



2017, A NEW INDEPENDENT ASSOCIATION

QUAMED is from now on an autonomous not for profit association which objective is to contribute to improving access to quality medicines.

Our will is to arouse consciousness of actors from all the continents involved in access to quality medicines in developing countries and to help them reinforce their Quality Assurance system. We believe that pooling resources is a key factor for success and that using synergies will enable create the necessary conditions to have a direct impact on the market on one hand, and to have the power of advocacy allowing a political impact on the other hand.

We therefore created this adapted structure and we developed and keep developing a series of activities aimed at helping you reinforce your QA and improving your practices in terms of procurement of pharmaceutical products.

These are the factors which will allow us to reach the ultimate goal of QUAMED, namely to improve access to medicines of better quality for the largest number.

Here is a summary of everything you need to know about the structure, the activities, the functioning and the financing.

THE STRUCTURE

QUAMED is a not for profit association as defined by French regulations.

The board consists of renowned professionals with long international experience in quality and access to medicines.

The executive direction is assured by a direction committee also consisting of experienced professionals and pharmacists coming from regulatory agencies, the industry, NGOs or the United Nations.

The Institute of Tropical Medicines (ITM) in Antwerp is involved with us on operational research and advocacy activities.

In addition to our core team, we can count on our network of experts available to meet the needs, whether it is on particular activities or for specific expertise, ranging from regulatory affairs, to quality control laboratories, pharmaceutical industry, international NGOs, Donors, purchase centres and distributors and finally United Nations agencies such as WHO, UNICEF or UNDP for instance.

We are capable of answering your expectations in English, French, Spanish or Portuguese.

THE ACTIVITIES

Access to information is essentially made via our on-line database to which you can subscribe. This database contains validated and standardized information on a large number of suppliers which can be international or local distributors, purchase centres or manufacturers.

This database is fed by all the activities realized by QUAMED on one hand, but also by public information which access is not always easy and for which centralizing it in our database make it more readily accessible.

The principle of information sharing via the database is an essential point of the resource pooling, and wherever the request for an activity comes from, the result is accessible to all the subscribers.

In addition to the database, we offer the following series of activities:

- Suppliers audits (purchase centres, distributors, manufacturers)

These audits are conducted using international references such as Good Manufacturing Practices, Good Distribution Practices or the Model Quality Assurance System for procurement agencies (MQAS). Results of the audits are presented in a formatted and standardized way in order to make it easy to compare various suppliers and a graphic representation helps have a quick overview.



Example of representation of an MQAS audit result – 14 criteria scored on a 5 levels scale

- Assessment of products dossiers

We use a questionnaire based on the WHO recommended one. Every dossier is reviewed as per a defined protocol in reference to international standards and the result of the assessment is also presented in a standardized way establishing a 5 levels score for manufacturing site, registration, finished product specifications, active ingredient specifications, packaging material, stability studies and bio-equivalence (where relevant).

Example of a product dossier assessment report (first pages)

► Local market assessments

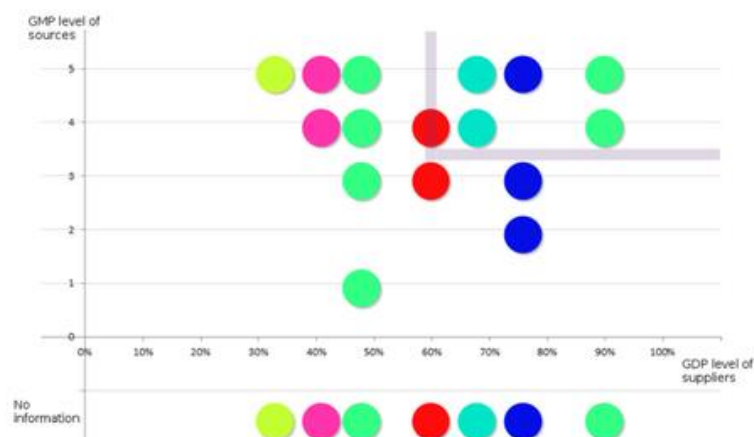
In order to give you recommendations for your local procurement in a given country and to select the suppliers offering the best level of guarantees, we can realize a series of technical visits of potential suppliers which you preselected or which we can select together (producers, distributors, wholesalers, importers) on a local market.

Result of the assessments and recommendations are detailed in a full report.

These recommendations are summarized in a table listing the first choice suppliers, the second choices, and the not recommended ones according to their level of distribution/manufacturing practices.

For distributors, you also find recommendations regarding the sources they propose.

A graphic representation helps you to compare the suppliers and to select them based on their performance in terms of distribution practices (horizontal axis) and in terms of quality of their sources (vertical axis).



Example of a local market assessment result

Results of these assessments feed the database.

- ▶ Support in the development of procedures / quality assurance policies

We help you to develop, implement or adapt necessary tools to quality assure your pharmaceutical procurement.

