



Initiative for coordinated antidotes procurement in the South-East Asia Region



Initiative for coordinated antidotes procurement in the South-East Asia Region



Initiative for coordinated antidotes procurement in the South-East Asia Region

ISBN: 978-92-9022-797-7

© World Health Organization 2022

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: “This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition”.

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization.

Suggested citation. Initiative for coordinated antidotes procurement in the South-East Asia Region. New Delhi: World Health Organization, Regional Office for South-East Asia; 2022. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Printed in India

Contents

Foreword	v
Acknowledgments	vii
Abbreviations and acronyms	viii
1. Introduction.....	1
Background	1
The purpose of this manual.....	1
How regional collaboration can help.....	1
The epidemiology of poisoning	2
2. Scope of iCAPS.....	3
What is iCAPS?	3
How do countries benefit?	3
What are the principles of collaboration?	4
How can iCAPS contribute to capacity building in countries and the Region?	4
Which are the key partners?.....	5
What are the two pathways for coordinated procurement?.....	6
3. Emergency response pathway	7
Overview.....	7
Procedures.....	9
Who does what? Key actions to be taken.	11
Pathway summary	13
4. Planned joint annual procurement pathway.....	14
Overview.....	14
Procedures.....	15
Who does what? Key actions to be taken	16
Pathway summary.....	18

5.	Supply management	19
	Antidote quantification and distribution	19
	Distribution of antidotes.....	20
	Antidote storage and quantification	21

Annexes

1.	Selected antidotes.....	25
2.	Emergency request form	26
3.	Delivery form.....	29
4.	Case evaluation form	30
5.	Annual antidote requisition form.....	31
6.	Frequently asked questions (FAQs)	33
7.	Sample supply contract terms	35

Foreword



Poisoning is a global public health problem and a significant cause of injury-related preventable death. In 2012 an estimated 193 460 people died worldwide from unintentional poisoning by chemical agents at home or at the workplace. 84% of these deaths occurred in low- and middle-income countries. While the rate of poisoning decreased globally from 1990 to 2013, not all countries and areas have witnessed a decline. In many countries and areas, it is likely that poisoning cases are underreported, especially where surveillance systems are weak.

Antidotes are important in the care and management of poisoned patients. When used in a timely and appropriate manner, combined with good supportive care, they may save a patient from death or long-term sequelae, and in doing so reduce the burden on the health system. However, antidote shortages are a problem globally, especially in low- and middle-income countries (LMICs). LMICs must therefore strike a balance between maintaining a sufficient well-distributed supply and minimizing losses through unused and expired medicines.

To better coordinate antidote supply, in 2018 the WHO South-East Asia Region created the Initiative for Coordinated Antidotes Procurement (iCAPS). The iCAPS supports 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. This manual has been developed to provide clear guidance to help medical practitioners coordinate and respond to poisoning emergencies, and also guide procurement agencies and relevant authorities on the regular procurement of essential antidotes.

As the Region improves access to essential antidotes, it is important to note that poison information and treatment centres play an essential role in monitoring the use of antidotes and providing specialized advice on their use. Poison centres can also help stockpile antidotes and coordinate supply and distribution. Establishing more poison centers and strengthening poison services in others will help build capacities in all countries.

The effective implementation of iCAPS will require close collaboration between key stakeholders and participating countries. The need for a systematic approach to procuring and managing the supply and distribution of quality-assured antidotes, and assuring appropriate use, is more important than ever. WHO will continue to support all countries in the Region to reduce poisonings and ensure that appropriate antidotes are accessible to all.



Dr Poonam Khetrpal Singh
Regional Director
WHO South-East Asia Region

Acknowledgments

Information contained in the iCAPS manual is based on the inputs provided by representatives of the Member States of the WHO South East Asia Region, the Thai Working Group, Regional experts, and WHO.

WHO promotes mutual collaboration among Member States. The iCAPS manual has been developed in advancement of the Regional Committee Resolution (SEA/RC70(3) to promote mutual collaboration on procurement to improve access to medicines in the region.

Abbreviations and acronyms

BP	British Pharmacopeia
FDA	Food and Drug Administration
GMP	Good Medicine Practices
GPO	The Government Pharmaceutical Organization
iCAPS	Initiative for Coordinated Antidote Procurement in the South-East Asia Region
INN	International Non-proprietary Names
IP	International Pharmacopeia
NAP	National Antidote Project (Thailand)
NEML	National Essential Medicines List
NHSO	National Health Security Office
NRA	National Regulatory Authority
QSMI	Queen Saovabha Memorial Institute
RPC	Ramathibodi Poison Center
SEA Region	South-East Asia Region
USP	United States Pharmacopeia
WCO	WHO Country Office
WHO	World Health Organization

1

Introduction

- Background
- The purpose of this manual
- How regional collaboration can help
- The epidemiology of poisoning

Background

Antidotes are important in care and management of poisoned patients and may save a patient from death or long-term sequelae. However, antidotes are commonly unavailable, and the consequences may be severe and fatal.

Antidotes have always been included in the WHO Model Essential Medicines List. Member States have also included some selected antidotes in their national essential medicines list (NEML) with the aim of ensuring adequate supply to the public health system. However, even when included by countries, access to certain antidotes, antivenoms or antitoxins during emergencies is generally challenging.

The purpose of this manual

This manual provides clear guidance on the processes to be followed to ensure coordination and timely response to poisoning emergencies to activate the different response pathways.

How regional collaboration can help

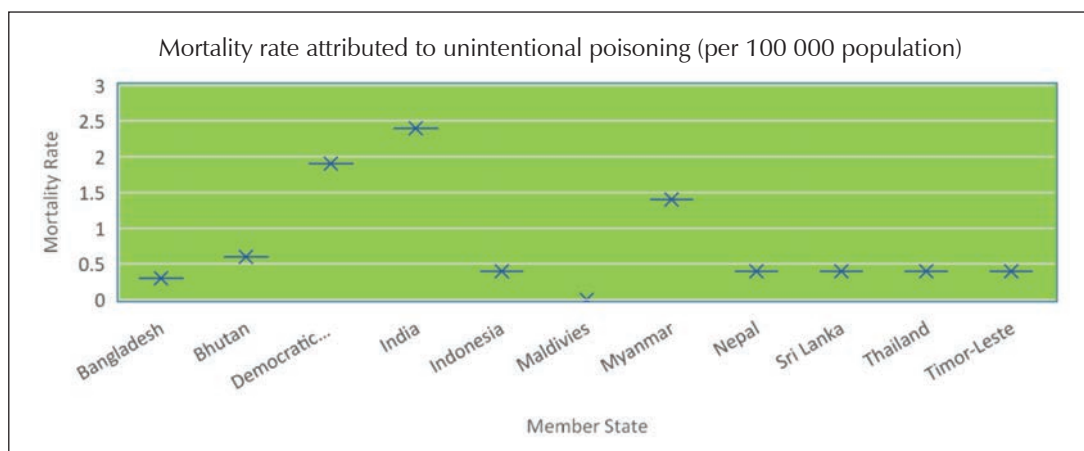
Regional collaboration in procurement of medicines can help in reducing the risk of shortages and stock-outs and improve access to essential antidotes in the South-East Asia (SEA) Region. Concerted efforts to coordinate supply, aggregating demand and coordinating quality assurance systems are required to effectively address these issues. A systematic approach is needed for procuring and managing the supply and distribution of quality-assured antidotes and ensuring their appropriate use. Procurement of antidotes with support from Thailand has been identified as the first target of intercountry collaboration within the SEA Region.

The epidemiology of poisoning

Poisoning is a global public health problem and significant cause of injury-related preventable deaths. In 2012, an estimated 193 460 people died worldwide from unintentional poisoning by chemical agents at home or at the workplace. Eighty-four per cent of these deaths occurred in low- and middle-income countries.¹ While the rate of poisoning decreased between 1990 and 2013 across the world, South Asia was the only region that did not experience the decrease.² The burden may even be underestimated, especially in countries where surveillance systems are weak.

