AUDIT ACCEPTANCE LETTER

Subject: Audit of suppliers in relation to QUAMED

About QUAMED

QUAMED is a program of the Institute of Tropical Medicine (Antwerp, Belgium) that seeks to improve the quality of the medicines on offer in developing countries by setting up a network of non for profit organizations working in the field of supplying medicines. QUAMED’s main objectives include pooling resources between partners, sharing checked and validated information, reinforcing the technical capacity of the network’s partners, applied research in the domain of quality of medicines and advocacy work with decision-makers and donors.

Scope and referential

Subject to the terms and conditions of this Audit Acceptance Letter ("Letter"), the company accepts the audit and commits to collaborate with an independent auditor mandated by QUAMED. The purpose of the audit is to verify the level of compliance of the auditee, with:

- For the manufacturers of finished products and/or Active pharmaceutical ingredients and/or sterile products:
  - the WHO GMP main principles for pharmaceutical products$^1$;
  - the WHO GMP for Active Pharmaceutical Ingredients$^2$;
  - the WHO GMP for sterile pharmaceutical products$^3$;

- For the wholesalers/distributors:
  - the WHO Model Quality Assurance System for procurement agencies 2007 (MQAS)$^4$;
  - the WHO GDP for pharmaceutical products$^5$;

$^4$ WHO MQAS (a Model Quality Assurance System for procurement Agencies): http://www.who.int/medicinedocs/index/assoc/s14866e/s14866e.pdf

Quamed is a project hosted by the Institute of Tropical Medicine
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Specific undertakings of the Auditee

Without prejudice to any other undertakings contained in this Letter, the auditee hereby undertakes that:

a) It will comply with any applicable legal requirements in the context of their activities in relation to QUAMED.
b) It will ensure that all necessary authorizations, approvals, consents and filings with regard to the audit contemplated herein, will have been made or obtained, and will refrain from any action which would be detrimental to the services to be rendered by QUAMED hereunder.
c) It will, on request of the auditors, prepare documentation which is required for the execution of the audit.
d) It will give full and transparent information to the auditors which is required within the scope of this audit.
e) During the term of this Letter, the auditee shall not instruct any other auditor in relation to the matters within the scope of this Letter or any similar transaction without the prior written consent of QUAMED.

Disclaimer

The auditee acknowledges that the auditor is limited in executing the audit by the information provided by the auditee. The audit is not designed to detect all forms of fraud or illegal acts.

Organization and schedule

The observations of the auditors will be compiled in an interim audit report, which will be sent to the auditee not later than 2 weeks after completion of the audit. Should it have comments, the auditee will get back to the auditors with proposals of modifications no later than 8 days after the date it received the interim report. The auditors will react (accept or refuse) to those received modifications within the 8 days. This last version will constitute the final audit report which will be sent to the auditee and implemented in the database, exclusively accessible to the partners of QUAMED.

Any MQAS/GMP deficiencies found during the audit will be reported by the Auditors in the report and in the closing meeting of the audit.

If the partners of QUAMED wish that specific MQAS/GMP topics relevant to their Medicinal Products Manufacturers are assessed during the audit, these specific points will be communicated in advance to the auditee.
Confidentiality of the information and non-disclosure

The purpose of disclosure of the information is to enable QUAMED auditors to conduct the audit in the facilities of the auditee with a view into the quality related procedures.

All parties acknowledge that in the course of the audit, confidential information of the audited company may be disclosed to the auditors. QUAMED auditors will have access to, make observations and become acquainted with various secrets.

This Letter shall govern the conditions of disclosure including any related and additional information thereafter to assert auditee's right with respect to any information disclosed and to protect any proprietary and novel features.

The confidential Information covered includes without limitation, technical, engineering, financial and commercial information.

QUAMED auditors;

➤ agrees that all information disclosed to and/or discovered on the occasion of the audit shall be held and treated in the utmost and strictest confidence.

➤ shall solely disseminate this information to QUAMED staff and partners and not disclose any of such information to any third party unless and until expressly authorized to do so in writing.

➤ agrees not to make used of any such information, especially for any industrial or commercial purpose.

QUAMED auditors shall, however, be under no obligation with respect to any information:

➤ which is or becomes part of the public by publication or otherwise

➤ which at the time of disclosure is already in the auditor possession

➤ which becomes known to the auditor through disclosure by a third party entitled to disclose it.

It is further agreed that the furnishing of information to auditor shall not constitute any grant, option or license to auditor under any patent or other rights.

