



PROCEDURE FOR THE PROCUREMENT OF ESSENTIAL ANTI MALARIAL DRUGS, COMMODITIES AND SERVICES FOR ANTI MALARIA CAMPAIGN OF SRI LANKA IN PREVENTION OF RE-INTRODUCTION PHASE OF MALARIA

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Anti Malaria Campaign Ministry of Health



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© Anti-malaria Campaign Headquarters Public Health Complex 555/5, Elvitigala Mawatha Colombo 5

Phone 011-2588408/2368173/2581918 Fax 011-2368360 Hotline- 011-7626626 Email - antimalariacampaignsl@gmail.com

The procedure for the procurement of essential anti-malaria drugs and commodities

Sri Lanka is certified as "malaria-free" country in September 2016, by the World Health Organization following successfully control of malaria transmission and elimination. Currently Sri Lanka is in the phase of prevention of re- introduction of Malaria to Sri Lanka. However, Sri Lanka constantly at risk of getting malaria back due to the large number of people travelling to and from countries having malaria and due to the presence of mosquitoes responsible for the spread of the disease in all parts of the country. Early diagnosis and treatment with radical cure has become the highest priority for prevention of reintroduction.

The Anti-Malaria Campaign (AMC) is continuously in the process of strengthening the mechanisms to assure uninterrupted supply of quality- assured anti-malaria drugs and commodities, equipment and services to achieve the objectives in the PoR Phase of Malaria. AMC finds difficulties at multiple points throughout the process causing drug shortages and procurement inefficiencies in purchasing high quality, cost effective anti-malarial drugs in the past years.

It is with great pleasure and pride I write this letter for the Anti Malaria Campaign (AMC) for developing a proper procurement process to manage the procurement and distribution system, to place efficient procedures, to select the most cost – effective essential drugs, to quantify the needs and to ensure good product quality.

The timing of a proper procurement of essential anti-malaria drugs and commodities for Anti Malaria Campaign, couldn't be better as the Sri Lanka marks 7th consecutive year of its Malaria free status. I trust the AMC Drug Review Committee (DRC) with the guidance of Technical Support Group (TSG) and the funds of The Global Fund for Fight -Aids, Tuberculosis and Malaria (GFATM) prepared a valuable document to streamline the procurement by adapting a proper and uniform process and I hope it would uplift the name of the country in the field of health around the world, in the way forward.



Director General of Health Services Ministry of Health, Nutrition and Indigenous Medicine

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ABBREVIATIONS

AMC	Anti Malaria Campaign
BMESD	Bio-Medical Engineering Services Division
CAPC	Cabinet Approved Procurement Committee
DDG	Deputy Director General
DPC	Department Procurement Committee
DTC	Drug Therapeutic Committee
G6PD test kits	Glucose 6 Phosphate Deficiency test kits
GF	The Global Fund
LLIN	Long Lasting Insecticide treated Nets
JICA	Japan International Cooperation Agency
MSMIS	Medical Supplies Management Information System
МоН	Ministry of Health
MPC	Ministerial Procurement Committee
MSD	Medical Supplies Division
NMRA	National Medicines Regulatory Authority
NPA	National Procurement Authority
NSP	National Strategic Plan
PoR	Prevention of Re-introduction
PPC	Project Procurement Committee
RDT kits	Rapid Diagnostic Test kits
RPC	Regional Procurement Committee
SCAPC	Standard Cabinet Approved Procurement Committee
SOP	Standard Operating Procedure
SPC	State Pharmaceutical Cooperation
SPMC	State Pharmaceutical Manufacturing Cooperation
TSG	Technical Support Group
UN	The United Nations
UNICEF	United Nations International Children's Emergency Fund
UNOPS	United Nations Office for Project Services
WHO	World Health Organization

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1 INTRODUCTION

Sri Lanka has been free from indigenous malaria since 2012 and no death due to malaria has been reported since 2007. In September 2016, Sri Lanka became the second country in the South-East Asia region to achieve malaria-free status. Currently, Sri Lanka is in the phase of prevention of re-introduction/ re-establishment (PoR) of malaria. The main objectives of the Anti-malaria Campaign (AMC) are to prevent re-introduction of malaria in Sri Lanka and to maintain zero mortality. This is achieved by focusing on intensified surveillance and response, outbreak preparedness, prevention, early diagnosis and treatment with radical cure. Accordingly, the National Malaria Strategic Plan (NMSP) 2018-2022 presents a roadmap and defines specific milestones to maintain 'malaria-free' status.

AMC is continuously in the process of strengthening mechanisms to ensure uninterrupted supply of quality-assured anti-malaria medicines and commodities, equipment and services to achieve the objectives in the PoR phase of malaria, through adopting the following key strategies,

- 1. Universal access to early diagnosis and treatment of malaria;
- 2. Surveillance, including both Parasitological and entomology; and response of vector control.
- 3. Information, education, communication and advocacy; and
- 4. Fostering partnerships

as outlined in the AMC publications. i.e. NMSP (2018-2022), Standard Treatment Guideline, Standard Operating Procedure (SOP) for parasitological Surveillance (RDT and Microscopy) and Guidelines on entomology and vector control.

