

## PROCUREMENT OF ARTEMETHER-LUMEFANTRINE (COARTEM®) THROUGH WHO

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## Why combination therapy?

Malaria is striking back. The parasite has defused one drug after another, including the safest and least expensive therapies. In recent years, the pace of drug resistance has been accelerating. As a consequence, the disease, which killed around one million people in 1970 now kills more than twice that number each year, tolling one child every 20 seconds. A new approach is needed, one that targets not just the disease but is aimed directly at the parasite's ability to develop drug-resistance. This is the goal of combination therapy.

Evolution drives malaria's drug-resistance. From one mosquito's inoculation, a few parasites can multiply inside the human host until tens of billions of parasites course through the blood. During this population explosion, random genetic mutations naturally occur. Very rarely, but too often for public health, a few of these mutations happen at the same time and in such a unique combination that they create a parasite which is invulnerable to drugs like chloroquine, sulfadoxine-pyrimethamine or mefloquine. If the host takes one of these drugs, this resistant parasite strain survives and reproduces to become the seeds of a new, more dangerous infection.

Combination therapy exploits the probability that the odds of a parasite developing resistance to two drugs at the same time are infinitesimal.

The theory has been validated with other infectious diseases including TB, leprosy and AIDS. For malaria, one of the best-documented experiences with combination therapy took place in the refugee camps along the northwestern border of Thailand. When half of all malaria cases became mefloquine-resistant, health workers switched to a combination of artemisinin plus mefloquine as the first line treatment. By 1999, after five years of use, the approach not only proved to be a highly effective therapy but both mefloquine-resistance and transmission rates plummeted.

Now a new combination therapy is being readied for malaria. Artemether- lumefantrine (Coartem®) is the first fixed-dose antimalarial combination containing an artemisinin derivative. The drug has passed extensive efficacy and safety trials, and it has been approved by more than 70 regulatory agencies. However, because this is a new drug, data concerning its safety and effectiveness in certain populations (for example pregnant women and infants below 10 kg) is incomplete. Therefore, as with all other new pharmaceuticals, its introduction requires post-marketing surveillance to monitor for adverse reactions and to alert health officials if they arise.

WHO experts convened in Geneva on 4-5 April 2001, have reviewed all current antimalarial drug combination therapies and recommended a short list of therapeutic options with potential for deployment (reference). This choice was based on available safety and efficacy data. The following drug combinations available now, have the potential for deployment, if costs were not an issue: 1) artemether-lumefantrine; 2) artesunate (3 days) plus amodiaquine; 3) artesunate (3 days) plus sulfadoxine-pyrimethamine (SP) in areas where SP efficacy remains high; 4) SP plus amodiaquine in areas where efficacy to both SP and amodiaquine remains high. Coartem® is the only fixed-dose combination therapy among them.

The drug is being packaged to discourage resale and encourage full dose compliance, which itself will slow drug resistance. And as the result of an agreement between the pharmaceutical firm Novartis and the World Health Organization, this drug is being made available to WHO at cost for use in the public sector of disease endemic developing countries, making this new approach to treating malaria more accessible to those who are most in need.

# Artemether-lumefantrine: Indications and Contraindications

Artemether-lumefantrine is indicated for the treatment of uncomplicated falciparum malaria, including multi-drug resistant malaria. It is not recommended for prophylaxis and should not be used in pregnant women, since safety in pregnancy has not yet been established.

It can be recommended as a first-line or second-line treatment of uncomplicated falciparum malaria, in the following situations:

As a first-line treatment of falciparum malaria, if:

- Chloroquine, amodiaquine and SP are not or no longer viable options as first-line treatment due to drug resistance (national malaria treatment guidelines are undergoing review or have been revised); and

As second-line treatment of falciparum malaria if:

- There is a significant level of SP resistance and amodiaquine is not or no longer a viable option as second-line treatment (national malaria treatment guidelines are undergoing review or have been revised).

Dosage schedules

WHO recommends that all countries register a 6-dose regimen of artemether-lumefantrine. The following dosage schedule should be followed:

<b>WEIGHT</b> (kg)	<b>NUMBER OF TABLETS</b> (each at time 0, 8h, 24h, 36h, 48h, & 60h)	<b>Artemether/Lumefantrine PER DOSE</b>
<10	not recommended at this time*	
10-14	1	20 mg A + 120 mg L
15-24	2	40 mg A + 240 mg L
25-34	3	60 mg A + 360 mg L
>34	4	80 mg A + 480 mg L

\* This could change as a result of ongoing clinical trials coordinated by WHO.