Lead, methanol, organophosphate poisoning and pharmaceutical overdose are important issues to address in the SEA Region. Methanol and ethylene glycol poisoning frequently reported in the Region is commonly associated with illegal substitution of diethylene glycol in medications, adulterated or homemade alcoholic beverages and moonshine liquor where methanol has been used to fortify illicit spirits because it is inexpensive. Lead poisoning remains a major issue in the Region due to its continued use in paint as pigment, in recycling of lead–acid batteries and other environmental and domestic sources. Figure 1 summarizes the preventable deaths due to unintentional poisoning in the SEA Region in 2016.³

Fig. 1: The burden of unintentional poisoning, 2016



- 1 WHO. International Programme on Chemical Safety. Poisoning prevention and management (<http://www.who.int/ipcs/poisons/en/>, accessed 26 July 2019).
- 2 Haagsma JA, Graetz N, Bolliger I, Naghavi M, Higashi H, Mullany EC et al. The global burden of injury: incidence, mortality, disability-adjusted life years and time trends from the Global Burden of Disease study 2013. *Inj Prev*. 2016;22:3–18 (<https://injuryprevention.bmj.com/content/injuryprev/22/1/3.full.pdf>, accessed 26 July 2020).
- 3 WHO. Global Health Observatory Data Repository (South-East Asia Region). Unintentional poisoning: burden of disease. Data by country. WHO; 2017 (<https://apps.who.int/gho/data/node.main-searo.SDGPOISON393?lang=en>, accessed 26 July 2020).

2

Scope of iCAPS

- What is iCAPS?
- How do countries benefit?
- What are the principles of collaboration?
- How can iCAPS contribute to capacity building in countries and the Region?
- Which are the key partners?
- What are the two pathways for coordinated procurement?

What is iCAPS?

The Initiative for Coordinated Antidote Procurement in the South-East Asia Region (iCAPS) seeks to improve access to essential antidotes and help prevent premature deaths due to poisoning. iCAPS does this by supporting public health systems to secure the supply of essential antidotes through multicountry collaboration.

How do countries benefit?

Access to antidotes

Many antidotes are orphan drugs that are difficult to procure. iCAPS helps to secure the supply of these life-saving medicines in the SEA Region through coordinated procurement and the emergency response pathway with support from Thailand's national antidote programme.

Stronger supply chains

Pharmaceutical supply chains need strong links to secure access to medicines. iCAPS seeks to strengthen these links through multicountry collaboration for the public procurement of essential medicines in the SEA Region. Securing the supply of antidotes is at the center of the initiative.

Promote targets of SDG 3: good health and well-being

- **SDG target 3.8.** Achieve universal health coverage (UHC), including financial risk protection, access to quality essential health-care services and access to safe, effective, quality, and affordable essential medicines and vaccines for all.

- **SDG target 3.9.** By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water, and soil pollution and contamination.
 - **Indicator 3.9.3.** Reduce mortality rate attributed to unintentional poisoning, soil, pollution and contamination.

What are the principles of collaboration?

Builds on what exists

Leverages the capacity and experience of the Thai National Antidote Project (NAP).

Starts with small but concrete steps

Selected eight initial antidotes to deliver via two coordinated pathways.

Keeps collaboration voluntary

All Member States of the SEA Region are invited to join and nominate focal points.

Builds trust

Encourages shared learning and transfer of knowledge between Thailand and other countries.

How can iCAPS contribute to capacity building in countries and the Region?

Participating countries can request the resources of iCAPS 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.

Other possible benefits

- Develop and set up a risk-based distribution and stock control system for antidotes, based on the lessons learnt in Thailand.
- Increase awareness about poisoning and its prevention.
- Train health professionals in diagnosis and management of poisonings.
- Develop and support poison information/treatment centres.
- Improve data on the epidemiology of poisoning in the SEA Region.

Which are the key partners?

Beneficiaries

- Populations of Member States of the SEA Region

Key stakeholders

- National focal points designated by the respective ministries of health
- National procurement agencies, poison centres and medicines regulatory agencies

Leadership and coordination (The Thai Working Group)

- Ramathibodi Poison Center (RPC), Faculty of Medicine Ramathibodi Hospital, Mahidol University
- National Health Security Office (NHSO), Ministry of Public Health
- The Government Pharmaceutical Organization (GPO), Ministry of Public Health
- Queen Saovabha Memorial Institute, The Thai Red Cross Society
- Thai Food and Drug Administration, Ministry of Public Health

Technical support

- WHO Regional Office for South-East Asia; WHO Country Office Thailand (WCO Thailand); WHO country offices in participating countries

Table 1. Initial list of eight antidotes available through iCAPS

Name of product	Dosage form	Strength	Pack size	Manufacturer	Ex Works Price per Unit (USD)
Activated charcoal	Powder	50 g	1 bottle	Vidhyasom (Thailand)	2.00
Dimercaprol	Injection (i.m.)	100 mg/2mL	2 ampoules	Samarth Life Sciences PVT (India)	61.50
Methylene blue	Injection (i.v.)	50 mg/5 mL	5 vials	The Thai Red Cross Society (Thailand)	18.70
Penicillamine	Capsule (oral)	250 mg	5X10'S	Samarth Life Sciences PVT (India)	32.50
Calcium disodium edetate	Injection (i.m.)	1 g/ 5 mL	2 ampoules	Samarth Life Sciences PVT (India)	52.00
Sodium nitrite	Injection (i.v.)	30 mg/mL	5X10 mL ampoules	The Thai Red Cross Society (Thailand)	18.70
Sodium thiosulfate	Injection (i.v.)	250 mg/mL	5X18 mL vials	The Thai Red Cross Society (Thailand)	18.70
Succimer	Capsule (oral)	200 mg	1X15'S	Laboratories Serb (France)	194.00

* The Manufacturer and pack size may be changed based on availability. The total cost may be adjusted depending on additional cost (customs duty expense, incoterms etc.), currency exchange rate and related factors*

** There may be additional items other than specified in Table 1 depending on situation which can be discussed and agreed upon by all Parties**

What are the two pathways for coordinated procurement?

The two pathways for coordinated procurement of antidotes through iCAPS by interested countries are the **“Emergency response pathway”** and **“Planned joint annual procurement”**. These are discussed in Chapters 3 and 4, respectively.

3

Emergency response pathway

- Overview
- Procedures
- Who does what? Key actions to be taken.
- Pathway summary

The procedures for the “Emergency response pathway” aim 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.

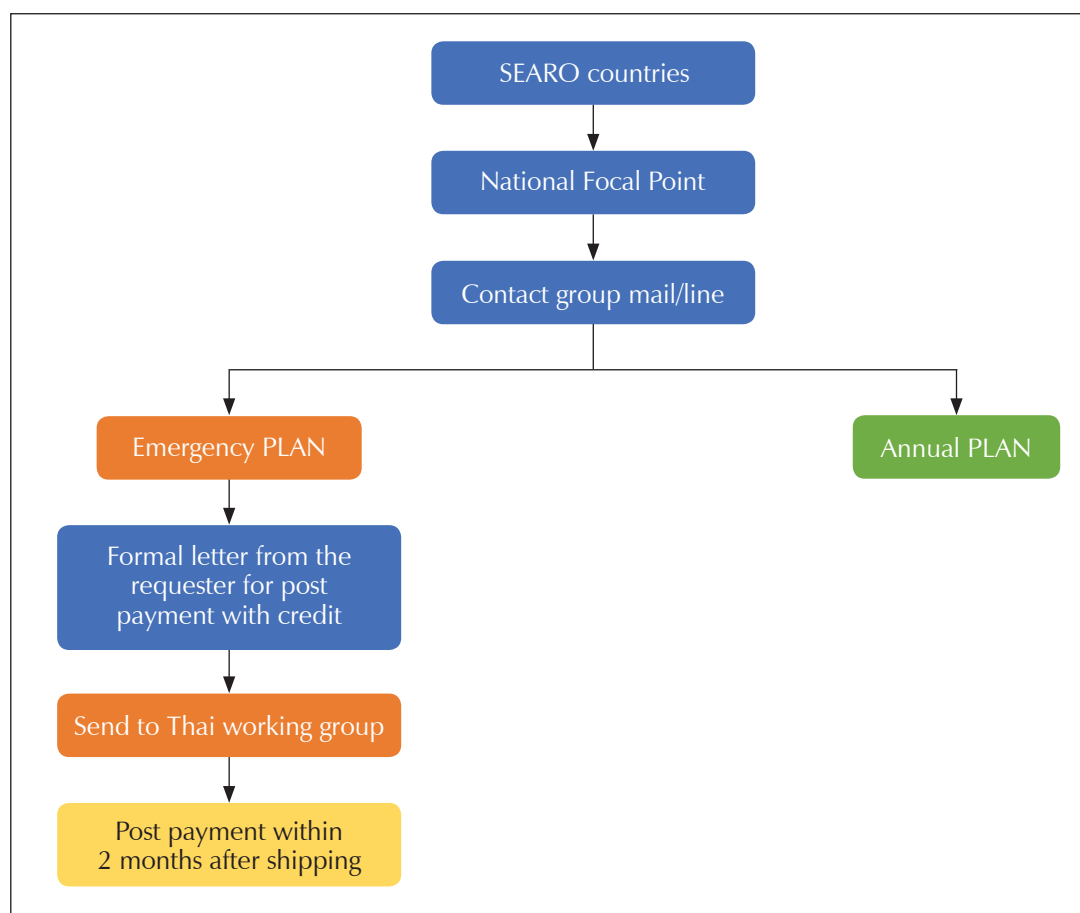
(<https://www.rama.mahidol.ac.th/icaps/pathways/emergencypathway>)