Routine drugs and commodities purchased by AMC can be categorized into 3 main groups (Annexure 1)

A. Anti-malaria drugs

- 1. Chloroquine Phosphate tablets
- 2. Primaquine Phosphate tablets
- 3. Quinine Sulphate tablets
- 4. Quinine Dihydrochloride injection
- 5. Artesunate Injection

- 6. Artemether Combined Therapy tablets
- 7. Mefloquine 250mg tablets
- 8. Doxycycline Hydrochloride 100mg capsules
- 9. Piperaquine Tetraphosphate/ Dihydroartemisinin tablets

B. Parasitological laboratory commodities

C. Entomology and vector control laboratory commodities

AMC Drug & Therapeutic Committee (DTC) works under the guidance of the Technical Support Group (TSG) to finalize this document relating to the procurement of essential anti-malaria drugs, commodities and services. AMC had preliminary discussions with Additional Secretary (Procurement), Additional Secretary (Public Health Services), Director General of Health Services, Deputy Director General (Public Health Services 1), Deputy Director General (Medical Supplies Division), Deputy Director General (Lab Services), Deputy Director General (BMESD), Director (Medical Supplies Division), Senior Assistant Secretary (Procurement) of MoH, GFATM Project Directorate and other related stakeholders.

1.1 Scope

This document introduces the principles applied for procurement of anti-malaria drugs and commodities to improve procurement practices. The "procedure for the procurement of essential anti-malaria drugs and commodities for AMC of Sri Lanka in PoR phase of malaria" will be adopted by AMC in the process of procurements of essential antimalaria drugs and commodities to ensure the smooth uninterrupted supply of such drugs and commodities.

1.2 Justification

Although Sri Lanka has eliminated indigenous malaria since November 2012, approximately 50-60 imported malaria cases (originated from malaria endemic countries) are reported annually. Being a tropical country, Sri Lanka is at a risk of resurgence of malaria. Therefore, the country is ready for unprecedented epidemic of malaria at any time. If not timely treated, malaria may leads to medical emergency. Therefore, Ministry of Health (MoH) shall maintain adequate stocks of drugs, essential commodities and resources at public and private health institutions.

Procurements of pharmaceuticals, commodities and services materialize in different circumstances at AMC. Hence, the procurement procedure presented here is applicable to all procurement settings.

1.3 Challenges and issues

Procurement of anti-malaria drugs and commodities and services are a complex process which involves many stakeholders such as Medical Supplies Division (MSD), National Medicines Regulatory Authority (NMRA), MoH, WHO, procurement agents and pharmaceutical manufacturers. At present AMC is in line with existing government policies, rules and regulations for its procurements. However, AMC may propose exceptional procurement mechanisms after consulting relevant stakeholders depending on situations to ensure the uninterrupted supply of essential anti-malaria drugs and commodities.

AMC finds difficulties at multiple points throughout the process causing drug shortages and procurement inefficiencies in the past. Some of the issues include:-

- 1. Non-response of bidders or suppliers to the request for quotations for the procurement of small quantities of anti malarial drugs due to low-profit margin;
- 2. The quoted unit prices of the drugs when procuring in small quantities were unexpectedly high. (this in some instances cannot be justified);
- Standard to procure World Health Organization (WHO) pre-qualified drugs may not be achieved as no bidders are interested in supplying WHO pre-qualified drugs. This may lead to substandard drugs in the system;
- Difficulties of securing emergency procurement of anti malarial drugs, in case of epidemic / outbreak of malaria and/ or unforeseen rise of demand of chemoprophylaxis;
- Difficulties in procuring some commodities and equipment eg- Long Lasting Insecticide treated Nets (LLIN), Microscopes, Rapid Test Kits (RDT), G6PD RDT kits etc. due to non-availability / unregistered suppliers within the country;
- 6. Difficulties in conducting Internal Quality Assurance processes during reception, storage or distribution due to lack of trained staff on procurement at AMC due to high staff turnover.
- 7. Delays in customs clearance in international procurement processes;
- Delay in payment modalities due to practical constrains beyond the control of AMC (e.g. delay in opening "Letters of Credit").

Therefore, AMC is in the process of developing a proper procurement mechanism to manage rational procurement and distribution system.

Summary of main problems

- Non-availability of registered suppliers leading to unacceptable unit prices for small quantity of drugs;
- Delays or constraints in payment modalities;
- Lack of trained staff on procurement; and
- Difficulties in emergency procurement.
- 1.4 Objectives of documenting the procedure of procurement of Anti Malarial drugs, Commodities and Services
 - The standard operating procedures for procurement of anti malarial medicines, commodities and services will enable AMC to:-
 - 1. Ensure sustainable availability of medicines and other health products required to prevent the re-introduction of malaria in the country by timely diagnosis and treatment of any imported malaria case;
 - 2. Streamline the procurement by adopting an accepted and uniform processes;
 - 3. Develop a mechanism to timely procure goods and services in a smooth manner without interruptions;
 - 4. Procure most cost effective, high quality anti-malaria drugs and commodities in correct (small) quantities from registered or reliable suppliers;

2 PROCUREMENT PROCEDURE OF PHARMACEUTICALS, COMMODITIES AND SERVICES

The recommended government rules and regulations are being followed by AMC in executing following procurements; -

- 1. Pharmaceuticals for treatment and chemoprophylaxis;
- 2. Essential commodities for diagnostics;
- 3. Essential commodities for parasitological and entomology laboratories;
- 4. Equipment for parasitology, entomology and vector control services; and
- 5. Consultancies and professional technical services.