# The WHO/Novartis Agreement

Given the potential of artemether/lumefantrine as a fixed dose combination therapy, WHO and Novartis have formally agreed to work together to increase the drug's access in developing countries. The following questions and answers provide the details and benefits of this collaboration.

Q: Why is Novartis making the drug available through WHO?

A: Company officials felt it would probably be more efficient to deal with one organization, with technical capabilities to deliver drugs either directly or indirectly to endemic countries.

Q: Why did WHO accept to distribute the drug?

A: WHO technical review of combination therapies available has recommended artemether-lumefantrine among the few artemisinin-based combination therapies with potential for large-scale deployment. WHO believes the arrangement allows for a broad and equitable access for malaria treatment and control of drug-resistance. Also, by linking WHO's role as a technical adviser to member states, with drug procurement and distribution, WHO believes it will be able to contribute to both national drug policy changes and rational drug use.

Q: What are the advantages to Novartis?

A: In addition to making a philanthropic contribution, the company doesn't have to negotiate with independent buyers. Economically, the arrangement provides the company with a forecasting of demand which allows it to plan production schedules more efficiently. The arrangement furthermore aims to reduce the risk of leakage of the drug into other markets with consequent risk of misuse.

Q: Is the drug included in WHO's model list of essential drugs?

A: The drug has been approved for inclusion in the WHO model list in April 2002. The WHO model list of essential drugs is compiled by a group of independent experts who selects essential medicines with regards to their public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness.

Q: Isn't lumefantrine known to be dangerous?

A: No. Safety concerns arose because this drug is related to another drug, halofantrine, which is known to have serious toxic effects on the heart (cardiotoxicity) in certain patients at risk. However, extensive investigations have not shown these effects with artemether-lumefantrine.

- Q: If this is humanitarian act by Novartis, why charge at all?  
A: Novartis is charging primarily for the cost of manufacture. At the special WHO price a treatment course costs US\$2.4 for an adult and US\$0.90 for the youngest age-group.
- Q: Doesn't this price include a profit?  
A: No, the price allows sustained procurement of the drug at no-loss and no-profit for the company. WHO may require independent auditors examine the company's production expenses to verify whether the price indeed only reflects "cost".
- Q: Why does WHO add a fee of 3% to the price of the drug?  
A: The 3% fee, which is assessed on the cost price of the drug, covers procurement and administrative costs. This can be waived under certain specific circumstances, i.e. in case of epidemics/emergency situations.
- Q: Why does the product supplied by WHO looks different from the product sold commercially?  
A: The commercial pack has a three-day supply of 16 or 24 tablets in individual blister (eight tablets per blister). The "Public Sector presentation " (produced in four age-specific formulations) puts the full three-day supply provided on one blister. After the tablets are removed from this single blister, they will begin to degrade within 24 hours. This is done to encourage patients take the entire course of drugs and not save them for a later use.
- Q: How will requests for supplies of the drug be evaluated?  
A: WHO has constituted a group of independent experts to evaluate the requests based on a number of criteria and conditions. They will *inter alia* verify whether applicants guarantee that the drug will actually reach the final user without a build-up in price and that it will be used appropriately.
- Q: Can the application be fast-tracked in an emergency?  
A: Yes, WHO is planning to establish a stock of 500 000 treatment courses that the company has agreed to hold at its warehouse and make available in an emergency.
- Q: Why does a request for supplies require so much forecasting information?  
A: Artemether-lumefantrine has a short shelf life (two years). Reliable estimates of future needs will help the company better schedule its production, and thereby keep cost as low as possible. It also ensures that countries get the drug when they need it and that in-country stocks are adequate to meet needs. The agreement between WHO and the company require that the company be given a 12-month forecast every three months. WHO provides this information to the company but only in an aggregate form; the requirements of any single country are not listed separately.

Q: What about drug leakage into the private market?

