region, the antidotes have not been fully included in national Essential Medicine Lists (EML). Globally, there is a shortage of specialist expertise in poisoning management and only in 45% of countries have poisons centres. In South-East Asia Region, poisons centres only available in six countries.

Nationwide access to antidotes: The Thailand Experience

Dr Winai Wananukul: Ramathibodi Poison Center briefed the participants on how the Thai National Antidote Program was established in 2010. The program was developed to solve the national shortage challenges of antidotes in the country. An antidote distribution system was developed based on the national poisoning data and urgency of need for the antidote. Logistics was supported by the use of Geographic Information System (GIS) and online stock logistics system. The program has managed to increase the number of patients who have access to antidotes and antivenoms with better clinical outcomes. The national budget for antidotes has been reduced by 60% during the implementation of the program. Thailand has managed to provide global support to countries that include Myanmar, Laos, Nigeria in response to poisoning emergencies. Support has also been provided in building country capacity in poison management and antidote supply management.

Antidote and Antivenom Production

The head of sterile production at Queen Saovabha Memorial Institute (QSMI) Ms Lalida Skolpap highlighted why production of antidotes and antivenoms is necessary. This is because antidotes are lifesaving products and the availability of quality product is essential. A number of antidotes are now being manufactured by QSMI and these include sodium thiosulfate injection, sodium nitrite injection, methylene blue and diphenhydramine injection. The production of medical products for human use by QSMI is in compliance with ASEAN harmonization standards. The facilities and manufacturing processes comply with regulatory guidelines concerning quality aspects and manufacturing practice (cGMP) requirements and are laid down in accordance with the recommendation of Pharmaceutical Inspection Cooperation Scheme (PIC/S).

Antidotes are orphan medicines as products are intended for a small number of patients and there is little interest from the pharmaceutical industry to produce under normal market conditions. Production of antidotes usually require high capital investments including special manufacturing processes but however, products are normally manufactured in small quantities which may not be profitable.

The Emergency Response Pathway

Dr Satariya Trakulsrichai presented on the emergency response pathway of the iCAPS. This pathway aims to ensure that national focal points, and/or authorized country representatives, can initiate contact with the Ramathibodi Poison Center (RPC) staff and follow the required steps to ensure a fast, flexible and rapid delivery of antidotes for a named patient. The pathway provides a fast, flexible and rapid delivery by courier services in response to a poisoning emergency. The key steps that need to be followed in activating the pathway were shared including the required documentation as indicated in the iCAPS manual.

The Joint Planned Annual Procurement

Mr Kritchai Pattanchan from the National health Security office (NHSO) gave an overview of how antidotes as orphan drugs are often difficult to procure, and thus unavailable to poisoned patients at the point-of-care. Support has been developed and is available to help secure a regular supply of antidotes through the iCAPS planned joint annual procurement pathway. National focal points should coordinate with national/state medicines procurement agencies and national poison centers to estimate the country's annual need for selected antidotes. The orders will be procured by Thailand's Ministry of Public Health via the NHSO and GPO, based on an annual agreement with agreed upon timelines and payment schedules. The national focal points will liaise with medicines regulatory agencies to confirm the registration status of the products in their country.

The key steps in executing a joint planned annual procurement includes planning, forecasting, agreement, and delivery. An annual antidote requisition form is completed by the country and submitted to NHSO for procurement based on the annual contract agreement. Payment is done within two months before delivery based on the bilateral agreement. Program monitoring and evaluation will be carried out annually.

Delivery and Necessary Documentation

The Thailand Government Pharmaceutical Organization (GPO) led by Miss Sirintip Kwanmueng provided an overview of the important information required for the importation of antidote from Thailand. It is important that import permission from the country is obtained prior to delivery of products. The sales contract between the GPO and the country should be finalized prior to purchase.

The purchase information required includes the customer details, shipping details, importation and billing details and the import/customs regulation and requirements.

Access to orphan drug and drug shortages: Policy management in Thailand

Miss Kakanang Tosanguan from the Thai FDA outlined the history of medicine shortages in Thailand and the policy management initiatives carried out to improve access to medicines. In 1992, Thai FDA introduced orphan drug policy for the first time, including appointment of subcommittee. The subcommittee is responsible for development of orphan drug list, selecting the medicines to be included in the list as well as addressing and providing advice on proper solutions.