Overview

In the case of emergencies:

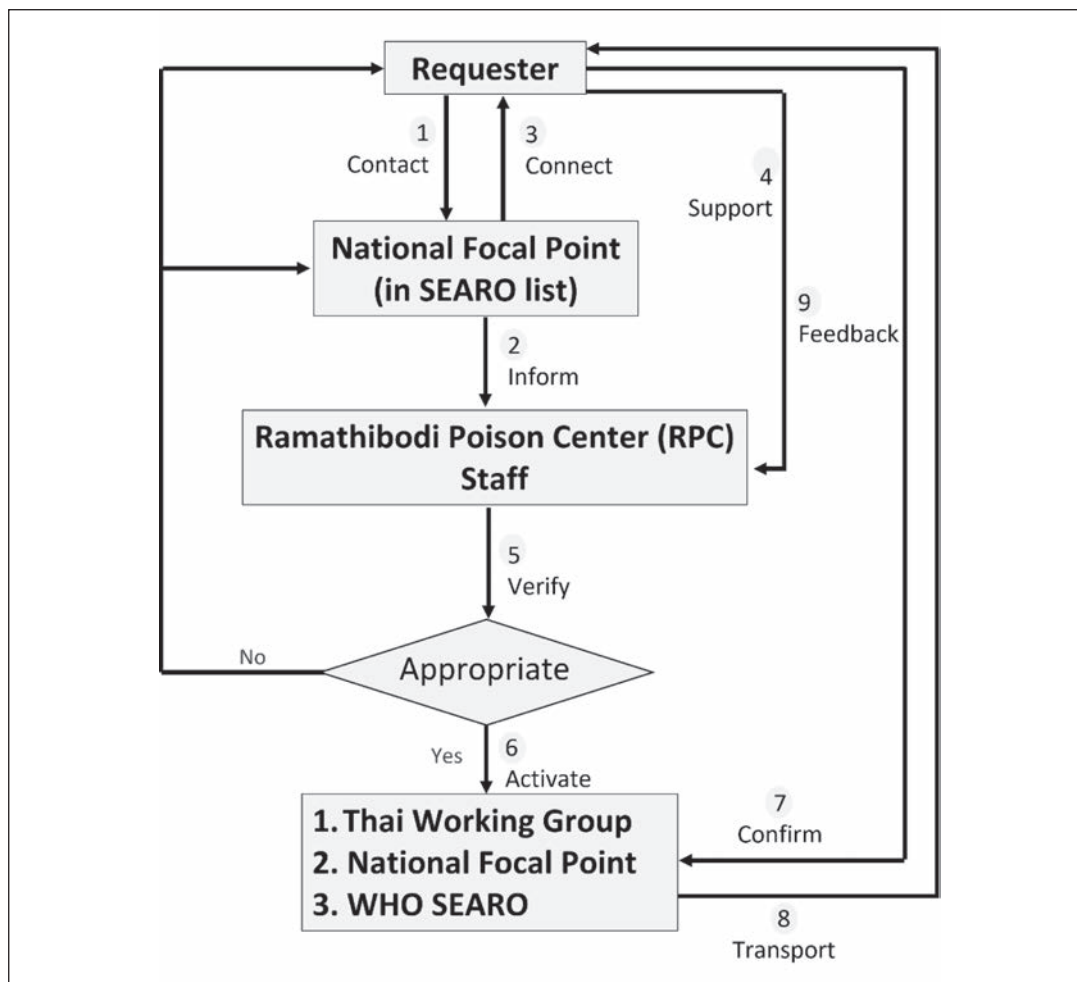
- On behalf of the poisoned patient, the requesting physician, or other responsible health professional, may request the **national focal point** and/or officially recognized **national poison center** to activate the **iCAPS emergency response pathway** to obtain the required antidotes.
- To ensure a rapid delivery of appropriate antidotes from the **Ramathibodi Poison Center (Bangkok, Thailand)** to the point of care, the best option for delivery will be identified on the basis of the level of urgency of the case.
- Further, fast-track importation on a named-patient basis via exemption or no objection letter will be sought with support from WHO, based on the requirements of the importing/receiving country. Shipping is coordinated by the **iCAPS working group**.

Fig. 2a: Overview of the emergency response pathway



Procedures

Fig. 2b: Steps to activate the emergency response pathway



*** The interval time process from 6th to 8th should be within 48 hours.

(1) Contact

- The requesting physician or authorized country representative [**Requester**]
- contacts the **National Focal Point**.

(2) Inform

- The **National Focal Point** informs the Ramathibodi Poison Center [**RPC Staff**] and the **RPC Staff** confirms contact based on a list of authorized country representatives.

(3) Connect

- The **National Focal Point** shares the contact information (name and phone number/email) of the **RPC Staff** and the **Emergency Request Form** (Annex 2) to the **Requester**.

(4) Support

- The **Requester** provides clinical information and antidote requested to the **RPC Staff**.

(5) Verify

- The **RPC Staff** verifies the diagnosis, clinical information and requested antidote. If an antidote is indicated, the emergency response pathway is activated. If the antidote is not appropriate, feedback is given to the **Requester**.

(6) Activate

- The **RPC Staff** informs the poisoned case and requested antidote to the **iCAPS Working Group**. The **iCAPS Working Group** is made up of the **Thai Working Group** and **WHO SEARO**. Then the **Thai Working Group** finds out antidote price and transportation method.

(7) Confirm

- The **RPC Staff** informs price and sends **Delivery Form** (Annex 3) to the **Requester**. After receiving written confirmation, the **RPC Staff** notifies The **iCAPS Working Group**.

(8) Transport

- The **Thai Working Group** transports the antidote to the **Requester**.

(9) Feedback

- The **Requester** fills in and sends the **Evaluation Form** (Annex 4) to the **RPC Staff** to track the outcome of confirmed poisoning cases.

iCAPS Working Group contacts:

- E-mail: contacttoicaps@gmail.com
- Website: <https://www.rama.mahidol.ac.th/icaps/>

Who does what? Key actions to be taken.

The table below describes who does what in the “Emergency response pathway” for coordinated procurement of antidotes. This table may be printed and used as a checklist for case management.

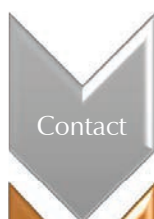
Emergency response pathway – who does what?			
	Key players	Function	Key actions
Receiving country	Requester (Requesting physician/ authorized country representative)	Case management of poisoned patient	<ul style="list-style-type: none"> • Confirms antidote unavailable at point-of-care, or within reasonable distance in-country • Contacts the national focal point and requests to activate the “Emergency response pathway” • Completes the emergency request form (Annex 2) and sends it to the focal point and RPC staff • If needed, requests additional clinical support (video call) from the Ramathibodi Poison Center • Confirms antidote price, complete the delivery form (Annex 3) and return the form to the RPC staff. • Completes the case evaluation form (Annex 4) after completion of treatment.
	National focal point	Authorized country representative	<ul style="list-style-type: none"> • Shares the contact information (name and phone number/email) of the RPC Staff and the Emergency Request Form (Annex 2) to the Requester. • Activates the emergency response pathway and requests an antidote on behalf of the requesting physician by contacting the RPC staff. • Coordinates the route of delivery to the point-of-care • Coordinates payments from the country to the National Health Security Office (NHSO), The Government Pharmaceutical Organization (GPO) (Thailand)