2.1 Annual forecast of pharmaceuticals and commodities

Forecasting the annual estimate of drugs and commodities requires consideration of different factors such as past consumption, maintenance of buffer stocks, projections for postulated moderate level outbreaks and treatment of other medical diseases. In addition logistics including warehouse capacities, conditions of storage and shelf life of drugs and commodities are also considered. The guidance of technical committees including TSG and guidelines on treatment, prophylaxis and surveillance are given due consideration in the above estimation process.

The NMRA updates the National Formulary / Essential Drug List based on WHO and AMC standard treatment guidelines. The minimum stock levels are estimated considering the number of patients at each institutional level. The forecasted deviation of $\pm -5 - 10$ % to the previous year estimated quantity is allowed. Further, maximum stock levels shall not be exceeded beyond the current epidemiology prevailing in the country. The quality unit of MSD has already prepared product specifications to be used in procurement of pharmaceuticals and reagents. An update or revisions of these documents done with the assistance of consultants and specification revision committee is headed by the DGHS when necessary.

The annual estimation of commodities is done by considering the previous year usage + (5 - 10%). But the estimates may differ in emergencies / outbreaks and non- predictable situations.

The procurement of equipment may be carried out by the AMC through Bio Medical Engineering Services Division (BMESD) of MoH where necessary. In addition, the MoH may delegate the procurement process to the district and regional levels in order to maintain diagnostic services, entomological and vector control services.

2.2 **Procurement Authority and Limits**

The cost estimation for relevant procurement of anti- malarial drugs and reagents are mainly done by the SPC taking into consideration of the ordered quantities, inflation of price and previous procurement records etc. The cost estimation for institutional level procurements is done by the AMC.

The estimated total cost of each procurement done by SPC or AMC used to determine the level of procurement authority as per the National Procurement Guideline (NPG), (Table 1) and reference of Procurement Manual-2006 (this will be amended according to the National Procurement Authority Guideline-2019 gazetted on 12.10.2019).

Limits of authority to make approval of proposals shall be decided from time to time communicated by circulars issued by the NPA Procurement Guideline Reference (Supplement 34/2.14.1 revised on 2018).

Authority	GOSL Funded Projects	Foreign Funded Projects	
Standing Cabinet Appointed Procurement Committee (SCAPC)	More than Rs. 250 Mn	More then De 600 Mr	
Cabinet Appointed Procurement Committee (CAPC)	More than KS. 230 Min	More than Rs.600 Mn.	
Ministry Procurement Committee (MPC)	Up to Rs.250 Mn.	Up to Rs.600 Mn.	
Department Procurement Committee (DPC)/ Project Procurement Committee (PPC)	Up to Rs.100 Mn.	Up to Rs.300 Mn.	
Regional Procurement Committee (RPC)	Up to Rs.10 Mn.	Up to Rs.10 Mn.	

Table 1. Procurement Authority and limits according to NPA Guidelines

*Estimated cost below Rs. 50,000.00 can be acquired through Director AMC for routine procurements as per the procurement authority guidelines and National Procurement Guidelines.

2.3 **Procurement procedure of Consultancy / Services**

AMC obtains local / non local technical consultancy / services from WHO through Government procurement process of consultancy/services of MoH. The prior approval shall be obtained by the Director AMC from the Secretary of MoH or DGHS. Time frame may change according to the nature of the service procurement. The Director AMC shall coordinate with WHO to ensure the procurement of consultancy/ Service.

2.4 Process adapted for approval hierarchy of procurement of Anti Malarial Drugs, Commodities and Services

AMC prepares procurement plan for identified procurements according to the decisions made in DTC under the guidance of TSG. Then, depending on the estimated cost based on past experiences the AMC submits the proposals to the appropriate procurement authority through relevant higher officials for the approval of the procurement procedure (Figure 2.1).

Approval hierarchy



Figure 2.1

Based on the requirement, AMC prepares a Master Procurement Plan for 3 years (Annexure 2) and a Detailed Procurement Plan for the current year (Annexure 3) as per the Procurement Reference Guideline 4.2.1.

2.4.1 Routine procurement process through MSD, BMESD and RPC at AMC

During routine procurement process (estimated cost below Rs. 50,000.00), AMC calls bids from national or international bidders preferably WHO prequalified bidders or registered bidders of NMRA. When the estimated cost is above the AMC-RPC authority limits comprehensive procurement process is carried out by MSD with the SPC as per the guideline of the procurement for pharmaceuticals and medical devices by National Procurement Authority of Sri Lanka – 2007.

Average Time Frame for each step of the procurement process at the procurement authority/ procurement entity is in line with the Procurement Guideline Reference: 4.2.3 of Procurement Manual by National Procurement Agency (NPA) 2007.

 Medical Supplies Division (MSD) – MSD is the main department involved in supplying of drugs/ commodities to AMC. The main procurement channel for pharmaceuticals and commodities of MSD is through the State Pharmaceutical Cooperation (SPC).

Pre-processing of procurement of pharmaceuticals and commodities -

- a. Drugs specific only to AMC, AMC collect past consumption data, analyze, forecast and prepare the annual estimate of drugs/ commodities in par with the Guideline and Circulars and send to MSD.
 Responsibility D/AMC
 Time line 2 weeks
- b. Drugs in the National Estimation List of MSD are requested through online system of MSD (MSMIS). MSD prepares the consolidated estimate considering the requirement of AMC and all other relevant institutions and place the electronic order requisition to SPC.

