

LFA Spot Checks of ACT Co-payment Mechanism First-Line Buyers: Terms of Reference

Background and Rationale

The Private Sector Co-payment Mechanism for ACTs (“Co-payment Mechanism”) is a financing model to expand access to ACTs in the private sector. The Country Coordinating Mechanism, informed by the country’s relevant national malaria control strategy, may decide to include the Co-payment Mechanism in a funding request to the Global Fund or to allocate funding to the Co-payment Mechanism in their existing Global Fund-supported malaria programs.

Private importers of drugs (“First-Line Buyers” or “FLBs”) are an entry point for co-paid ACTs into countries. First-Line Buyers sign an agreement with Principal Recipients which specifies their obligations with regards to participating in the Private Sector Co-payment Mechanism for ACTs.

LFA spot checks of First-Line Buyers in the private sector will assist the Global Fund to check whether the obligations and commitments of the First-Line Buyer Agreement are being met.

The Global Fund provides to Principal Recipients a template First-Line Buyer Agreement for local adaptation and finalization. Generally, by signing the agreement, First-Line Buyers commit to provide all necessary documentation and all reasonable assistance to the Principal Recipient and Global Fund in order to permit the verification of the buyer’s compliance with applying reasonable margins (including copies of price lists and details of product costs and selling prices). The spot checks will be carried out against the following key obligations and commitments specified in the ‘template’ agreement:

a) *Reasonable Margin*: The First-Line Buyer will use all its reasonable efforts to ensure that the Private Sector Co-payment Mechanism operational priority and objectives are achieved by applying a reasonable margin on co-paid ACT prices directly or indirectly distributed or sold by the Buyer in the host country, taking into account that the end-user prices of the co-paid ACTs are expected to be competitive with those of other malaria treatments. In any event, such reasonable margin must not exceed the percentage margin on cost price which the buyer applies to other malaria treatment products (purchased for the same price by the buyer), sold and/or distributed by or through the buyer in the host country.

b) *No Diversion*: The First-Line Buyer will use all its reasonable efforts to ensure that the co-paid ACTs procured and held by the buyer are not diverted from their intended purpose or used for a purpose other than furtherance of the objectives and goals of the Private Sector Co-payment Mechanism. The buyer will only sell, distribute and/or otherwise dispose of the co-paid ACTs through nationally recognised distribution entities within the host country. The buyer will not directly or indirectly sell, distribute and/or otherwise dispose of the co-paid ACTs outside the host country.

c) *Monotherapies*: The Global Fund discourages the First-Line Buyers from selling or marketing oral artemisinin-based monotherapies for the treatment of patients in any Private Sector Co-payment Mechanism host country and encourages the First-Line Buyers to use reasonable commercial efforts to discourage such sale or marketing downstream.

d) *Individual and Hospital Packs*: The First-Line Buyer may purchase through the Co-payment Mechanism individual packs¹ of co-paid ACTs for distribution for use outside hospital, health centre and clinical settings. The buyer must not directly or indirectly sell and/or distribute hospital packs² for use beyond hospitals, health centres and clinics and must use all its reasonable efforts to ensure that hospital packs purchased by the buyer are not used outside hospital, health centre and clinical settings.

e) *ACTm logo*: The First-Line Buyer acknowledges that co-paid ACTs will be marked with the ACTm logo. The ACTm logo is expected to be used in a nationwide marketing campaign managed by or in coordination with the relevant health authorities in the host country to promote the distribution, sale and use of the co-paid ACTs. The buyer will not tamper with or remove the ACTm logo, from such primary and secondary packaging. The buyer must not use the ACTm logo in promotional materials unless it has signed a sub-license agreement with the organization managing the nationwide campaign. The buyer is solely responsible for negotiating, concluding and complying with all contractual and other arrangements with the relevant authorities relating to the buyer's conduct and participation in the nationwide marketing campaign.

f) *Storage*: According to the First-Line Buyer Agreement standard template, First-Line Buyers are required to ensure adequate storage for preserving the integrity of products (in terms of temperature, humidity, cleanliness).

Objectives

- To check a First-Line Buyer's compliance with the commitments and obligations of its specific First-Line Buyer Agreement.
- To make a recommendation to the Global Fund as to whether the First-Line Buyer is in compliance with its obligations under its specific First-Line Buyer Agreement, as part of the process for considering whether the First-Line Buyer continues to be eligible to be a Private Sector Co-payment Mechanism First-Line Buyer.

Methodology

General

Upon request from the Global Fund, the LFA proposes to the Global Fund the selection of private First-Line Buyer(s), including NGOs, on which to perform spot checks using market intelligence and other available information³ which should guide the selection, and the

¹ An individual pack means a box or wallet of Co-Paid ACTs containing a single course of treatment intended for a single patient.

² A hospital pack means a box of Co-Paid Products containing multiple courses of treatment (typically 25-30) and intended for use by multiple patients in a hospital, health care or clinical setting.