- ▶ Standard or customized trainings

We propose a catalogue of standard training modules and we can also organise customized on demand modules (pharmaceutical markets, quality assurance, suppliers' assessments, forecasting and quantification...) to answer the needs of your staff, be it at headquarters or operational field level.

Training sessions on a predefined theme are organized periodically and opened to all.

Finally, self-training modules will be available for distant training.

- ▶ Hotline & Forum

We propose a hotline service to answer your doubts and questions related to sources, suppliers, regulations for instance. Answers go to our forum which is also the place for direct exchange between members.

- ▶ Operational research and advocacy

A full time position is dedicated to these activities within the ITM. Info from QUAMED database may be used to conduct operational research and publish reports and articles which in turn may be used for advocacy purpose towards decision makers and other actors such as donors for instance.

And finally, we are now developing a quality label system which will make the selection of quality sources easier by simplifying and standardizing even further the presentation of the information:

- ▶ A label for distributors (MQAS and GDP)
- ▶ A label for manufacturing sites (GMP)
- ▶ A several levels label allowing comparison of various sources and a gradation according to the guaranteed level of quality assurance



The label can be granted following audits and will arise from our rating system (see example of MQAS audit above). Only sources which can be recommended as potential suppliers (guaranteeing the necessary minimum of quality assurance) will be offered the label.

The label will present different levels in order to establish a gradation according to the observed level of quality assurance. This gradation will on one hand allow to give a preference to suppliers which obtained a better level, and on the other hand, to incite companies to invest in their quality assurance should they wish to gain a better label level.

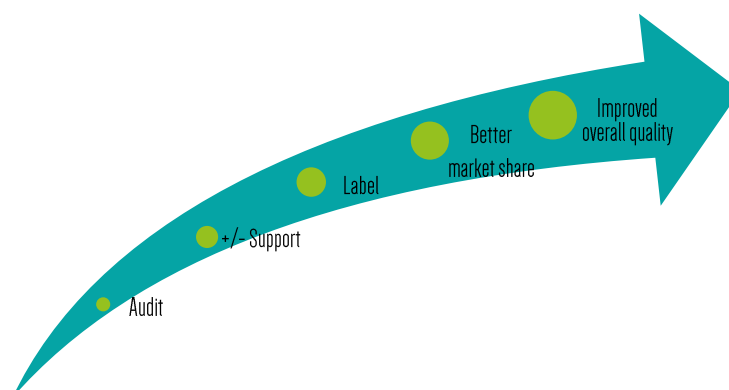
Support can be proposed to the audited suppliers to help them reach this goal.

This system of label will allow to determine which are the manufacturers / distributors with better quality standards, and whereas these had little means so far to objectively emphasize their quality standards, this will allow them to be in a better position than the companies against which they compete on the market.

This will also help answer the growing request of some donors to be in a position to favour quality sources.

The companies can be audited on a voluntary basis on their demand or on request of the members. An initial audit will allow to have an objective image at a given moment of their quality level and to possibly grant a label.

When needed, a support will be proposed to the companies to allow them to progress and to possibly obtain a better level of label.