Responsibility – D/MSD Time line – 8 weeks

Step	Process	Time frame	Responsibility
1.	Yearly estimate of drug/commodities by AMC under the guidance of TSG*	2 weeks	AMC
2.	Requirement estimate is uploaded to MSD online system*	1 week	AMC
3.	Consolidation and prepare the order requisition*	8 weeks	MSD
4.	Level of procurement is decided depending on the estimated value of the order requisition forwarded by MSD**	2 weeks	SPC
5.	TEC appointed	1 week	DGHS
6.	Approval of Specifications and Bidding Documents by TEC	2 weeks	TEC
7.	Calling of Bids	6 weeks	SPC
8.	Bid opening	1day	Procurement branch
9.	Prepare the summary of bids	2 weeks	SPC
10.	Technical evaluation	2 weeks	TEC
11.	Taking the procurement decision considering the TEC report by the Procurement Committee	1 weeks	Procurement Committee
12.	Appeal stage for the bidders	3 weeks	Appeal Board
13.	Convey the decision of the Procurement Committee to the most successful bidder and request the letter of acceptance	2 weeks	SPC
14.	Request the performance bond from the successful bidder	2 weeks	Supplier
15.	Awarding/ releasing the purchase order / indent to the successful bidder	1 week	Procurement entity
16.	LC opening	1 week	Supplier
17.	Production started depending the nature of the item***	14 weeks	Supplier
18.	Copies of shipping documents sent to SPC after handing over to the shipper	1 week	Supplier
19.	Obtain original documents from the local shipping agent	1 week	SPC
20.	Documentary Checking for conformity to specifications and indent conditions	2 weeks	SPC
21.	Get the Bank endorsement on the shipping documents	1 week	SPC
22.	Custom clearance and delivery to MSD	1 week	MSD
23.	Items supplied to AMC on request through MSMIS	1 week	MSD
	Total time duration	57 weeks	

Table 2 Detail time frame and responsibility for national estimation process based

 annual procurements through MSD

*Steps 1, 2 and 3 are exempted in case of drugs specific only to AMC with respect to storage and distribution to end user. These items are estimated based on collected past consumption data, analyze requirement, formulate the specifications, supply conditions, decide the delivery schedules, prepare the order request manually and forward to MSD. (Responsibility – D/AMC, Time line – 2 weeks). MSD convert the said request to an electronic order requisition and forward to SPC through MSMIS online. (Responsibility – D/MSD, Time line – 2 weeks).

**Procurement methods: International Competitive Bidding (ICB), National Competitive Bidding (NCB), Limited/restricted International Competitive Bidding (LIB), shopping

*** This period can be varied depending on the nature of the item

 Biomedical Engineering Services Division (BMESD) – AMC procures microscopes and / or other identified equipment through Bio Medical Engineering Services Division under National Procurement Guideline (Table 3).

Table 3 Detail time frame and resp	onsibility in routing pr	rocurements through BMESD
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Step	Process	Time frame	Responsibilit y
1.	Yearly estimate of commodities by AMC under the guidance of TSG	1 week	AMC
2.	Approve the estimate from secretary of Health Services through DDG (PHS) I, DDG (LS), DGHS according to the estimated cost	1 week	AMC
3.	Approved estimate requested from BMESD	1 week	BMESD
4.	Appoint TEC	1 week	DGHS
5.	TEC prepares the biding documents according to the requirement of AMC and get approval from the procurement board	2 weeks	TEC/ BMESD
6.	Call for bidding according to the selected procurement method	6 weeks	BMESD
7.	Evaluate the bidders according to the quality, safety and efficacy criteria approved by the TEC	2 weeks	TEC- BMESD
8.	TEC recommendation is approved by the procurement board (PB) and contract awarding to the most responsible bidder including appeal period as well	4 weeks	PB- BMESD
9.	Inform the selected bidder and purchasing process started (Eg. Letter of Credit)	2 weeks	BMESD
10.	Goods receive to the BMESD depend on the nature of product	6 weeks	BMESD
11.	BMESD confirm the goods are in accordance with specification	2 weeks	BMESD
12.	According to need BMESD issue commodities to AMC and complete the procurement process		BMESD /AMC
	Total time duration**	28 weeks	

*Procurement methods: International Competitive Bidding (ICB), National Competitive Bidding (NCB), Limited/restricted International Competitive Bidding (LIB), Shopping

******Total time duration can be varied according to item.

3. Regional Procurement Committee (RPC) of AMC – Secretary of MoH appoints the RPC for AMC to purchase other commodities such as insecticide or LLIN. The routine procurement method of RPC is National Competitive Bidding (**Table 4**).

Step	Process	Time frame	Responsibility
1.	Yearly estimate of commodities by AMC under the guidance of TSG	1 week	AMC
2.	D/AMC appoints TEC	1 week	AMC
3.	TEC prepares the biding documents according to the requirement of AMC and get approval from the RPC*	2 week	TEC- AMC
4.	Procurement method** decide by PB according to Guidelines for procurement of pharmaceuticals and medical devices 2007 (except urgent and emergency procurements)	1 week	RPB
5.	Call for bidding according to the selected procurement method	6 weeks	AMC
6.	Evaluate the bidders according to the quality, safety and efficacy criteria approved by the TEC	2 weeks	TEC- AMC
7.	TEC recommendation is approved by the RPC and contract awarding to the most responsible bidder including appeal period as well	2 weeks	PB- AMC
8.	Inform the selected bidder and purchasing process started (Eg. Letter of credit)	2 weeks	AMC
9.	Goods receive to the AMC depend on the nature of product	8 weeks	AMC
10.	AMC confirm the goods are in accordance with specification	2 weeks	AMC
11.	According to need AMC issue commodities to regions and complete the procurement process		AMC
	Total time duration***	27 weeks	

Table 4 Detail time frame and responsibility in routing procurements through RMC of AMC

*No need the special approval for each procurement if the RPC is properly appointed.

