



Frequently Asked Questions

QUAMED Local Market Assessment (LMA)

What is a Local Market Assessment (LMA)?

A QUAMED local market assessment is a generic term for a combination of pharmaceutical quality assurance related services that are conducted in one country over a limited period.

A LMA can include:

- One or more Good Storage and Distribution Practices (GSDP) technical visits
- One or more GSDP audits
- One or more Model Quality Assurance System (MQAS) audit
- Visits to the national regulatory authority (NRA), the national laboratory, and the WHO office.

Most LMAs that we organise consist of GSDP technical visits. But we also have LMAs that combine GSDP technical visits and GSDP or MQAS audits. For more details on the GSDP technical visits or GSDP and MQAS audits, please see our notes on those services.

How many suppliers can be included in a LMA?

The number of suppliers included in a LMA depends on the type of assessment: technical visit or audit. In general, a LMA does not include more than 14 suppliers and does not last longer than 2 working weeks in-country but variations are possible.

What is in a LMA report?

A LMA report presents the results of the technical visits and audits, where each supplier is rated from Level 1 to Level 4 according to the internal QUAMED GSDP level system. If visits to the NRA or others were included, the report also gives a description of the pharmaceutical environment in the country. In addition to the LMA report, a separate report for each of the included suppliers is produced.

How long does a LMA take?

An LMA consists of three phases (see below): preparation, in-country visit and analysis/reporting. This can take anywhere from 2 months to 6 months and longer. The preparatory phase often takes most time because of identification of the suppliers, budgeting and getting the funds together. Once the in-country visit has started, the whole process is often wrapped up within 2 months.

Who initiates an LMA?

A LMA is usually initiated by one or more member NGOs active in a country.

What are the costs of an LMA?

That depends on the specifics of the LMA: which country, how many activities and how many suppliers and the duration.

Who pays for the LMA?

The participating organisations together finance the budget for the LMA. It is up to the participating organisations to agree on individual contributions. QUAMED can play a facilitating role (ask other organisations to be involved) but is not further involved in the budget.

How is a LMA organised?

In the organisation of an LMA, there are three main phases: A. Preparation, B. In-country visit, C. Analysis and reporting.

These phases include the following steps and responsibilities. Please note that these are the general steps but that in particular cases, the process may be slightly different.

A. Preparation phase

1. One or more organisations (NGOs or others) contact QUAMED
2. If there are more organisations involved, one lead organisation is designated by them to facilitate the communication.
3. The communication lines are:

QUAMED – lead organisation – other participating organisations.

4. The lead organisation proposes a Field Focal Point (FFP). This person will be the main point of contact for the QUAMED team.
5. QUAMED and the lead organisation organise an introductory meeting to introduce the LMA. QUAMED briefs the participants on the content of the LMA and the process and the organisations present their expectations. The meeting is usually virtual.
6. QUAMED shares the preparation and monitoring tool with the lead organisation
7. The organisations agree on a draft list of suppliers that they would like to have included in the LMA
8. The lead organisation communicates the list to QUAMED
9. An invitation letter and a pre-visit questionnaire is sent to the listed suppliers. In principle this is done by the lead organisation..
10. The QUAMED expert will analyse the pre-visit questionnaires and make recommendations:
 - a. Which type of assessment to use for which supplier: a technical visit or an audit
 - b. Which suppliers to remove from the list as they will most likely not achieve a satisfactory result even when a technical visit is organised.

11. Concurrently, QUAMED develops a draft budget in a standard format and draft terms of reference and shares them with the lead organisation.
12. The results of the analysis are communicated to the lead organisation.
13. The lead organisation agrees with the other participating organisations on a final list of suppliers
14. QUAMED finalises the budget and the terms of reference using the final list of suppliers
15. The lead organisation negotiates with the other participating organisations about financial contribution to the budget and communicates the contributions to QUAMED
16. QUAMED prepares Service Agreements for each of the participating organisations with their financial contribution mentioned.
17. QUAMED sends the Service Agreements to each participating organisation for signature
18. The lead organisation proposes a program / itinerary for the QUAMED expert and discusses this with QUAMED.
19. The lead organisation makes the appointments with the suppliers and with the national pharmaceutical regulatory authorities, the national quality control laboratory and the WHO office, if required, and communicates the final calendar to QUAMED.
20. The lead organisation will provide a staff person to accompany the QUAMED expert on the suppliers' visits.

B. In-country visit.

During the in-country visit of the QUAMED expert, the lead organisation will be asked to take on the following responsibilities::

21. Arranging transfers to and from the airport.
22. Assisting in organizing the expert's accommodation for the duration of the mission with access to internet
23. Ensuring that the expert receives a safety briefing prior to the start of activities.
24. Organising an introductory meeting by the QUAMED expert to present the contents of the assessment, if required
25. Recruiting or designating an interpreter, if necessary.
26. Arranging or facilitating the expert's transportation within the country.
27. Organizing the debriefing meeting with all organisations at the end of the mission if required.

C. Analysing and reporting

After the in-country visit of the QUAMED expert:

28. Within 30 days after the visit in-country, QUAMED produces the draft report or the final report. This depends on the type of technical visits or audits were part of the LMA.

29. The lead organisation organises a virtual debriefing session once a draft report has been produced.
30. At this moment, QUAMED sends the final invoices to all participating organisations.
31. QUAMED sends a copy of the final report to each of the participating organisation.
32. The LMA report is uploaded to the QUAMED database within 75 days after the last day of the in-country visit.