QUAMED partners and confidentiality policy

The auditee is herewith informed and aware of the fact that partners in QUAMED ("Partner Institutions") have subscribed amongst other the following conditions when adhering to the QUAMED program:

➤ Access Rights to the QUAMED Database will be granted by the Coordinating Institution (The Institute of Tropical Medicine) to the Partner Institutions. In principle a Partner Institution shall be granted access to the Quamed Database, unless it is prevented or
restricted by commitments or obligations to third parties (notably linked to confidentiality) which could imply a breach of its confidentiality undertakings under present agreement. Each Partner Institution designates one single, adequately qualified representative it employs, as QUAMED focal point (referred to in this Agreement as the ‘Focal Point’). Each Partner Institution shall guarantee that its Focus Point access and use of the QUAMED Database and Confidential Information shall be consistent with the assurances and obligations set forth in this Agreement. Each Partner Institution shall obtain from its Focus Point the personal agreement and undertaking to maintain and preserve the confidentiality of the QUAMED Database and Confidential Information and to comply with each of the terms and provisions of the present Agreement in this respect.

- Access Rights can only be exerted by the designated Focus Point representative (of the Partner Institution) on a strictly personal basis. They are as such non-transferable without and subject to prior validation of the Coordinating Institution and the concerned Partner Institution.

- Partner Institutions shall not disclose or use any Confidential Information applying to the Project or Quamed Database, except for the sole and strict purpose of the Project and under the condition that no local, national or international laws and regulations are violated.

- Parties agree that the Project and the Quamed Database will be guided by the following principle: ensure that the Quamed Database, or any end product resulting of or using such Quamed Database that is developed jointly or independently by Partner Institution(s) is affordable and accessible for patients who need them, especially in low and middle-income countries. Parties agree that they will avoid prohibitively costly approaches, restrictive intellectual property strategies, or other issues that may inhibit or delay the use of the Quamed Database or any end product resulting of the Quamed Database to the benefit of patients in low and middle-income countries.

- Quamed Database or developments cannot be commercially exploited or used in any way to obtain financial benefit apart from objectives such as securing funding for the objectives defined in the consortium agreement. In addition, the QUAMED Database or developments shall only be used in line with the not-for-profit guidelines of the Parties or in line with the research guidelines of the Institute of Tropical Medicine.

The information that the auditee provides to QUAMED shall not only be shared with the current QUAMED partners but also with the partners who will join QUAMED in the future. Those QUAMED partners will be required to sign the same confidentiality clauses as described above. The list of
QUAMED partners is updated on its website on an ongoing basis and the auditee shall not request QUAMED to inform it in the event that a new partner joins the network.

Conflict of interest

The auditors herewith declare their independence and assure the auditee of not being employed or supported by a competing company for at least 5 years.

Monitoring and follow-up

QUAMED auditors are responsible for follow up to check that corrective actions have been appropriately addressed in a timely manner. QUAMED auditors and partners will also decide if a specific follow up audit related to the deficiencies is necessary. After agreement with the customer, QUAMED can follow up regularly the progress of the corrective actions according to instructions given by its auditors.

Use of the information

The information generated by QUAMED’s audits is intended for the network of QUAMED’s partners, which are bound by a contract and a confidentiality clause. The use of all or part of the information produced by QUAMED for commercial or promotion purposes, or any use which would be outside the scope of the QUAMED network, including, but not exclusively, the results of the audits carried out by QUAMED in procurement agencies, is subject to prior written approval by QUAMED.

Liability

QUAMED shall not be held liable for unsuccessful inspections by authorities after having been audited under this Letter.

QUAMED shall not be held liable in the case of users of the audit report are taking measures leading to any kind of financial impact on the Company.

It is the understanding of the Institute of Tropical Medicine that all necessary precautions have been taken so that the confidentiality of the information that an auditee provides to QUAMED auditors is fully respected and utilized in the strict framework of this Letter. Should one of QUAMED partners breach those confidentiality clauses, the Institute of Tropical Medicine could not been considered as responsible of it and the auditee would not be entitled to sue the Institute of Tropical Medicine.
Duration and termination

The Letter shall be effective from the date hereof until the earlier of: i) the date of dissolution of QUAMED; ii) the date of receipt of the final report of the audit.

The provisions "Confidentiality of the information and non-disclosure", "QUAMED partners and confidentiality policy", "Disclaimer", "Liability" and "Courts and Law" shall survive the duration of the Letter.

Courts and law

This clauses of this Letter shall be governed by and construed in accordance with Belgian law and subject to the jurisdiction of the Antwerp courts.

Salvatore Clause

Should any of the above provisions in this Agreement be invalid, this shall not impair the validity of this Letter. It is to substituted by the provisions coming closest to the intention of both parties which has to be laid down in writing.

Acceptation of the audit

The auditee which accepts to be audited is reputed to have entirely and automatically accepted all the terms of this Letter and will refrain from making any claims after it has been audited.

Date: 31/03/2012

Name of legal representative: Jose Luis Barroqui Martinez

Function: President

Signature: [Signature]