



## FREQUENTLY ASKED QUESTIONS

### Product dossier evaluation

#### **What is a Product Dossier evaluation?**

An evaluation of a product dossier of a Finished Pharmaceutical Products (FPP) is an assessment of product information provided by a manufacturer by qualified QUAMED experts.

#### **What is the goal of a product dossier evaluation?**

The aim of a FPP product dossier evaluation is to seek advice on product information related to the quality, safety and efficacy of a finished pharmaceutical product.

#### **Why are Good Manufacturing Practices (GMP) certificates not sufficient?**

GMP certificates are provided when a manufacturing site comply with the requirements of GMP standards. This is not a proof that products produced in this manufacturing site are safe, efficient and of sufficient quality.

#### **What is a product dossier evaluation report?**

A QUAMED product dossier evaluation report contains the following elements:

- The QUAPAS (QUAMED Product Assessment Sheet), which is a standardized tool that record findings related to the evaluation
- Conclusion and recommendations about the evaluation (strengths and weaknesses of the product information).
- The report is accessible in the QUAMED database and valid for 3 years.

#### **What are the reference guidelines used by QUAMED?**

The standard used by QUAMED to conduct product dossier evaluation is based on the WHO MQAS standards<sup>1</sup>.

#### **How long does a product dossier evaluation take?**

A product dossier evaluation can take anywhere from 1 month to 3 months. Delays may occur if it is necessary to request additional documentation or clarifications from the manufacturers.

#### **What is the cost of a product dossier evaluation?**

That depends on the specifics of the product dossier and the complexity of the finished pharmaceutical products. This will be evaluated at the initial phase of the activity.

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<sup>1</sup> [https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs986-annex3-syst%C3%A8me-mod%C3%A8le-d-assurance-de-la-qualit%C3%A9-de-l-oms-pour-les-agences-d-approvisionnement.pdf?sfvrsn=322ee5f3\\_2](https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs986-annex3-syst%C3%A8me-mod%C3%A8le-d-assurance-de-la-qualit%C3%A9-de-l-oms-pour-les-agences-d-approvisionnement.pdf?sfvrsn=322ee5f3_2)

### **What resources are required for a product dossier evaluation?**

Resources may vary depending on the complexity of the product: For instance, vaccines, biological products, innovator products or generic products may require different level of effort. However, at least two evaluators are commissioned to conduct the evaluation of product information. QUAMED technical coordinator reviews and approves the report.

### **Who pays for the product dossier evaluation?**

This depends on who requests the product dossier evaluation. It usually is a group of organisations (NGOs) but can also be one organisation.

### **How is a product dossier evaluation organised?**

In the organisation of a product dossier evaluation, there are three main steps: A. Preparation, B. Evaluation, 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**

1. One or more organizations (NGOs or others) contact QUAMED. If there are more organizations involved, one lead organization is designated by them to facilitate the communication.
2. Concurrently, QUAMED develops a draft budget in a standard format and draft terms of reference and shares them with the lead organization.
3. The lead organization agrees with the other participating NGOs on the scope of work and budget.
4. The lead organization negotiates with the other participating organizations about financial contribution to the budget and communicates the contributions to QUAMED
5. QUAMED prepares service agreements for each of the participating organizations with their financial contribution mentioned.
6. QUAMED sends the service agreements to each participating organization for signature
7. The lead organization liaises with the manufacturer(s) to get the required information and documentation

#### **B. Evaluation**

8. The validated and qualified QUAMED experts review the documentation provided by the manufacturer and the Interagency finished pharmaceutical product questionnaire and completes the QUAPAS for the following section : GMP status, Active pharmaceutical ingredients specifications, finished product specifications, stability studies, Packaging/label/notice, safety and efficacy information.
9. If required, they may contact the manufacturer(s) for further documentation or clarifications.

#### **C. Analysing and reporting**



10. Usually within 30 days after the reception of the product dossier (but this may be extended due to delays in receiving clarifications from the manufacturers), QUAMED produces the product dossier evaluation report.
11. QUAMED sends the report to the manufacturers for their feedback.
12. QUAMED sends a copy of the final report to each of the participating NGOs and uploads the report to its database.