Emergency response pathway – who does what?			
	Key players	Function	Key actions
Supplying country (Bangkok, Thailand)	Ramathibodi Poison Center (RPC)	Receives and coordinates emergency request, provides clinical support	<ul style="list-style-type: none"> • Verifies the emergency request form and confirms the cause of poisoning and what antidote is indicated for the poisoned patient • Checks antidote stockpile at RPC and GPO and other hospitals (http://drug.nhso.go.th/Antidotes) and confirms the availability of the antidote at the nearest location to the patient or what is most feasible for delivery • Decides the best transportation route based on urgency of the case and location of the poisoned patient (see Table of “Antidotes types classified by urgency of treatment”) • Coordinates delivery with GPO • Confirms import requirement • Confirms fast-track importation on a named-patient basis via available social media between two countries (WhatsApp, WeChat, email, Line App; @rpc1367) • Receives the case evaluation form; follows up as needed
	NHSO	Requests payment	<ul style="list-style-type: none"> • Determines if any costs can be waived for humanitarian assistance
	GPO	Coordinates logistics	<ul style="list-style-type: none"> • Confirms the shipping method • Confirms the total estimated cost to the receiving facility (cost of antidote, shipping cost, etc.) • Coordinates shipment of the antidote • Sends the final invoice for payment • Receives payment within 2 months after shipping
World Health Organization	WHO (receiving country office, Thailand and Regional Office for South-East Asia)	Technical and logistical support	<ul style="list-style-type: none"> • Supports coordination of delivery of the antidote and identification of the best delivery option based on the level of urgency of the case • Supports fast-track importation on a named-patient basis via exemption or no objection letter; liaises with WHO country offices • Supports operational activities of iCAPS

Pathway summary



- Fast, flexible, rapid delivery by courier services
- Delivery of antidote to country from Thai working group
- Post-payment to GPO within 2 months after shipping
- Fast-track importation of antidote via exemption or no objection letter or importation on a named-patient basis



Contact

- Contact to the national focal point or RPC staff by authorized country representative; submit of the **Emergency Request Form (Annex 2)**.



Deliver

- Rapid delivery of antidote for individual case via ad hoc, fast track exemption on a named-patient basis; using the **Delivery Form (Annex 3)**.



Track cases

- Feedback of outcome of antidote use to Ramathibodi Poison Centre using the **Case Evaluation Form (Annex 4)**.

4

Planned joint annual procurement pathway

- Overview
- Procedures
- Who does what? Key actions to be taken
- Pathway summary

The procedures for the “Planned joint annual procurement pathway” aim to ensure that national focal points and national poison centres, who are authorized country representatives, can initiate steps for well-planned, annual orders of essential antidotes that are procured by the NHSO, Thailand, based on an annual agreement.

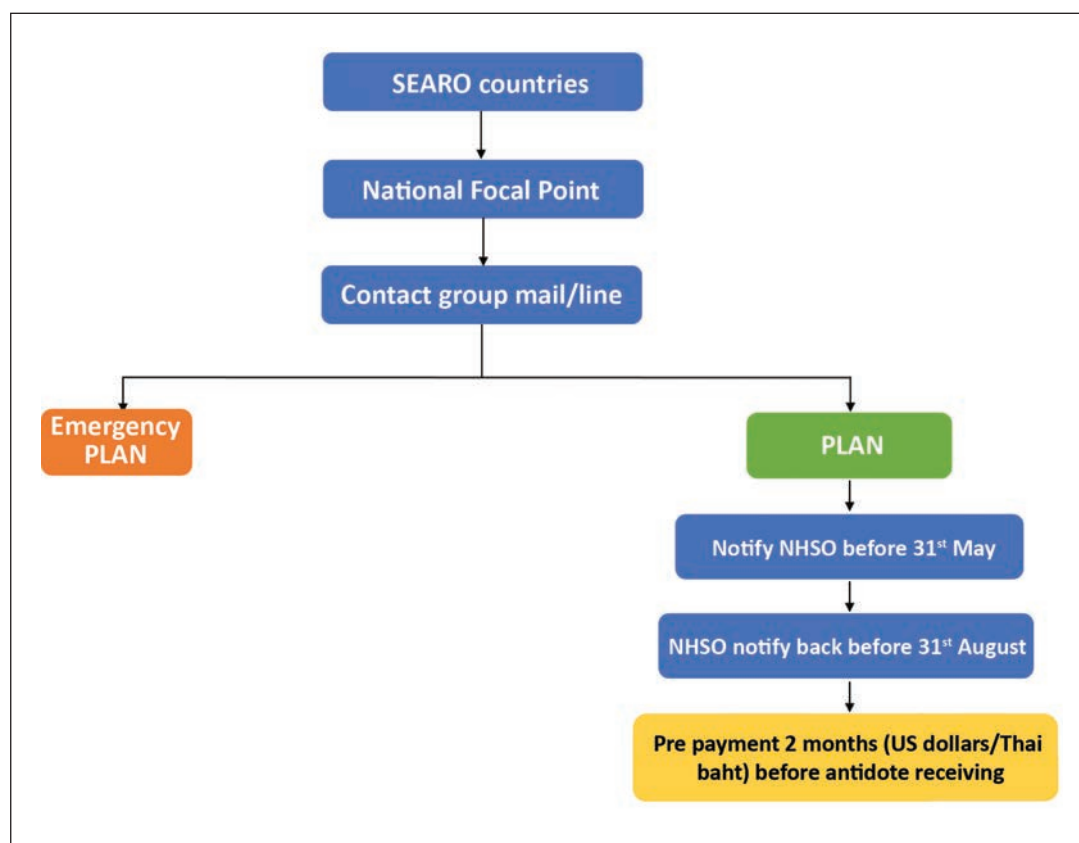
A broad bilateral agreement may also support the operational activities of iCAPS in participating countries.

Overview

In the case of collaborative annual procurement

- Recognizing antidotes as orphan drugs that are often difficult to procure, and thus unavailable to poisoned patients at the point-of-care, support is available to countries of the SEA Region to help secure a regular supply of antidotes through the **iCAPS planned joint annual procurement pathway** with procurement assistance from Thailand’s national antidote programme.
- Specifically, **national focal points** will coordinate with **national/state medicines procurement agencies** and **national poison centres** to estimate the country’s annual need for selected antidotes.
- Following this, 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. If the antidote is not registered, a special importation waiver is requested according to national laws.

Fig. 3: Overview of the planned joint annual procurement process



Procedures

Key steps to executing joint annual procurement	
Date completed:	
Planning	<ul style="list-style-type: none"> Review the “Key questions when drafting bilateral agreements and purchase contracts for planned joint annual procurement via iCAPS” Review the options and plan clearance of product importation with the national regulatory authority (NRA) <ul style="list-style-type: none"> Seek approval/exemption for importation of the product based on Thai Food and Drug Administration (FDA) documents (i.e. manufacturer license and product certificate for legally marketing and monitoring by Thai FDA) OR complete the market authorization process by NRA in each country

Key steps to executing joint annual procurement	
Forecasting	<ul style="list-style-type: none"> Thailand/WHO Regional Office for South-East Asia to share with countries the “Annual antidote requisition form” of initial eight selected essential antidotes with product list and prices. The request should be sent via national focal point(s) and national poison centres. The country responds with the “Annual antidote requisition form (Annex 4)” of selected essential antidotes. Compiled country requests received by NHSO/GPO.
Agreement	<ul style="list-style-type: none"> Portfolio of documents shared by NHSO/GPO to countries expressing interest and submitting the “Estimation of annual need.” <ul style="list-style-type: none"> Broad bilateral agreement to support operational activities of iCAPS. “NHSO/GPO quotation” (including estimating shipping costs and estimated shipping date) based on country estimation shared given. Selected product registration and approval documents by Thai FDA to be shared with country to support registration in country. “Sample supply contract terms” shared by NHSO/GPO with countries [see sample] to facilitate next steps. Final “Supply contract” and “Purchase order” from buyer/participating country for the provision of essential antidotes to country by NHSO/GPO.
Delivery	<ul style="list-style-type: none"> A “Confirmed delivery order” and “shipment advice” (with expected arrival date) sent by NHSO/GPO in advance of shipment.

Who does what? Key actions to be taken

The table below describes who does what in the “Planned joint annual procurement pathway” for coordinated antidotes procurement. This table may be printed and used as a checklist.