In 2006, Thai FDA has developed the guidelines regarding the registration of orphan drugs, and which was then revised and in 2013. According to the guideline, some requirements for the assessment of orphan drugs are exempted, particularly if the orphan drugs have been used more than 10 years and its efficacy and safety have been well established. Thai FDA granted the privilege for these drugs in order to create more incentives for manufacturers and importers such as 'fast track' regulatory registration and exemption of drug registration fees including approval and other amendments' fee. In 2019, the Council of Ministers of Thailand agreed to exempt importation tax on certain orphan drugs.

4. Session – Day 2

iCAPS promotional Video

This video was played and summarized the processes that need to be followed to ensure collaboration in procurement of essential antidotes and timely response to emergency cases of poisoning in the South-East Asia Region.

Member States Procurement Cycle and Processes

Bhutan

- Mr Chhimi Tshewang highlighted that health facilities identify their procurement requirements that are consolidated at national level. Local suppliers participate in the tender of medicines. International suppliers specifically in India are contacted to fill in the supply gap.

Maldives

- Mr Fazeen Mohamed from the Maldives Food and Drug Authority indicated that there is limited data available on the epidemiology of poisoning in Maldives. The management of patients in the country starts is started at the all the levels of health facility. However, very serious cases are transferred to the atoll level Hospitals or Tertiary level Hospitals. None of the medicines in the initial eight antidotes supported by the iCAPS initiatives are registered in the country. All the medicines included in the Essential medicines are included in the Approved drug list so that it can be imported. The medicines can be imported under a PA approval.
- As per the medicine import data of MFDA, all these drugs were imported in small quantities in the previous year. The State Trading Organization (STO) responsible for procurement of medicines is a government owned organization which has the biggest pharmacy chain in the country. Forecasting for the coming year is based on the number of reported cases. However, if anytime the order is placed whenever required to prevent stockouts.

Sri Lanka

- Six out of eight antidotes selected for iCAPS have been registered in the country, but registration status expired, and action needed to consolidate registration status through fast-track registration and waiving off the registration fee. National importation permits are acceptable for products that are not yet registered but found to be acceptable by the Thai regulatory assessment. The State Pharmaceutical Company (SPC) is the national and sub-national procurement urgency. Procurement process is done between October and February.
- The current challenges include lack of reliable disease burden, consumption data and the lack of registered suppliers in the country. The opportunities in the country include the well-established logistics management information system, a functional healthcare system and a well-trained health workforce.

Timor-Leste

- The country has an annual incidence of 100 poisoning cases/year and a mortality of 35 cases/year. Seven of the selected antidotes have been previously procured by SAMES (national procurement urgency). A product not authorized for market in the country but registered in Thailand and be imported through SAMES through short-term waiver. However, the registration process should be initiated as a long-term solution.
- The distribution of the antidotes to health facilities is done through the pull system whereby the health facilities send their monthly requisition form to SAMES and delivery is based on the quantity requested. Technical assistance is required on the forecasting of antidotes.
- The challenges have been identified in
 - Forecasting due to availability of data, consumption data available not accurate and the challenge of data quality.
 - Procurement as there is supplier inconsistency with the contract agreement, not many suppliers able to source antidotes.

Regulatory considerations to support access

Dr Adrien Inoubli, Regional Advisor: Medicine product Regulations, emphasized the regulatory consideration in accessing antidotes using the identified pathways. In emergency response there is need for discussion between the NRA, customs, iCAPS national focal persons on the presence or absence of legal provisions preventing or slowing importation. SOPs should be in place, staff trained, and all institutions should be well coordinated.

During annual planned procurement consideration should be in place to ensure market authorization of antidotes procured. Product registration can be expedited through expanded use or compassionate use initiatives. There can be system in place for recognition and reliance of the Thai marker authorization. Pharmacovigilance system should be strengthened and is even more important when using orphan drugs. Planning is key for preparedness, including urgent requests.

Annual procurement cycle and annual quantification of antidotes including stock control

Mr Kritchai Pattanachan on behalf of NHSO showed the importance of central procurement for speciality medicines. This is because of the low accessibility of orphan drugs on the open market that is coupled by the inefficient stock system and delivery system. There is need to annually plan in advance, initiate budget approval early and be able to submit annual requisitions by May to ensure delivery in the forth quarter of the year.

Poor planning could potentially lead to antidote shortages that may result in delayed treatment, suboptimal management of disease, increase in complications and mortality. Collaborative procurement systems have been used globally in HIV, TB and malaria medicine procurement.