**Procurement methods: National Competitive Bidding (NCB), Limited/restricted, Competitive Bidding.

*** Total time duration can be varied according to item.

2.4.2 Procurement of Drugs, Commodities and Services in special situations

In special situations anti-malarial drugs, commodities and services are procured through

- 1. WHO
- 2. Diplomatic Services
- 3. Crown Agents
- 4. Urgent procurement methods
- 5. Emergency procurement methods

2.4.2.1 Procurement of drugs and commodities through WHO

AMC procures anti-malarial drugs through WHO, to preserve the minimum stock of drugs for index cases considering the current trend, within the limits of WHO biennium funds. This will enable to obtain WHO prequalified drugs from registered suppliers, in limited quantities, at a reasonable low cost to fill the unexpected gaps in the supply chain through MSD and other supply sources.

Following Anti-malarial drugs and commodities have been procured through WHO by the AMC in the past:-

- 1. Tablet Chloroquine Phosphate
- 2. Tablet Primaquine Phosphate
- 3. Tablet Quinine Sulphate
- 4. Injection Artesunate
- 5. Tablet Mefloquine
- 6. G6PD Rapid Diagnostic Test kits (RDT)

Responsibility: WHO Sri Lanka country office (WHO is the single source of professional consultancy/ service procurement authority to AMC.) (**Table 5**)

Step	Process	Time Frame	Responsibility
1	*Approve WHO Biennium proposals from Secretary of Health and Indigenous Medicine	4weeks	D/ AMC, DDG (Planning)
2	Secretary of Health request items from WHO	2weeks	D/ AMC
3	WHO procure through WHO prequalified suppliers	6-9 months	WHO
4	WHO inform the D/ AMC once the requested items just before sending	1days	WHO
5	D/ AMC inform the MSD to initiate the custom clearance	1days	D/AMC
6	Obtaining the No Objection Letter from NMDRA	3 days	D/ AMC
7	Custom clearance	3 days	MSD

Table 5 Detail time frame and responsibility in procurements through WHO

*The process is beyond the control of AMC.

2.4.2.2 **Procurement of pharmaceuticals through Diplomatic Services**

Identified anti-malaria drugs (second line anti-malaria drugs which are required in small quantities but unable to procure through routine procurement channels) will be procured from regional countries through the facilitation of the Ministry of Foreign Affairs. Following Anti-malarial drugs have been procured through the Diplomatic Services by the AMC (

Table 6).

- 1. Injection Quinine Di-hydrochloride
- 2. Tablet Piperaquine Tetraphosphate/ Dihydroartemisinin

Timeline: 1-3 months

Responsibility: Secretary of MoH and Secretary of Ministry of Foreign Affairs

Step	Process	Time frame	Responsibility
1	D/ AMC informs the Secretary of MoH the requirement with justification and get approval through DDG (PHS 1), DGHS, Additional Secretary (PHS) for procurement through diplomatic Services	1 week	D/ AMC
2	The request is made to the Secretary of Ministry of Foreign Affairs through the Secretary of MoH or DGHS	1 week	D/ AMC
3	Secretary of Ministry of Foreign Affairs send the request to the Ambassador/ High Commissioner of the relevant country	8 weeks	Foreign Ministry
4	The Ambassador/ High Commissioner request from the Ministry of Health of the country to provide the requested items.		
5	The Ambassador inform if any deviation from the required item to D/ AMC through the Foreign Secretary		
6	If AMC agreed, item is supplied and inform the D/ AMC through the Secretary of Ministry of Foreign Affairs		
7	D/ AMC initiate the clearance procedure (obtain no objection letter from NMRA, duty waves etc),	3 days	D/ AMC
8	Items receive to AMC	1 day	D/ AMC

Table 6 Detail time frame and responsibility in procurements through Diplomatic Services

• After receiving the items AMC will distribute to institutions/RMO offices as per need.

• Steps 3-7 can be further reduced through special requests made to the Foreign Secretary by the DGHS

2.4.2.3 Procurement through International Procuring Agents such as Crown Agents

Recently Ministry of Health approved the purchasing of items through Crown Agents. Initially, Quinine Sulphate and Mefloquine tablets have been identified by the MSD to procure via this method.

Step	Process	Time Frame	Responsibility
1	Approval of Secretary of Health/ DGHS to procure the item from Crown Agents	1 day	D/ AMC
2	Specifications, quantity and delivery requirement are communicated to Crown Agents by email	2 days	D/ MSD
3	Obtained the quotations received by them with quality and performance certifications by mail to MSD	1-3 weeks	D/ MSD
4	Quotations are evaluated and selected through tender process	3days	D/MSD
5	Indent place through Treasury with the release of necessary funds from the advanced credit facility provided to the Crown Agents by the Treasury.	1 week	D/MSD
6	Requested item is delivered to MSD	2 weeks	SPC
	Total time period	6-8 weeks	

Table 7 Detail time frame and responsibility in procurements t	through Crown Agents
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2.4.2.4 Urgent Procurement

AMC may request in limited quantities of essential pharmaceuticals and commodities for urgent procurement and supply (until the resumption of normal supply) from MSD to procure through their supply agents such as SPC as an urgent procurement (Reference 4) due to one or more of the following causes:-

- (a) Withdrawal of a product/s due to quality failure;
- (b) Shortage of a product/s due to suppliers default;
- (c) Shortage of a product/s due to an event/circumstance of Force Majeure; and
- (d) On a written request made by a consultant in order to treat a grave/life
 - threatening situation of a patient, on a case by case basis.