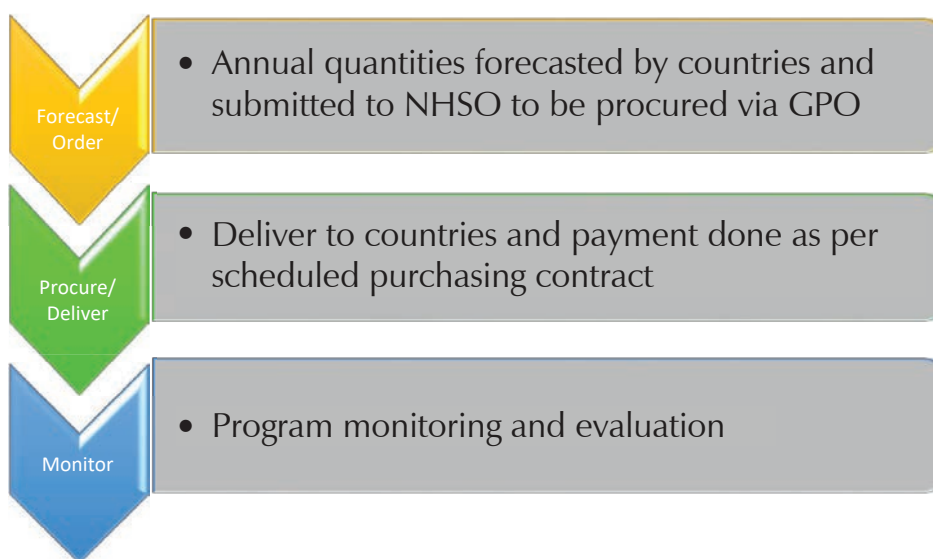
Planned joint procurement pathway – who does what?			
Country	Key players	Function	Key actions
Requesting country	National focal point and/or national poison center focal point	Authorized country representatives	<ul style="list-style-type: none"> Follows “Key steps to executing joint annual procurement via annual contract to supply essential antidotes through iCAPS” Confirms who will pay for order and shipping costs (pre-payment within 2 months before shipping)

Planned joint procurement pathway – who does what?			
Country	Key players	Function	Key actions
Supplying Country- Bangkok Thailand	Ramathibodi Poison Center (RPC)	Resource for help to estimate annual need	<ul style="list-style-type: none"> • If requested, can support in estimating annual need for antidotes and knowledge
	National Health Security Office (NHSO)	Coordinates logistics	<ul style="list-style-type: none"> • Coordinates shipment
	The Government Pharmaceutical Organization (GPO)	Coordinates logistics	<ul style="list-style-type: none"> • Confirms import requirements • Confirms fast-track importation • Confirms shipping method • Confirms total estimated cost to receiving facility (cost of antidote shipping cost, etc) • Sends final invoice for payment • Coordinates shipment • Receives payment within 2 months before shipping
World Health Organization	WHO (Receiving Country Office, Thailand and Regional Office) <i>Emergency contact</i>	Technical and logistical support	<ul style="list-style-type: none"> • Supports National Focal Point as required to coordinate with Thailand • Supports operational activities of iCAPS

Pathway summary



- Well-planned, annually forecasted quantities to be procured by NHSO/GPO Thailand, based on annual contract agreement and payment to GPO within 2 months before delivery
- Promote registration of products by the National Regulatory Authority, possibly via joint dossier assessment



Purchaser Required Documents

1. Customer details;
 - Certificate of Incorporation issued by authorized government sector
 - Passport copy of authorized person of company
 - Company address, email and contact number
2. Shipping destination details;
 - Shipping address (for door to door courier) or Port of Discharge / Airport of Destination
 - Recipient and contact details
3. Bill to contact details;
 - Bill to address and contact detail (If different from above details)
4. *Please prepare Import permit based on the requirements of the importing country*

Note

Please prepare Import permit based on the requirements of the importing country

5

Supply management

- Antidote quantification and distribution
- Distribution of antidotes
- Antidote storage and quantification

Antidote quantification and distribution

Antidotes can be divided into four categories:

- (1) Critical antidotes, which must be administered in less than 1 hour; these should be available in every emergency facility.
- (2) Emergency antidotes, to be administered within 1–6 hours; these should be stockpiled in the regional and/or district distribution hubs.
- (3) Urgent antidotes, to be administered within 6–24 hours.
- (4) Other antidotes (succimer); can be stockpiled nationally or in most prevalent regions depending on demand. Ramathibodi can also be able to supply on an emergency basis.⁴

Priority of antidotes

Category	List of antidote
1. Critical antidote (0–1 h)	Cyanide antidote
2. Emergency antidote (1–6 h)	Methylene blue Antivenom for neurotoxin Antivenom for hematotoxin in case severe systemic bleeding BAL: acute arsenic poisoning Lead encephalopathy CaNa ₂ EDTA: lead encephalopathy Diphenhydramine

⁴ Suchonwanich N, Wananukul W. Improving access to antidotes and antivenoms, Thailand. Bull World Health Organ. 2018;96:853–7 (<https://www.who.int/bulletin/volumes/96/12/18-217075/en/>, accessed 26 July 2020).

Category	List of antidote
3. Urgency antidote (6–24 h)	Botulinum antitoxin CaNa ₂ EDTA Dimercaprol (BAL) Antivenom haematotoxin Diphtheria antitoxin
4. Non-urgency antidote	Succimer

Source: *The Thai Society of Clinical Toxicology*

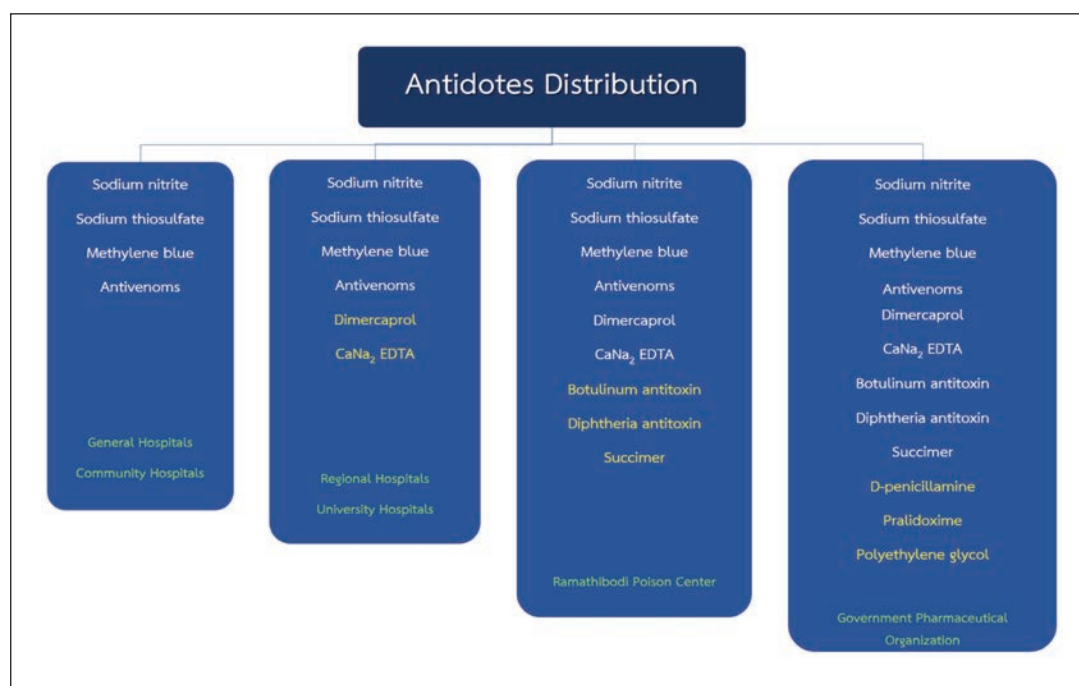
Distribution of antidotes

Efficient distribution can be supported by the establishment of national and subnational hubs of stock. In deciding where antidotes should be stocked, several factors should be taken into consideration, notably the following:

- The size of the country and the area to be covered by a hub. Each facility should be at least within 6-hour reach of the nearest distribution hub.
- The incidence of poisonings that require special therapeutic measures and/or antidotes.
- The social and economic activities of the region that may be associated with a high risk of poisoning.
- Communications (road, air services, etc.) between the depot and the hospitals or health centres.
- The cost of antidotes and of the wastage caused by expiry of effectiveness compared with the cost of transport in case of emergency.

The ideal location for a regional distribution hub is a poison center or central hospital pharmacy. This will be responsible for real-time monitoring of each antidote across the facilities, redistribution and stockpiling.

National antidote distribution system in Thailand



Source: *The Thai Society of Clinical Toxicology*

Antidote storage and quantification

Emergency facilities should be able to stock antidotes that are to be administered within the first hour of poisoning. The recommended minimum stock at some primary (community) or the secondary facilities should be based on an amount that can complete treatment for at least two adult patients.

The recommended stock level to be kept in the regional distribution hub can be estimated according to the epidemiologic data of the areas. Higher stock levels may be adjusted based on the epidemiology of poisoning presentation in the facility and the costs of the drugs. A national 10% buffer stock can be kept in the national poison center or distribution center.