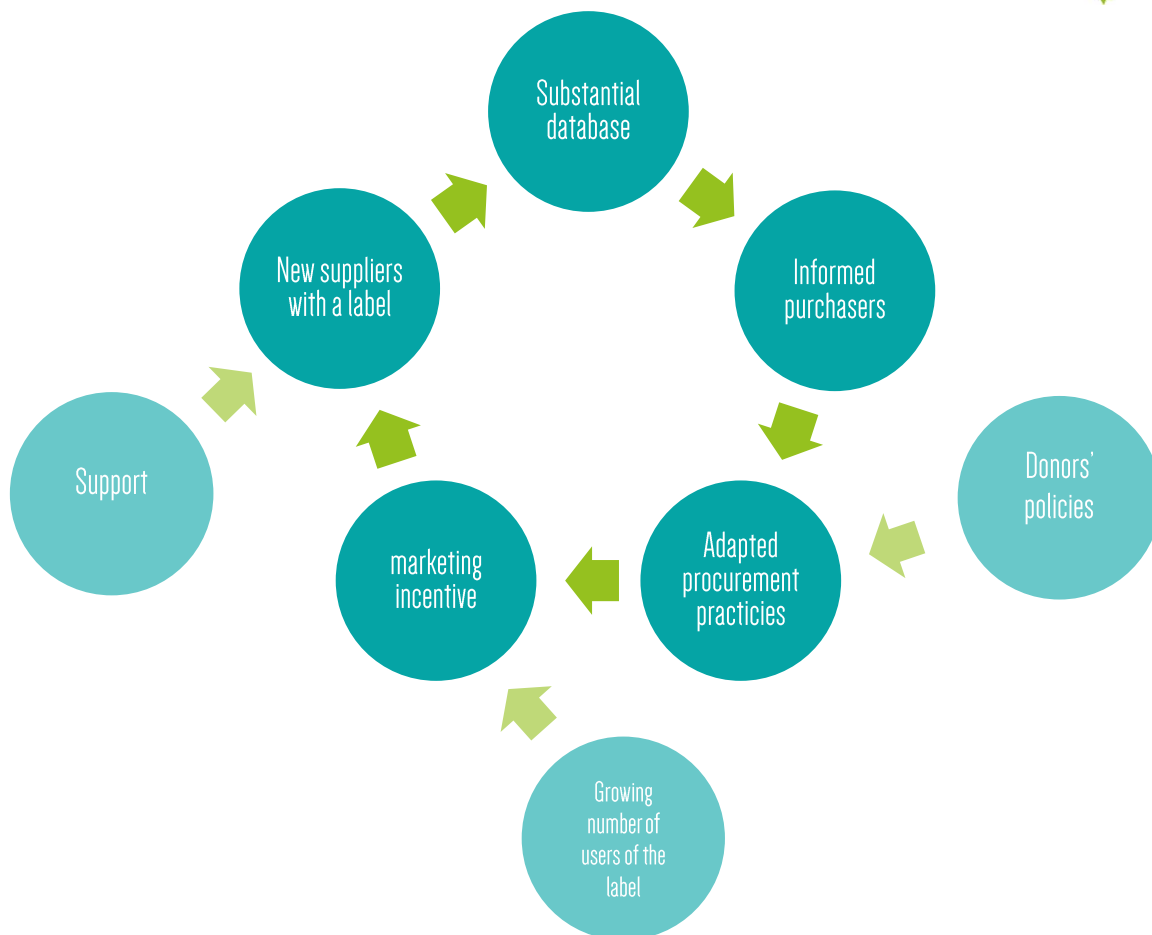


All the results will be available in the database. There will thus be a marketing incentive for these companies with better quality standards, and the obtaining of the label should allow them in turn to increase their market shares.

Recognition of this label by donors and implication of purchasers will be key to strengthen its impact and thus increase the interest of the suppliers.

Key points to guarantee the success of the label will therefore be:

- ▶ A sufficient number of suppliers with a granted label in the database
- ▶ A recognition of the label by donors which will support its use by purchasers (advocacy work with these actors will be essential)
- ▶ Involved purchasers who adapt their procurement practices accordingly



THE FUNCTIONING

The association is administered in a classic way by a Board stemming from the General Assembly of the members.

You can support QUAMED and participate in the association by becoming a member. Membership is opened to individuals and organisations, and these last ones get automatically access to the hotline and forum services (optional for individuals).

All members can take part in the general assembly, but only individuals get a voting right through a college system whereas organisations only have a consultative role.

In addition to the hotline and forum services, member organisations get priority to request other QUAMED services.

Member fees are different depending on the type of member, and the size of the organisations:

- ▶ 50 € for an individual
- ▶ 200 € for an individual with access to the hotline and forum services
- ▶ 200 € for an organisation with a global budget lower than 60 million euros
- ▶ 400 € for an organisation with a global budget between 60 and 200 million euros
- ▶ 600 € for an organisation with a global budget higher than 200 million euros

Access to the database is possible independently, and regardless of the membership status. Subscription is open on a civil year basis and fees are also based on the organisations size:

- ▶ 2000 € for an organisation with a global budget lower than 60 million euros
- ▶ 4000 € for an organisation with a global budget between 60 and 200 million euros
- ▶ 6000 € for an organisation with a global budget higher than 200 million euros

THE FINANCING

QUAMED being an autonomous organization, it is necessary to secure financing to cover the fixed costs and assure its functioning on one hand, and allow the development of the new activities and the growth and continuity of the association on the other hand.

The objective of QUAMED is to become self-sufficient and to this end to reach the critical size with a sufficient number of:

- ▶ Members
- ▶ Subscribers to the database
- ▶ Suppliers registered with a label
- ▶ Income generating activities

Financing is therefore partially direct (subscriptions, membership fees and latter label) and partially indirect via the activities we perform for you. It is therefore your responsibility to secure funding for the activities you request.

To make it easy for you to plan the necessary budget, QUAMED works on an “all inclusive” rate which includes the expert fees, transportation, lodging, visa and a small margin to cover part of the functioning costs of the association. These standard rates might have to be slightly adapted on a case by case basis depending on the circumstances (late planning leading to higher transportation costs, specific needs...) but they will not vary much and thus will allow you to get a rather precise idea of the cost of the services you may request:

- ▶ Local market assessment: 1250 € per day (consider 1 to 2 days for preparation and 1 day of reporting per each 5 days in the field)
- ▶ GMP and MQAS audits : 2000 € per day
- ▶ Training : 800 to 1250 € per day (depending on length and localisation)
- ▶ Remote technical support (SOP, QA policies, dossiers assessment...): 800 € per day

The system of label will also be a source of funding via the invoicing of the audits, the possible support and the label registration to the interested suppliers.



We are convinced that this way we will eventually reach the financial balance which will guarantee QUAMED's independence and its continuity!

Do not hesitate to contact us for any further explanation or to become a member or subscribe to the database.

Memberships and subscriptions are opened!

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