³ For instance volumes of co-paid ACTs delivered and reports and assessments from health development partners, documented or informal information from national drug authorities, drug manufacturers or other stakeholders along the supply chain.

reasons for selection. The Global Fund reviews the selection and proposes changes as deemed necessary. A number of spot checks and the scope of the LFA work should be agreed between the Global Fund and the LFA prior to the provision of service.

1. The LFA should obtain from the Principal Recipient a copy of the country-specific agreements signed between the Principal Recipient and participating First-Line Buyers in the host country. The LFA should familiarise itself with the obligations of the Agreement.
2. The spot checks can be announced by the LFA to the First-Line Buyer between one to two weeks prior to the inspection visit. If necessary, the Global Fund will send the initial announcement indicating that the LFA will be following-up. A list of the required documents that should be made available by the First-Line Buyer at the time of the spot check should be part of the announcement.
3. These documents should include at a minimum:
 - a. List of customers who have purchased co-paid ACTs within a defined period
 - b. Sales lists including price per type of products / packaging (hospital / individual)
 - c. Stock registers, which include the movement of drugs and balances for co-paid ACTs

A review of the country-specific agreement signed between the Principal Recipient and First-Line Buyers may indicate additional documents which should be requested.

4. The spot checks should be done using a standardized checklist (Private Sector Co-payment Mechanism LFA Spot Check Template, attached).

It is expected that on average one working day of both a Finance Professional and PSM Expert will be required per site. The number of spot checks per country will not be the same but rather depends on the number of First-Line Buyers per country.

Below please find a description of the methodology to be applied for completing the Private Sector Co-payment Mechanism LFA Spot Check Template relating to the minimum standards to be met by First-Line Buyers:

Reasonable margin

- The margin per product line should be established and compared with a reference value. The reference value would be the percentage of the input price of an anti-malaria product other than ACT with a similar input price. The LFA may adapt the definition of a reasonable margin to local market conditions as the LFA sees fit.
- The mark-up should be established as a percentage of the official retail price (if available) or against retail price levels as per their availability through market research. In settings where mark-ups are regulated by law, this paragraph does not apply.

Diversion

- The distribution entities to which co-paid ACTs had been directly sold should be registered by the local authority of a Private Sector Co-payment Mechanism country.
- Where possible, LFA should check whether the First-Line Buyer had indirectly sold co-paid ACTs to non-registered entities within the country or to any entity outside a Private Sector Co-payment Mechanism country. To that effect, information gained during the on-site spot checks should be triangulated with other available sources and in collaboration with the National Drug Board.

Monotherapies

- The First-Line Buyer should provide the list of oral artemisinin monotherapies on stock and sold since the introduction of co-paid ACTs (if any).

Hospital Packs

- The final distribution point (e.g. pharmacist) which purchased hospital packs should be private clinics or hospitals (and retailed pharmacies when selling blister packs is authorised).
- In case the final distribution point cannot be established, the available evidence should be described and the reasons be given for the non-establishment of the final distribution point.

ACTm logo

- The ACTm logo should not be used on buyer promotional material without the agreement of the organisation conducting the marketing campaign.

Storage Conditions

- The storage conditions of co-paid ACTs should be checked against the list of adequate compliance points (appropriate temperature, cleanness, humidity).

Deliverables

As a result of the spot check, the LFA should promptly provide a report outlining activities, results, and an overall assessment of the compliance of the First-Line Buyer within the framework of the First-Line Buyer Agreement signed with the Principal Recipient. The Global Fund should be informed immediately if the LFA becomes aware or suspects that the First-Line Buyer does not meet the minimum standards.

The Private Sector Co-Payment Mechanism LFA Spot Check Template (annexed) should be used for the reporting purpose.

In principle, the outcome of the assessment should be determined by the number of categories where compliance is found or not found. The minimum set of categories as described above is:

1. Registration and legal documents, as defined by the agreement
2. Margins

3. Diversion
4. Monotherapies
5. Hospital Packs
6. Logo use
7. Storage conditions

The report should have one of the following recommendations for the Global Fund's consideration:

1. "Green": the First-Line Buyer complies with all categories and remains an eligible First-Line Buyer
2. "Yellow": the First-Line Buyer complies with more than 5 of the categories and is given a time of not more than six months to ensure full compliance. During this time the First-Line Buyer's eligibility should continue. If, however, the First-Line Buyer lacks compliance in the category "registration", he is considered ineligible.
3. "Red": the First-Line Buyer does not comply with more than 5 categories or does not comply with the "registration", and is no longer eligible to participate in the Co-payment Mechanism. New confirmation of co-payments should not be issued by the Global Fund, and the First-Line Buyer, Principal Recipient and relevant suppliers should be notified by the Global Fund of such non-compliance. The Global Fund reserves the right to cancel on-going orders by this First-Line Buyer and to withdraw confirmation of co-payment.