Thailand minimum stock levels

Level of hospital	Minimum stock level (no. of patients)
Community (primary) (for some areas)	2
General (secondary)	5–10
Regional (tertiary)/Medical school	>10
Medical school/super tertiary	>10 + specific antidote for some area

Example of stock levels at different levels of facilities based on the Thai National Antidote Program

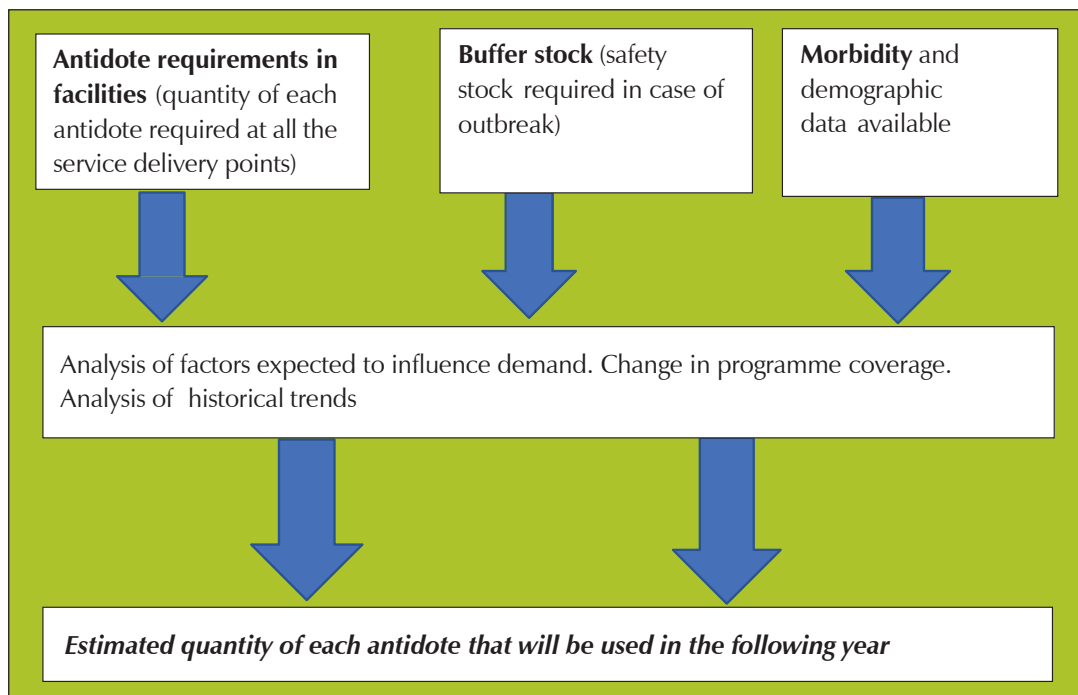
Antidote	Pack size (per pack)	Level of care	Packs/Number of patients		
			Secondary facilities	Regional hubs	National centre
Activated charcoal (50 g/pack)	1	Primary and secondary	5/5	10/10	50/50
Sodium nitrite (30 mg/ml) 10 mg/ampoule	5	Secondary + primary	1/2	2-4/5-10	4-8/10-20
Sodium thiosulfate (250mg/ml) 18ml/vial	5	Secondary + primary	3/2	6-12/5-10	12-24/10-20
Methylene blue (10 mg/ml) 5ml/vial	5	Secondary + primary	2/2	5-10/5-10	10-20/10-20
Dimercaprol (50 mg/ml) 2 ml/ampoule	2	Regional		5-10/2	25-50/10 patients
CaNa2 EDTA (200 mg/ml) 5 ml/ampoule	2	Regional		3-8/2 patients	14-40/10 patients
D penicillamine (250 mg/capsule)	50	Regional		4/2 patients	40/20 patients
Succimer (200 mg/capsule)	15	Regional			30-75/5 patients

Antidote annual quantification involves estimating supply needs. A robust and accurate forecast will ensure that sufficient quantities of antidotes are procured taking into consideration the assumptions for poison management service and programme scale up. Proper quantification will help avoid stock-outs and wastages due to excess stock.

Key steps towards forecasting

- (1) Quantity of each antidote required in each emergency facility.
- (2) Quantity of each antidote required in each regional distribution hub including the buffer stock.
- (3) Quantity of each antidote required in the national poison center. A national 10% buffer stock can be kept as reserve at the national poison center.
- (4) Consolidation of the annual national requirements (See attached annual antidote requisition form)
- (5) Reconcile national requirements with available budget.

National forecasting procedure



These are the detailed roles and responsibilities of the stakeholders involved in the initiative.

I. Key beneficiaries of iCAPS

Beneficiaries

Poisoned patients in need of essential antidotes unavailable at the point-of-care

- **Populations of Member States of the WHO South-East Asia Region Poisoned patients** under the care of a **treating physician**, or health professional, who needs antidotes for treatment that are unavailable at the point-of-care, or within a reasonable distance within the country for various reasons.

II. Key players of iCAPS team – roles and responsibilities

Receiving country – key champions

Request antidotes on behalf of requesting physician; coordinate delivery and payments

National focal point(s) designated by the Ministry of Health	National poison centres http://www.who.int/gho/phe/chemical_safety/poisons_centres/en/
<i>Requests essential antidotes in emergencies and coordinates joint annual procurement</i>	<i>Requests essential antidotes in emergencies and requests procurement support, if needed</i>

Receiving country – key partners

Work with national focal points to support coordinated antidotes procurement

National and state procurement agencies	Medicines regulatory agencies	Various Ministries, e.g. Health, Trade, External Affairs
Facilitate annual procurement planning	Ensures product registration in country	Supports intercountry collaboration

Supplying country – key partners from Thailand's National Antidote Programme

Coordinate and deliver antidotes (and clinical support when requested)

Ramathibodi Poison Center (RPC), Ramathibodi Hospital, Mahidol University, *WHO Collaborating Centre*	National Health Security Office (NHSO), Ministry of Public Health, Thailand	The Government Pharmaceutical Organization (GPO), Ministry of Public Health, Thailand	Queen Saovabha Memorial Institute (QSMI), The Thai Red Cross Society	Thai Food and Drug Administration, Ministry of Public Health, Thailand
Receives and coordinates emergency request via call center 24 h/day; provides clinical support	Coordinated logistics	Coordinates logistics Requests and receives payment	Manufacturer and coordinator	Coordinates and facilitates logistics

III. Technical and logistical support – support coordination and delivery of antidotes as needed

WHO country office of beneficiary/receiving country	WHO country office of supplying country, Thailand (WCO Thailand)	WHO Regional Office of South-East Asia
Technical and logistical support	Technical and logistical support	Technical and logistical support

Annex 1

Selected antidotes

Table 1: List of eight selected essential antidotes*
Included in the WHO Essential Medicines List (2019)

*For emergency cases, additional antidotes may be available through iCAPS (with support from Thailand), such as diphtheria antitoxin and botulism antitoxin. Please enquire.	<ul style="list-style-type: none"> (1) Activated charcoal (2) Dimercaprol (BAL) (3) Methylene blue (4) Penicillamine (5) Sodium calcium edetate (EDTA) (6) Sodium nitrite (7) Sodium thiosulfate (8) Succimer (DMSA)
--	--

Table 2: How are the eight selected antidotes used to treat acute poisoning?

Non-specific poisoning	Activated charcoal (most effective within one hour of ingestion)
Heavy metal poisoning	Dimercaprol (antimony, arsenic, bismuth, gold, mercury, possibly thallium) Penicillamine (heavy metals, particularly lead and copper) Sodium calcium edetate (EDTA) (with dimercaprol in lead poisoning)
Cyanide poisoning	Sodium nitrite followed by sodium thiosulfate
Lead poisoning	Succimer (treatment of children with blood lead concentrations between 45 mcg/dL and 69 mcg/dL) [#] Dimercaprol [#] and EDTA (treatment of children with blood lead concentrations 69 mcg/dL or signs of encephalopathy) [#] Penicillamine [#]
Methaemoglobinaemia*	Methylene blue (methylthioninium chloride) *blood haemoglobin unable to release oxygen to body

Source: WHO Model Formulary (2008). [#]Review of succimer for treatment of lead poisoning (2010).

Annex 2

Emergency request form

- This form is to be used to activate the emergency response pathway for the Initiative for Coordinated Antidotes Procurement for South-East Asia (iCAPS).
- It is to be used for ad-hoc use for the emergency delivery of an antidote on a named-patient basis.
- It is to be completed by Requester.
- If you have any questions, please contact Ms Uhjin Kim, Regional Adviser Essential Medicines, WHO Regional Office for South-East Asia, kimu@who.int.

Instruction: To be completed by responsible physician or authorized person and sent to Ramathibodi Poison Center via designated national focal point and/or authorized channel(s).