Timelines: 1-4 weeks (If the stocks are readily available this time period can be further reduced)

Responsibility: Director AMC, DDG Medical Supplies, DDG Laboratory Services

Step	Process	Time frame	Responsibility
1	D/ AMC obtain the approval from secretary of MoH for urgent procurement with the evidence based justification including quantity (less than 3 months requirement) and estimated value	< 3 days	D/ AMC
2	D/ AMC submit the approval of the Secretary of MoH to DDG Medical Supplies or DDG Laboratory Services	1 day	D/ AMC
3	Send the request on the urgent procurement from SPC	3 days	DDG (Medical Supplies)/ DDG Laboratory Services)
4	 SPC decide the mode of urgent procurement and implement adopting Direct quotation/ Restricted Quotation system Local or International procurement 	1 week	SPC
5	Technical evaluation, Tender negotiations and decision making on the delivery and supply	2 weeks	Relevant TEC & Procurement Committee

2.4.2.5 **Emergency Procurement**

AMC will request for emergency procurement procedures from MSD to procure required quantities of essential pharmaceuticals and medical devices in an emergency situation which has arisen due to either of the following causes:-

- (a) Natural disasters which is declared as an emergency by the Government of Sri Lanka;
- (b) Sudden outbreak of disease as declared by the Government/MoH.

Step	Process	Time frame	Responsibility
1	D/ AMC obtain the approval from secretary of MoH for emergency procurement with the evidence based justification including quantity (less than 3 months requirement) and estimated value	< 3 days	D/ AMC
2	D/ AMC submit the approval of the Secretary of MoH to DDG Medical Supplies or DDG Laboratory Services	1 day	D/ AMC
3	Send the request on the emergency procurement from SPC	3 days	DDG (Medical Supplies)/ DDG Laboratory Services)
4	 SPC decide the mode of emergency procurement and implement adopting Direct quotation/ Restricted Quotation system Local or International procurement 	<1 week	SPC
5	Technical evaluation, Tender negotiations and decision making on the delivery and supply	<1 weeks	Relevant TEC & Procurement Committee

Table 9 Detail time frame and responsibility in emergency procurements

Timeline: - 1-2 weeks (Depending on the availability and urgency of the item, this time period can be further reduced)

Responsibility: Director AMC, DDG Medical Supplies, DDG Laboratory Services

3 MONITORING AND EVALUATION OF PROCUREMENT PROCESS

The original procurement plan and performance are regularly monitored, reviewed and updated based on changing priorities, estimates of time of delivery etc. The objective is for early detection of causes for delays, ensure efficiency of procurement process and improve forecasting and planning of similar operations. A reliable e-based information system (eg DHIS 2) shall be incorporated for real-time rational management of procurement. Either internal or external audit need to be carried out to verify accounting records of the procurement office annually (Operational principals of good pharmaceutical procurement- 1999/WHO).

Timeline: Real time monitoring of the availability of drugs, RDTs and pesticides. Technical staff of AMC reviews the statutes of the ongoing procurement process and recommend proactive measures to avoid unnecessary delays at the monthly review meetings. The Procurement plan is reviewed quarterly.

Responsibility: D/ AMC

3.1 **Receipts of procurement orders and issues**

The Goods Received Note (GRN) is generated through MSMIS by the warehouse staff when receiving procured goods / materials as per the Purchase Order (PO). The quantities received are documented in stock report, stock card, bin card etc and the stocks are physically checked for:-

- Compliance of batch/serial numbered quantities;
- Product dating with the details in suppliers invoice ; and
- Compliance to indented of specifications, quantity, conditions of supply and other information against the supplier's shipping/delivery documents

Any discrepancies are reported back in the SPC delivery documents and in the GRN. In respect to direct receives by AMC any damages, shortages or any other receiving discrepancies should be brought to the notice of MSD/SPC within 24 hours.

Timeline: Within 3 days

Responsibility: Director/ AMC

3.2 **Issues on implementation**

AMC aims to implement a transparent, efficient, reassured and qualitative procurement procedure with the assistance of MSD, MoH, supply agencies and other organizations involved in supply of pharmaceuticals and other commodities. However, the following conditions/issues may be inevitable. (Reference from Operational Principals for Good Pharmaceutical Procurement- 1999, by WHO):-

- 1. Lack of bidders who full fill the criteria's of the National Medicinal Drug Policy, regulations and legislations;
- 2. International/ External agencies may not adhere to national procurement procedures; and
- 3. Pricing policy issues;
- 4. Inadequate trained staff, because of the high staff turn-over.

4 THE WAY FORWARD

The following measures are being implemented by the MoH to increase the efficiency of the procurement process to ensure uninterrupted availability of Anti Malarial Drugs, commodities and Services.