A: Packs will carry a date and batch number. If packs are found in the private sector, these identifiers will make it easier to trace them to their source. Should WHO confirm a deviation has occurred, a warning will be issued that the responsible purchaser is in danger of losing access to the WHO price. If the problem continues, new applications may be denied and drug shipments may be stopped until safeguards have been established.

# How to Place an Order for Coartem® through WHO

## *What to bear in mind prior to placing an order:*

### 1. National approvals

The product must either be registered for use in the country by the appropriate regulatory authority or have a legally acceptable exemption allowing its use in specific circumstances pending regulatory review of the product.

The use of the drug should be consistent with changes, or foreseen changes, in pertinent treatment guidelines and/or drug formularies that guide the use of antimalarial drugs in the country.

Nongovernmental and bilateral or multilateral agency purchasers must obtain written approval from the Ministry of Health (MoH) of the disease endemic developing country ascertaining that the MoH is in agreement with the planned purchase and use of the drug.

### 2. WHO procurement procedures (& applicable fees)

WHO shall procure the drug on behalf of disease endemic developing countries, recognized nongovernmental organizations and bilateral and multilateral agencies, working by permission of, or in association with, such countries, using the following “reimbursable” procurement system:

- Before WHO makes commitment on behalf of a requesting authority or organization, funds equal to the total cost as estimated by WHO shall be deposited in US dollars or Swiss francs or other freely convertible currencies, to the credit of WHO either by cheque or bank transfer payable unconditionally to WHO at sight.
- If the amount reimbursed to WHO is in a currency other than US dollar the requesting authority will be liable to reimburse WHO for the amount of any foreign exchange loss due to exchange rate movements occurring between the date of payment by WHO and the date of re-imbursement to WHO.
- A charge of three per cent shall be levied by WHO from the public sector agency involved and shall be applied on the net cost of items of purchase. Under certain specific circumstances, i.e. in case of epidemics/emergency situations, this charge may be waived. Charges to other UN organizations are determined by independent agreements made by WHO with these organizations.

- Partial shipment may be made, and upon completion of the transaction, WHO shall send to the purchaser a statement of account with the supporting documents. The requesting authority may ask for a statement of account at the end of the transaction and require that any uncommitted balances of the advance made, be refunded to it.
- Any discount or other saving shall be passed on to the requesting authority concerned.
- Once the request for supplies has been approved, the requesting authority shall be responsible for ensuring that import permits (if required) are granted.
- The forwarding agent indicated in the purchase order shall dispatch the supplies to the WHO Offices in countries or to other UN agencies as the case may be.
- Further information can be obtained from Mr Paul Acriviadis or Mrs Françoise Mas, WHO Supply (PRS), World Health Organization, Avenue Appia 20, CH-1211 Geneve 27, Switzerland, telephone (41 22) 791 2187 or 791 1254, fax (41 22) 791 4196, email: [masf@who.int](mailto:masf@who.int) and [acriviadisp@who.ch](mailto:acriviadisp@who.ch).

### 3. Package presentations and cost

Coartem® packs especially designed for use in the public sector are available as of the second quarter of 2002.

<b>“Public Sector” Presentations</b>	<b>Price per box in US \$</b>
Box containing 30 full treatment packs for patients of 10-14 kg (6 tablets per treatment) = 180 tablets	27
Box containing 30 full treatment packs for patients of 15-24 kg (12 tablets per treatment) = 360 tablets	42
Box containing 30 full treatment packs for patients of 25-34 kg (18 tablets per treatment) = 540 tablets	57
Box containing 30 full treatment packs for patients of >35 kg (24 tablets per treatment) = 720 tablets	72

#### 4. Minimum order size per destination

The minimum size per order and per destination is limited to 108 boxes of 30 treatment packs, corresponding to 3'240 individual treatment courses. This minimum lot size applies to each of the four "public sector" presentations described above, under paragraph 3. This implies that purchase orders should be made by multiples of 3'240 individual treatment courses for each of the individual weight-specific treatment packs.

On a case-by-case basis, WHO can provide assistance in the purchase of smaller amounts needed for implementation of clinical trials.

#### 5. Shelf life and lead time

The company has placed considerable effort in ensuring that the product has a maximal shelf life. Notwithstanding these efforts, artemether-lumefantrine has a relatively limited shelf life of 24 months which dictates that the supply chain must be as efficient as possible to avoid stock outs, waste or improper use.

The company requires a minimum period of four months from the time it receives an order from WHO to when it ships product. In addition to this time, requesting parties should add a minimum of one month from the initial receipt of the funds by WHO to the placement of the order with the company.

Hence, for routine use, a request for purchase of the drug should be made at least 6 months prior to the time that the product is required at the port of entry within the country. To determine the proper time for purchase, the requesting agencies must also add the time needed for distribution within the country to the territories/areas where the drug is intended to be used.

For emergency use, it is recognized that these lead times are too long. Expedited procedures for review of requests have therefore been put into place. In addition, WHO is trying to raise the funds necessary to establish an emergency stock of the drug intended for situations where rapid availability of product is crucial.

#### 6. Conditions for access to the "public sector" price and continued use of WHO procurement services

All disease endemic developing countries, nongovernmental organizations or other agencies potentially interested in obtaining artemether-lumefantrine through WHO should express this interest to WHO (even prior to the time that an actual purchase is planned) and agree to collaborate in providing regular and frequent forecasts of potential purchases.

In addition, according to the terms of the Agreement between the company and WHO, governments procuring the drug shall :

- Justify the use of the drug based on a report of the relevant malaria situation, control activities, and treatment guidelines;
- As appropriate, revise malaria treatment guidelines to include artemether-lumefantrine and other antimalarial drugs according to WHO-recommended drug regimens;
- Support the introduction of artemether-lumefantrine as first- or second- line antimalarial treatment with appropriate training of health professionals and consumer education;
- Provide assurances that the supplies will not be diverted from their agreed use;
- Take all possible steps to prevent parallel exportation of the product;
- Not unduly increase the price to the end-user due to tariffs, duties and taxes;
- Apply due diligence in onward distribution of supplies to the treatment points and in strengthening weak links in the national drug management and distribution systems; and
- Provide reports on the supply situation prior to new requests of the drug.

### ***What to submit, to whom, and how***

A Request to Purchase form that is to be submitted with each request is available in the subsequent section of this document, on the Web <http://www.rbm.who.int>, or can be obtained from WHO by contacting: Mr R Prohom, WHO, telephone: +41 22 791 2679; e-mail: [prohomr@who.int](mailto:prohomr@who.int)

This form should be filled completely and completion to include all appropriate signatures. Incomplete forms will returned for further information/completion and will necessarily result in undesirable delays. Should assistance or more information be required regarding the form, please contact: Mr R Prohom, WHO, telephone: +41 22 791 2679; e-mail: [prohomr@who.int](mailto:prohomr@who.int).

As official signatures are required, this form should be mailed as a hardcopy to World Health Organization, Roll Back Malaria, attn.: Dr A. Bosman, Av. Appia 20, 1211 Geneva 27, Switzerland. To expedite review for routine procurements and in all emergency situations this form should also be faxed to Roll Back Malaria at the number: (+41 22) 791 4824.

The completed form will be reviewed by the WHO appointed group of experts who will issue a recommendation to WHO within 7 working days for routine use and within 24 hours for emergency use. WHO will make a final decision regarding the request, and following administrative procedures, forward it for action to WHO Procurement Services who will place the order with the company.

Those parties who wish to know the status of their request or orders at any time after submission can contact Mr Rémy Prohom, WHO, telephone +41 22 791 2679;  
e-mail: [prohomr@who.int](mailto:prohomr@who.int).