<ol style="list-style-type: none">1. Call your national focal point or authorized channel: <input type="checkbox"/> Yes <input type="checkbox"/> No Date and time of call: _____2. Call Ramathibodi Poison Center staff: <input type="checkbox"/> Yes <input type="checkbox"/> No Date and time of call: _____
Requester <ol style="list-style-type: none">1. Name of person completing form:2. Position:3. Organization:4. Organization address:5. Telephone:6. Mobile phone:7. Email:
Physician contact information <ol style="list-style-type: none">1. Name of person completing form:2. Position:3. Organization:4. Organization address:5. Telephone:6. Mobile phone:7. Email:

Patient information

Age:

Sex:

Nationality:

Exposure site:

Address of residence:

Exposure information

Name of exposure:

Exposure amount:

Route of exposure:

Type of exposure:

Date and time of exposure:

History:**Initial Diagnosis:**

1. Date of Evaluation and Diagnosis:
2. Treatment before request:

Antidotes information

Number of antidotes needed:

1. Medicine 1:

- a. Name
- b. Quantity

2. Medicine 2:

- a. Name
- b. Quantity

3. Medicine 3:

- a. Name
- b. Quantity

4. Date required (by when): _____

Annex 3

Delivery form

1. Customer details	
Documents required:	<ol style="list-style-type: none">1. Certificate of Incorporation issued by authorized government sector2. Passport copy of authorized person of company
Company information Address: _____ _____ _____ Contact number/position: _____ E-mail: _____	
2. Shipping destination details <input type="checkbox"/> Door to door courier <input type="checkbox"/> Port of Discharge / Airport of Destination Shipping address: _____ _____ _____ Contact number/position: _____ E-mail: _____ Recipient details: Name: _____ Contact number: _____	
3. Bill to contact details <input type="checkbox"/> The same as customer details <input type="checkbox"/> The same as shipping destination details <input type="checkbox"/> Different from above details Bill to address: _____ _____ _____ Contact number: _____ E-mail: _____	

Note: Please prepare Import permit based on the requirements of the importing count

Annex 4

Case evaluation form

This form is to be completed *by the Requester* and sent to the Ramathibodi Poison Center to track the outcome of confirmed poisoning cases for which iCAPS is applicable.

Case evaluation

1. Patient information

Age _____

Sex : ☐ Male ☐ Female

Nationality: _____

Final diagnosis: _____

2. Case evaluation

Number of antidotes using: _____

Name of antidote: _____

Date and time Receiving Facility confirmed receiving antidote: _____

Date and time poisoned patient received antidote: _____

3. Medical outcome

Medical outcome of patient:

- Survived without sequelae
- Survived with sequelae
- Death from poisoning
- Death from complication

Annex 5

Annual antidote requisition form

Initiative for Coordinated Antidote Procurement in South-East Asia (iCAPS) Annual Estimate

Information needed:

the aim of this form is to estimate approximate order size for any of the eight antidote products listed below to be procured by your facility/agency for the following year through this initiative. We will use this preliminary information to guide the set-up of a planned, joint annual procurement of these selected antidotes via support from Thailand's National Antidote Programme

- (1) Complete Part A with your contact information and details of your facility
- (2) Complete Part B (yellow cells only) by indicating approximated quantity of each antidotes needed for 2021. Feel free to share any comments on your experiences.
- (3) Send the completed form to fusiret@who.int; tisockik@who.int; salilc@who.int

Please note, providing this preliminary information is not a commitment to purchasing the estimated amount, and is not a guarantee of supply. Please do not hesitate to contact us with questions.

Thank you for your efforts! We will contact you to discuss and confirm the next steps after we have shared this approximated forecast of your needs with Thailand's National Antidote Programme.

A. Contact Information

1. Contact details of the person completing the form

2. Name and contact details of the facility

B. Product list

			Information provided by Thailand			To be completed by country focal point		
Antidote name	Strength	Dosage form	Pack size	Ex Works Price per Pack (USD)	Manufacturer	Previous year's consumption	Estimated annual need	Any comments
Charcoal, activated	50 g	Powder	1 bottle	2.00	Vidhyasom (Thailand)			
Dimercaprol	100 mg/2mL	Injection (i.m.)	2 ampoules	61.50	Samarth Life Sciences PVT (India)			
Methylene blue	50 mg/5 mL	Injection (i.v.)	5 vials	18.70	The Thai Red Cross Society (Thailand)			
Penicillamine	250 mg	Capsule (oral)	5X10'S	32.50	Samarth Life Sciences PVT (India)			
Calcium disodium edetate	1 g/5 mL	Injection (i.m.)	2 ampoules	52.00	Samarth Life Sciences PVT (India)			
Sodium nitrite	30 mg/mL	Injection (i.v.)	5X10 mL ampoules	18.70	The Thai Red Cross Society (Thailand)			
Sodium thiosulfate	250 mg/mL	Injection (i.v.)	5X18 mL vials	18.70	The Thai Red Cross Society (Thailand)			
Succimer	200 mg	Capsule (oral)	1X15'S	194.00	Laboratories Serb (France)			

*The Manufacturer and pack size may be changed based on availability. The total cost may be adjusted depending on additional cost (customs duty expense, incoterms etc.), currency exchange rate and related factors**

*** There may be additional items other than specified in Table 1 depending on situation which can be discussed and agreed upon by all Parties***

Annex 6

Frequently asked questions (FAQs)

Key Questions and Possible solutions	
Question	Solution
Defining Needs	
1. Is the medicine included in National Essential Medicines Lists (NEMs) of both countries?	<ul style="list-style-type: none"> • If yes, check strengths and dosage form are same for easy pooling. • If no, consider revision of NEML to include new medicines.
2. Is the medicine registered in both countries	<ul style="list-style-type: none"> • If yes, proceed with the planned joint annual procurement. • If no, the available options include <ol style="list-style-type: none"> (a) Complete market authorization by National Regulatory Authority (NRA) in each country (b) Use reliance mechanism for faster registration and accept regulatory decision by a reference NRA (e.g. stringent regulatory authority) (c) If medicine is a WHO prequalified product, use the “WHO Collaborative Procedure for accelerated registration”.
3. Do you know how much you will jointly purchase	<ul style="list-style-type: none"> • If yes, proceed with planned joint annual procurement. • If no, the available options include <ol style="list-style-type: none"> (a) Fixed quantity, scheduled delivery contract where price is fixed for ordered quantity. Accurate forecast is needed by each country (b) Estimated quantity with periodic order with contract price fixed, regardless of actual quantity procured. An indication of approximation of quantity is sufficient. ***Preferred iCAPS option***
Quality Assurance	
4. Are the medicines quality standards and specifications the same	<ul style="list-style-type: none"> • If yes, in single source procurement this may be the case • If no, in multisource there will be need for some alignment of some standards <p>Agree on mutually accepted standards and other specifications requirements and agree on the process to accept outputs of the unit responsible for procurement including:</p> <ul style="list-style-type: none"> • Establishing specifications (pharmacopoeia standards, package size, packaging requirements package insert information etc.) • Assessment of product data information to check compliance with agreed specifications and standards • Inspection of manufacturing site for compliance with GMP. (agree on acceptability of GMP standards and mode of verification)

Key Questions and Possible solutions	
Question	Solution
5. Criteria to select NHSO/GPO as supplier	<ul style="list-style-type: none"> • Agree on mutually acceptable standards and requirements for suppliers/manufacturers • Agree on responsibilities to monitor compliance to agreed standards • Maintain a common list of prequalified products and prequalified suppliers/manufacturers.
6. Who will monitor quality pre- and post- delivery?	<ul style="list-style-type: none"> • Develop common standards and processes for sampling for any pre- and post-shipment quality control testing. • Agree on how to handle rejected products and communicate with suppliers/manufacturers.
Contract Management	
7. Who is responsible for what when managing contracts?	<ul style="list-style-type: none"> • Develop mutually agreed contract terms once supplier selected with clarity on: <ul style="list-style-type: none"> – Lead unit responsible for handling/issuing contracts and managing contracts and any disputes with suppliers • Payment terms a) direct payment to suppliers by each country using bank transfer or letter of credits or paying via bilateral country arrangements b) Currency of payment

Annex 7

Sample supply contract terms

The purpose is to provide sample supply contract terms participating countries (Purchasers) may consider when drafting a supply contract for the planned joint annual procurement of selected essential antidotes from Thailand's National Health Security Office (NHSO) and Government Pharmaceutical Organization (GPO) via The Initiative for Coordinated Antidotes Procurement in the South-East Asia Region (iCAPS).