Priority of antidote administration

The factors affecting the priority of antidotes include the severity of disease and the prognosis of poisoning as presented by Dr Satariya Trakulsria. Antidotes are prioritised as:

- Critical antidotes- these should be administered within one hour
- Emergency antidotes- these should be administered within six hours
- Urgency antidotes- these should be administered withing 24 hours
- Non-urgency antidote

Prevention and management of poisoning: The rational use of antidotes

Prof Sahaphume Srisuma from Ramathibodi Poison Center presented two poisoning case studies for discussion. The cases outlined what was needed for case management to ensure treatment success. The need for access to antidote and an efficient transfer system is important. Early recognition and diagnosis is important and this comes through a properly trained workforce. An efficient logistics transportation model is important in the delivery of the appropriate antidote at the right time.

Poison prevention is important and there is need for the use of data for prediction and prevention. Public educational campaigns can be structured in response to potential exposure throughout the year.

5. Recommendations for strategic interventions

- There is urgent need for collaborative procurement of antidotes to ensure access in the Region and beyond. Countries outside the Region have begun to also express interest in participating in the initiative.
- The participants will start the discussion in their respective countries to start benefitting from the initiative. Countries in the Region with small markets can immensely benefit from pulling of resources.
- WHO South-East Asia Regional Office will continue to provide technical support to countries that need assistance in accessing antidotes. Individual country support is also available from Thailand in setting up poison management structures in the country
- Planning and submission of annual requisitions for 2023 in interested countries can begin to ensure that requirements are consolidated by May 2022.
- Regulatory support is available from WHO to facilitate expedited market authorization and harmonization of regulatory processes.

6. The Way Forward

Access to antidotes is critically important. However, there are limitations and challenges due to the nature of antidotes, market failures, high cost of production and low volume requirements. Member States are faced with difficulties in sourcing quality assured products at affordable cost. The different roles by the stakeholders are summarized as follows:

Member States

- Provide data on chemical exposure cases (if data is available)
- Provide data on past consumption of antidotes
- Discuss with country senior management on placing orders via collaborative procurement
- If 2022 procurement cycle is missed, to consider placing orders for 2023

WHO

- Consolidate data from the Member States to estimate the potential volume requirement
- Coordinate communication between the Member States and the Thai Working Group
- Organize a physical workshop in late 2022
- Awareness raising and support poison centres and strengthen surveillance

Thai Working Group

- Support countries to procure antidotes
- Supply the needed information and documents for registration and importation of antidotes
- Support capacity building training and co-organize the next meeting

7. Concluding Remarks by Mr Manoj Jhalani: Director, Health Systems and Development, WHO

The death related to chemical exposure can be prevented, and antidotes can reverse and negate the effects of poisoning. To address access challenges in the Region, the WHO South-East Asia Region created the initiative for coordinated antidote procurement. However, there has been limited progress in operationalizing the initiative and countries can identify the regulatory and purchasing requirements and processes, the procurement timelines and begin to utilize this mechanism.

The iCAPS initiative will be very useful for countries with small markets whose demand is very low, and the support will be available from Thailand for pooled procurement and capacity building.

Progress can be made in saving lives through collaboration by all stakeholders and collective learning within the Region. Utilization of the initiative can start with the available resources and efforts for continuous improvement will be in place.

Annex 1

Agenda

30 March 2022

Welcome remarks - SEARO HSD

Participant introduction (slides prepared in advance) - EDM

Meeting objectives and expected outcomes - SEARO EDM

The challenges in antidote availability and the epidemiology of poisoning - SEARO HPN

Nationwide access to antidotes: The Thailand experience - Ramathibodi Poison Centre (RPC)

Antidote and Antivenom Productions - Queen Saovabha Memorial Institute

The Emergency Response Pathway - RPC

The Joint Planned Annual Procurement and financial aspect - NHSO & GPO

Delivery and Necessary Documents - GPO & Thai FDA

Closing Remarks- SEARO EDM

31 March 2022

Quick summary of Day 1 - SEARO EDM

iCAPS Promotional Video - All

Member States procurement cycle and processes - All

Legal and regulatory processes and requirements - SEARO

Annual procurement cycle and annual quantification of antidotes including stock control - NHSO & RPC

Prevention and management of poisoning: The rational use of antidotes - RPC

Question and way forward for iCAPS scale up - SEARO EDM

Annex 2

List of participants

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Annex 3:

Group Photos



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