- a. Strengthening the Procurement, Monitoring and Evaluation Unit at AMC (PMEU) A Medical Officer, a Public Health Inspector and supportive staff are attached to the PMEU under the guidance of Consultant Community Physician (CCP) and headed by D/AMC.
- b. A pharmacist post will be created at AMC to streamline the supply chain management of drugs.
- c. Identify a focal point at the stakeholder institutions of the procurement process to improve the coordination.
- d. Strengthening the web based system (DHIS2) for stock position monitoring mechanism at central and regional level.
- e. Monthly review of procurement process by the technical staff headed by the D/AMC to identify procurements delays and issues enabling to take timely action.

- f. AMC has requested from the financial authorities of MoH to maintain uninterrupted cash flow for procurement of essential anti malarial drugs, commodities and services.
- g. Detailed identification of steps, responsibilities and time line in the procurement process will enable AMC and other stakeholders involved to streamline and fast track the procurement procedures. This will improve the efficiency of the procurement process.
- h. Initiation of manufacturing Chloroquine by the State Pharmaceutical Manufacturing Corporation, Sri Lanka D/AMC had already discussed with the Director of JICA-SPMC Expansion Project in this regard to ensure the continues supply of Chloroquine tablets at reasonable price in future.
- i. AMC and TSG have requested from NMRA to reduce/ remove the registration fee of suppliers of anti malarial drugs at a high-level stakeholder meeting. This may encourage bidders for quoting anti malarial drug procurement.
- j. In 2019, procurements such as RDT, DHAPPQ carried out through WHO and Diplomatic Services were found to be efficient. Therefore AMC will keep these channels opened for future procurements.
- k. Ministry of Health approved the procurement through International Procuring Agents such as Crown Agents. Initially, Quinine Sulphate and Mefloquine tablets have been identified by the MSD to procure via this method.
- 1. AMC explores the possibilities of procuring drugs and commodities through supplementary pathways such as UN agencies (UNICEF and UNOPS) and online procurement through WAMBO platform.
- m. AMC propose to review the possibility of exchanging the anti-malarial drugs which have shelf life less than 1 year with regional countries to avoid wastage with assistance of WHO.

REFERENCES

- 1. Operational Principles for Good Pharmaceutical Procurement https://apps.who.int/medicinedocs/en/d/Jwhozip49e/t
- Procurement Manual by Department of Public Finance 2006 <u>http://www.treasury.gov.lk/web/guest/Procurement-Manual#</u>
- Procurement Guideline by Department of Public Finance 2006 <u>http://www.treasury.gov.lk/web/guest/Procurement-Guidelines#</u>
- Guideline for the procurement for the pharmaceuticals and medical devices by National Procurement Authority of Sri Lanka – 2007 <u>http://www.treasury.gov.lk/web/guest/guidelines-for-procurement-of-pharmaceuticals-medicaldevices-2006#</u>
- 5. (Procurement Guideline Reference (Supplement 34/ 2.14.1 revised on 2018)), http://www.nprocom.gov.lk/web/images/pdf/notice/2144-68_E.pdf
- Revised Guidelines for malaria entomological surveillance in PoR phase <u>http://www.malariacampaign.gov.lk/images/Publication%20Repository/SOP/Revised%20Guideli</u> <u>ne%20for%20entomological%20%20surveillance%20in%20PoR_2017.pdf</u>
- Standard treatment Guideline <u>http://amc.health.gov.lk/Circulars/Treatment-guidelines_Malaria.pdf</u>
- Parasitological Surveillance
 <u>http://www.malariacampaign.gov.lk/images/Publication%20Repository/SOP/SOP%20RDT.pdf</u>
 <u>http://www.malariacampaign.gov.lk/images/Publication%20Repository/SOP/SOPMM.pdf</u>
- 9. National Strategic Plan 2019 2022

ANNEXURE

Annexure 1

Pharmaceuticals and commodities- basic list based on "Guidelines on malaria chemotherapy and management of patients with malaria" (General Circular No: 02-112/2014) and National Strategic Plan for Prevention of Re-introduction of Malaria in Sri Lanka 2018-2022

- 1. Injection Artesunate 60mg
- 2. Injection Quinine Di-hydrochloride 600mg/2ml
- 3. Tablet Artemether + Lumefentrine (ACT) (20mg+120mg) / blister packs
- 4. Tablet Chloroquine Phosphate 250mg
- 5. Tablet Dihydroartemisinin-Piperaquine (40 mg DHA + 320 mg PQ)
- 6. Tablet Mefloquine (250mg)
- 7. Tablet Primaquine Phosphate 7.5mg
- 8. Tablet Quinine Sulphate 300mg
- 9. Capsule Doxycycline hydrochloride (100mg)

Parasitological Laboratory Commodities

- 1. Anisol/ Immersion oil
- 2. Beaker 50 ml
- 3. Blood Lancets
- 4. Bottle Dropping Amber grid stopper 100 ml
- 5. Cotton Wool 500 g
- 6. Di-Sodium Hydrogen Phosphate
- 7. EDTA Collecting Tubes neonates
- 8. Ethyl Alcohol
- 9. Examination Gloves Medium
- 10. Examination Gloves Small
- 11. Filter Paper circular.dia 36cm
- 12. Filter Paper for blotting 46x57cm
- 13. G6PD Rapid Diagnostic Test kits (RDT)
- 14. Gauze
- 15. Giemsa Stain