Supply agreement

This Supply Agreement hereinafter referred to as **"Agreement"** is entered into and made on _____ (**"Commencement date"**) by and between the following parties:

The Government Pharmaceutical Organization, 75/1 Rama 6 Road, Ratchathewi, Bangkok 10400, Thailand, (hereafter referred to as the **"Supplier"** which expressions shall include its successors in interest and permitted assigns) of the **ONE PART**

AND

_____ (**"Country Name"**), (hereafter referred to as the **"Purchaser"** which expressions shall include its successors in interest, Procurement Agency and permitted assigns) of the **OTHER PART**

WHEREAS:

- (a) The Supplier shall provide selected antidotes through the **iCAPS** Initiative
- (b) The Purchaser shall request selected antidotes through both the **Annual Procurement Pathway and Emergency Response Pathway**.
- (c) The Supplier is agreeable to provide selected antidotes to the Purchaser within the ICAPS initiative framework.

NOW, THEREFORE the parties agree the following:

Article (1) Scope

- (a) The Initiative for Coordinated Antidotes Procurement in the South-East Asia Region (iCAPS) aims to improve access to essential antidotes and help to prevent premature deaths due to poisoning. The iCAPS initiative secures the supply of essential antidotes through multi-country procurement collaboration.
- (b) Both Parties acknowledge that this agreement forms the basis of contractual relationship between the parties.

Article (2) Period of contract and renewal

- (a) The period of the contract shall be one calendar year and shall be renewable for every 1 (one) year automatically unless the Parties decide to terminate this contract. The intention not to renew the contract shall be submitted in writing 2 (two) months before the expiration date.
- (b) Parties hereby acknowledge and agree that the terms of any agreement to renewal may be different, including the prices of the selected antidotes.
- (c) The Supplier may not be the sole source of supply for the duration of the contract.

Article (3) Supply of products

- (a) The Supplier shall deliver, and the Purchaser shall accept the products in accordance with the delivery schedule agreed upon.
- (b) The Supplier shall deliver the products either directly, or through its affiliates, to the Purchaser, in number and quality as set out in the specifications and according to the prices and conditions set out in this agreement.
- (c) The Supplier shall ensure that each delivery is done as per agreed delivery schedule.
- (d) The purchaser shall inform their purchase order, indicating the name of products and quantities to the supplier. And thereafter, the supplier shall provide Proforma invoice quoting the quantities and offer price with incoterm as per agreed by both parties to the Purchaser for confirmation.

Article (4) Payment terms

- (a) The contract price is the maximum price of the item packaged and delivered for the duration of this contract and payable in U.S. dollars.
- (b) Incoterms: Quoted prices shall be in CIF (Cost, Insurance and Freight) unless otherwise specified. This means that the Supplier shall be responsible for the payment of all costs of pre-carriage, insurance and delivery of products to the named destination. Additionally, the Supplier quotation shall require that

shipping cost, insurance, freight charges, duties, etc. be listed separately, along with total cost.

- (c) Direct payment to the Supplier by the Purchaser shall be by either bank transfer (T/T) in U.S. dollars to GPO FCD Banking Account or a confirmed irrevocable letter of credit (L/C) at sight. Deferred payment will be acceptable within 60 days of delivery for Emergency Response. In term of Planned joint Annual procurement, deferred payment will be made as pre-payment 60 days before shipment.

Article (5) Quality and inspection

- (a) The Supplier shall ensure that all the products on this contract shall:
 - (i) meet the requirement of manufacturing legislation in the country of origin and be approved for use in that country;
 - (ii) be of BP, IP, USP standard, standard of the country of origin of the manufacturer;
 - (iii) contain a lot or batch number and expiry date on the label of every dispensing unit;
 - (iv) be certified in accordance with the WHO Certification Scheme for Pharmaceuticals Moving in International Commerce (WHO Resolution 28.65B). This certificate should be issued by the health authorities of the country of original manufacture.
- (b) The Purchaser shall examine and inspect all Products to check whether the Products comply with the requirements specified in the specifications upon delivery and shall notify in writing of any deviation from the specifications. The Supplier shall be notified of any visible defects immediately after delivery of the Products and in case of any hidden defects immediately after they become detectable.
- (c) The Supplier shall ensure that supplies conform to the specifications indicated. No alterations, unless confirmed in writing, are acceptable.
- (d) It is further agreed that the following shall not give rise to any claims based on defects:
 - (i) Loss and damage that arises after delivery as a result of incorrect storage, distribution and use by the Purchaser.

Article (6) Performance guarantee

- (a) The Supplier shall ensure that shipment shall be made as specified, unless an alternative delivery date has been agreed upon in writing.

- (b) For each consignment the Supplier shall send a shipment advice, clearly indicating date of shipment, name of the vessel, and estimated time of arrival in [Specified port/location]. A purchase order can be completed in one (1) or more partial shipments as agreed. Each payment for goods requested shall be made upon delivery.
- (c) Should the Supplier fail to deliver the supplies by the specified date or to the specified port, a full refund will be made of all money previously paid to the Supplier to the purchaser originally paid for the goods.

Article (7) Packaging and labelling

- (a) The supply shall be packed in immediate and external export containers, suitable to withstand rough handling in transit and storage under tropical conditions.
- (b) Containers should be sealed in a manner that makes tampering with the pack during transit easily detectable.
- (c) The Supplier shall be liable for all losses, damage, or expense due to insufficient or unsuitable packing.
- (d) Labels shall be in English (except Activated Charcoal Powder). The containers should be labelled with the INN for the active ingredient and should contain the important information such as: quantity of active ingredient, dosage form, number of units per pack, batch number, date of manufacture, expiry date.
- (e) Items requiring cool storage and transport, where applicable should be shipped by air with proper insulating packing, ensuring that the product remains below 8 °C for at least forty-eight (48) hours. A written pre-advice with exact shipment details should be sent at least five days before the actual arrival of the consignment.

Article (8) Expiry date

- (a) The supplier shall inform the Purchaser the details of product's shelf life and expiry date. The purchaser must acknowledge and confirm to accept before shipment will be executed. Expiry date of product should be clearly stated on the containers.

Article (9) Import documentation

- (a) The Supplier shall provide all documents necessary for taking possession of supplies and clearing them.
- (b) The Purchaser shall provide all documents necessary for taking possession of purchases/ imports and clearing item.
- (a)

Article (10) Disputes settlement and applicable law

- (a) Any and all disputes arising out of or in connection with this supply contract, shall so far as possible, be settled amicably between the two Parties.
- (b) In the event that any dispute arises under this supply contract, the Parties shall first try to settle such dispute amicably. Any dispute, difference, controversy which cannot be amicably resolved between the Parties shall be finally submitted to the competent court in Bangkok, Thailand.
- (c) Each Party shall bear its own costs and expenses related to preparation and execution of this supply contract.
- (d) This supply contract shall be governed by and construed in accordance with the laws of the Kingdom of Thailand.

Article (11) Assignment

The agreement shall not be assignable by or any Party without prior written consent of the other party.

Signed on behalf of

The **Supplier** _____

Full name _____

Position _____

Email address _____

AND

The **Purchaser** _____

Full name _____

Position _____

Email address _____

Disclaimer

Information contained in the iCAPS manual is based on the inputs provided by representatives of the Member States of the WHO South East Asia Region, the Thai Working Group, regional experts, and WHO.

WHO promotes mutual collaboration among Member States. The iCAPS manual has been developed in advancement of the Regional Committee Resolution (SEA/RC70(3)) to promote mutual collaboration on procurement to improve access to medicines in the region.

The information contained in the manual does not in any way imply an endorsement, certification, warranty of fitness or recommendation by WHO of any company or product for any purpose and does not imply preference over products of a similar nature that are not mentioned. WHO furthermore does not guarantee that:

the information is complete and/or error free; and/or that

the products listed are of acceptable quality, have obtained regulatory approval in the participating countries, or that their use is otherwise in accordance with the national laws and regulations of any country, including but not limited to patent laws.

Inclusion of products in iCAPS does not furthermore imply any approval by WHO of the products in question (which is the sole prerogative of national authorities). WHO will not accept any liability or responsibility whatsoever for any injury, death, loss, damage, or other prejudice of any kind that may arise as a result of, or in connection with the procurement, distribution and use of any product listed in the iCAPS manual.

Any final arrangement of procurement of essential antidotes will be guided by the mutual agreement between the participating Member States.

Poisoning is a significant global public health problem. This manual provides 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. There are two different response pathways that can be initiated to respond to poisoning. The emergency response pathway provides a fast, flexible and rapid delivery of antidote to the patient in addition to appropriate clinical support. The planned joint annual procurement pathway ensures that a well-planned annual order is procured by countries based on the annual contract.