## ***Disclaimer***

*"The submission of a request for supplies of artemether-lumefantrine does not mean that such a request will automatically be awarded. The award of any such requests is subject to the terms and conditions set further above, and the evaluation thereof by the above mentioned group of WHO appointed experts, as well as WHO's final decision, in its sole discretion, based on the recommendation made by this group. WHO does not accept any responsibility or liability for the award or non-award of any requests for supplies of the drug. It should be noted furthermore that once any such request has been awarded and the funds for the corresponding order have been paid by the requesting authority to WHO, circumstances beyond the Organization's reasonable control may prevent WHO from actually being able to supply and deliver the drug, including at the quantities and on the delivery date requested. In the event of WHO being unable to supply whole or part of the order, WHO will, upon request, reimburse any uncommitted balance of funds to the requesting authority concerned. It should be noted furthermore that WHO does not endorse the use of any particular product over another. In addition, WHO does not provide any warranty or representation in regard of the manufacture, distribution and/or use of Coartem, including but not limited to its quality, safety and/or efficacy; and/or that Coartem has obtained regulatory approval (either as a six dose regimen or a four dose regimen) for use in the treatment of malaria in every country of the world, or that its use is otherwise in accordance with the national laws and regulations of any country (including patent laws). In addition, WHO wishes to alert requesting authorities that the improper storage, handling and transportation of Coartem may affect its quality, efficacy and/or safety, and that the drug should not under any circumstances be used after its shelf life. WHO disclaims any and all liability and responsibility for any injury, death, loss, damage or other prejudice of any kind whatsoever that may arise as a result of, or in connection with the procurement, distribution and use of Coartem, except to the extent directly caused by WHO's gross negligence or wilful misconduct."*

# SUBMISSION FORM FOR COUNTRY APPLYING TO WHO FOR COARTEM®

## 1. Authority Requesting COARTEM®

1 Please provide the name of the authority/organization making the request

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2 Contact details (responsible officer, position, address, telephone, fax and e-mail):

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3 What is the priority for approval (“deployment under emergency/epidemics” or “routine health care delivery”): \_\_\_\_\_

4 Country name: \_\_\_\_\_

5 If this request is not made by the Ministry of Health, describe the organization’s role in country:

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5.1 Do you have approval from the National Health Authority of the country: If so, please enclose.

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5.2 Do you have approval from the UN Health Coordination Authority in case of complex emergencies: If so, please enclose.

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5.3 If no approval by National Health Authority or UN Health Coordination Authority, please provide an explanation why:

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## 2. Drug approval by national health authority

6 Is there regulatory approval for artemether/lumefantrine in this country (dose-regimen approved for registration or expected approval date, specific exemptions for use and other approval requirements for in-country program use, research use, etc)

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7 Are there national malaria treatment guidelines in this country: (Describe or attach):

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7.1 What is the current role of artemether/lumefantrine within these guidelines:

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7.2 What is the expected role of artemether/lumefantrine within these guidelines:

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7.3 What is the current position of artemether/lumefantrine in National Formulary or Essential Drug List:

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7.4 What is the expected position of artemether/lumefantrine in National Formulary or Essential Drug List:

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8 What is the area of intended deployment in country (Describe):

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9 Describe the malaria situation in this area:

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10 Please estimate the percentage of all malaria that this amount of drug will cover in the area of intended deployment: \_\_\_\_\_

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### 3. Requested specifications

11 What is the quantity of Coartem® requested:

11.1 What is the total number of tablets:

11.1.1 Number of packs 1x6 (tablets x doses): \_\_\_\_\_

11.1.2 Number of packs 2x6 (tablets x doses): \_\_\_\_\_

11.1.3 Number of packs 3x6(tablets x doses): \_\_\_\_\_

11.1.4 Number of packs 4x6 (tablets x doses) \_\_\_\_\_

12 Please justify the amounts requested (and attach relevant sheet, if available): \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

13 When is the first delivery requested: \_\_\_\_\_

14 What is the expected purchasing cycle for Coartem® (once per year, several times per year, other): \_\_\_\_\_

\_\_\_\_\_

15 What is the desired delivery time (once per year, several times per year, other): \_\_\_\_\_

\_\_\_\_\_

16 What is the expected source of funding and are there concerns regarding sustainability: \_\_\_\_\_

\_\_\_\_\_

17 Please provide a full consignee address for shipping the product \_\_\_\_\_

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18 To comply with WHO procurement procedures, please provide full bank details concerning the financing for purchase including name of bank, address, account number, funds available and currency in which it is available: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

#### 4. Other Conditions and Understandings of Requesting Authority/Organization

19. The country health authority's approval is required on the following:

19.1 Agreement with WHO procedures for procurement of Coartem® (see: How to Place an Order for Coartem® through WHO):

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19.2 What are the current tax/tariffs applied to Coartem® delivered through WHO

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19.3 Statement that deployment will be only within the public sector of the country concerned and by approved agency(s):

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19.4 Statement that the health authority and pharmaceutical control program understand and will adhere to the limited shelf-life of the product (24 months total) and description of methods to assure no loss due to spoilage:

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19.5 Statement of agreement to train health workers in proper use of drug:

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20 How will Coartem® deployment be monitored (Describe or attach): \_\_\_\_\_

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# INDICATORS FOR MONITORING THE PROVISION OF ARTEMETHER-LUMEFANTRINE (co-artemether)

Monitoring	Level measured	Indicators	Operational Definition	Measurement and reporting frequency
Access	Small set of “pilot” countries/ districts With co-artemether 1 <sup>st</sup> -line	<u>Access- Appropriate Use</u>  1 <sup>st</sup> line therapy: Percent of uncomplicated malaria patients attending a health facility who receive co-artemether within 24 hours of onset of symptoms	(# pts presenting at a given health facility per unit time with uncomplicated malaria and receiving co-artemether as first line drug/ total # of patients presenting at the same given health facility per unit time with uncomplicated malaria and receiving an antimalarial treatment x 100  Number of patients receiving co-artemether within 24 hrs of symptom onset / # pts receiving co-artemether) X100	Survey of health facility records every 12 months  Clinic exit surveys every 12 months
	Small set of “pilot” countries/ districts with co-artemether 2 <sup>nd</sup> -line	<u>Access- Appropriate Use</u>  2 <sup>nd</sup> line therapy: Percent of uncomplicated malaria patients requiring a 2 <sup>nd</sup> line treatment who receive co-artemether	(# pts presenting at a given health facility per unit time with uncomplicated malaria and receiving co-artemether as second line drug treatment x / Total number of patients receiving a 2 <sup>nd</sup> -line antimalarial) x 100 at the same facility per unit time	Survey of health facility records every 12 months

Monitoring	Level measured	Indicators	Operational Definition	Measurement and reporting frequency
Access	Small set of "pilot" countries/districts	<p><u>Access- Supply</u></p> <p>Average number of health facilities without stockout of co-artemether</p> <p>Average duration in days of stock outs of co-artemether in a sample of public sector health facilities during last 3 months of malaria transmission</p>	<p>Number of health facilities reporting no disruption of stock of co-artemether (as specified in the national drug policy) for more than one week during the previous 3 months/number of health facilities surveyed x100</p> <p><math>\sum</math># days of stock out during last 3 months of malaria transmission / <math>\sum</math># facilities surveyed</p> <p>(to be further broken down by health facility levels, e.g. dispensaries, health centers, district hospitals)</p>	<p>Survey with review of stock records every 12 months</p> <p>Survey with review of stock records every 12 months</p>
		Percent of public sector health facilities with co-artemether dated beyond expiration limit	# health facilities with any co-artemether stock beyond expiry date / # facilities surveyed x100	Sample collection every 12 months

Monitoring	Level measured	Indicators	Operational Definition	Measurement and reporting frequency
Collaboration WHO HQ and Novartis	WHO	Number of countries purchasing through WHO within a six month period	# of countries formally requesting to purchase co-artemether from WHO in a six month period	WHO Records Every 6 months
	WHO	Number of agencies purchasing through WHO within a six month period	# of agencies formally requesting to purchase co-artemether from WHO in a six month period	WHO Records Every 6 months
	WHO	Amount of co-artemether procured through WHO within a six month period	Total # tablets procured (purchase orders placed) through WHO within a six month period	WHO Records Every 6 months
	WHO	Amount of co-artemether procured through WHO by country	# of tablets procured (purchase orders placed) through WHO per country per year	WHO Records Every 6 months
	WHO	<u>Routine</u> Average time between availability of financing and placement of order with Novartis	$\sum$ # of days between an financing availability for purchase / $\sum$ # of requests for which financing became available in the 6 months prior to the reporting date	WHO Records Every 6 months
	WHO and Novartis	<u>Routine</u> Time between order placement with Novartis and delivery at port of entry	<u>Routine</u> $\sum$ # of days between PO received and ETA at port of entry/ $\sum$ # of shipments arriving at entry ports within the 6 month period prior to the reporting date.	WHO and Novartis Records Every 6 Months
	WHO and Novartis	<u>Emergency</u> Time of response to meet full request	<u>Emergency</u> # of days between official request and when full amount requested is available at entry port in country for each emergency request made in the previous 6 month period	WHO and Novartis Records Every 6 Months