Entomology and Vector control laboratory

- 1. Adult susceptibility Test Kits
- 2. Bio assay cones
- 3. Block heater digital
- 4. Block heater digital
- 5. Boots
- 6. Cattle Baited Trap Net
- 7. CDC mini light traps
- 8. Chamber for tunnel for LLIN
- 9. Chloroform
- 10. Compound Microscopes
- 11. Cornell cabinet
- 12. Cornell drover
- 13. Cotton wool
- 14. Delta logger
- 15. Dippers with extendable handle
- 16. Disposable Gloves
- 17. Dissecting Microscopes
- 18. Dissecting Microscopes
- 19. Dissecting Sets
- 20. Ethanol
- 21. Ether
- 22. Filter Paper
- 23. Folding Beds
- 24. Folding chairs
- 25. Folding Tables
- 26. Formalin
- 27. Hand Lance Magnifier 10* hasting
- 28. Holding boards for fixing nets
- 29. Insect blocks

- 16. Glass Slides
- 17. Glycerol AR
- 18. Lens Cleaning Tissue
- 19. Malaria Rapid Diagnostic Test kits(mRDT)
- 20. Measuring Cylinder 10 ml
- 21. Measuring Cylinder 25 ml
- 22. Methyl Alcohol AR
- 23. Microscope Olympus cx 32
- 24. Plaster
- 25. Potassium Dehydrogenate phosphate
- 26. Silica gel granules for desiccation
- 27. Slide Box poly propylene 50&100
- 28. Sodium Hypochlorite
- 29. Teepol
- 30. Wash Bottle 250ml
- 30. Insect Dissecting kit
- 31. Insecticide impregnated papers
- 32. Larval pupael separator
- 33. Larval susceptibility Test Kits
- 34. Larval Trays
- 35. Larval Vials
- 36. Membrane Feeder
- 37. Microscopic Slides
- 38. Microscopic Slides
- 39. Mosquito Cages (bugdom)
- 40. Paper Cup
- 41. pH meters bench
- 42. Pin vice
- 43. Pin vice
- 44. pins 12mm
- 45. pins 39mm
- 46. Pipettes
- 47. Polyporus strips
- 48. Safety Kit
- 49. Slide box plastic
- 50. Specimen transfer cage
- 51. Stand mouth aspirator
- 52. Water quilt meter Hanna
- 53. Well Net
- 54. Window Trap Frame
- 55. Window Trap Net

Annexure 2

PROCUREMENT GUIDELINE REFERENCE 4.2.1

The Master Procurement Plan - Template Procurement Plan for year 20.... - 20.... Anti-Malaria Campaign, Ministry of Health

Department/ Line Agency/ Ministry	Procurement Category (Goods, Works, & Services etc.)	Estimated cost (Rs. Mn)	Source of Financing/ Name of the Donor	Procurement method (ICB, LIB, LNB, NCB and National Shopping etc.)	Level of Authority	Priority Status U=Urgent P=Priority N=Normal	Current status of procurement preparedness activities	Scheduled Date of commencement	Scheduled date of completion.	Remarks

Prepared by

Approved by the Secretary to the Ministry

.....

Date:

Procedure for the procurement of essential anti-malaria drugs and commodities/ AMC

A	nnexure	3	

PROCUREMENT GUIDELINE REFERENCE 4.2.1

The Detailed Procurement Plan - Template

Procurement Plan for year 20 – 20 Ministry of

Se. No	Ref. No	Description			Proc. Method	1 App: CATB & TEC	2 Prep: Bidding Documents	3 App: Bidding Documents by	4 NOL from FFA	5 Pre: PQ Applications	6 Scruting PQ Applications	7 App: PQ Applications by CATB		8 NOL FFA	9 Advt: PQ Application	10 Issue PQ Application	11 Select pre-Qualified Bidders	12 App: Pre Qualified Bidders by	13 NOL FFA	14 Invite Bids	15 Clarific./ Pre- Bid Confere	16 Respond to Clarifica.	17 Bid Received/Bid Opening	18 Tech. Eva.	19 Fin. Eva.	20 Final Eva.	21 Recmm by CATB	22 NOL from FFA	23 Cab: Approval	24 Con. Award	25 Con. Signed	26 Complete Works/ Goods/ Service	27 Copntract No. Amopunt Nmae of the Contractor	
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AMC WORKING GROUP

- Dr. Prasad Ranaweera Director
- Dr. Jagath Amarasekara Consultant Community Physician
- Dr. Muzrif Munas Consultant Community Physician
- Dr. Gayan Piyasena Senior Registrar / Health Informatics
- Dr. Sumudu Karunarathna Registrar/ Community Medicine
- Dr. Priyanganie De Silva Medical Officer
- Dr. Ranusha Silva Medical Officer
- Dr. Harshini Vitharana Medical Officer
- Dr. Sarangi Jayasena Medical Officer
- Dr. Shyamali Ratnayake Medical Officer
- Ms. Jeewani Harischandra- Entomologist
- Ms. Priyadarshani Somasundaram Entomologist
- Mr. Thilan Fernando Entomologist
- Ms. Kumudu Gunasekara Parasitologist
- Mr. B. Nadeeka Lakmal Public Health Inspector
- Ms. H D L Padmini Public Health Laboratory Technician
- Mr. A Y K Perera Health Entomology Officer
- B. M. Hiran Jeewanka Health Management Assistant

PROCEDURE FOR THE PROCUREMENT OF ESSENTIAL ANTI-MALARIA DRUGS, COMMODITIES AND SERVICES FOR ANTI - MALARIA CAMPAIGN OF SRI LANKA IN PREVENTION OF RE-INTRODUCTION PHASE OF MALARIA

Endorsed by:



